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Presidential Documents

Title 3—

The President

Executive Order 13189 of January 15, 2001

Federal Interagency Task Force on the District of Columbia

By the authority vested in me as President by the Constitution and the laws of the United States of America, and in order to further the revitalization of, and to improve prospects for the success of ''home rule'' in the District of Columbia, the Nation's Capital, it is hereby ordered as follows:

Section 1. *Background and Policy.* The District of Columbia is the Nation's Capital, and the Federal Government is the largest employer, landholder, and purchaser in the region. The Executive Office of the President has established and maintained an interest in fostering the Federal relationship with the District of Columbia since 1963. This Administration has long sought to strengthen the relationship between the Federal Government and the District of Columbia by initiating a historic restructuring of this relationship. At the request of the President, in 1995, the Federal D.C. Interagency Task Force, chaired by the Director of the Office of Management and Budget, and directed by the Special Advisor to the President and Executive Director of the Federal D.C. Interagency Task Force, was created to revitalize the District of Columbia and improve prospects for ''home rule'' to succeed in the Nation's Capital. The Federal D.C. Interagency Task Force Office has worked with Federal agencies, the Congress, and local officials to promote long-term financial stability, economic growth, and opportunity for self-government for the District of Columbia. In 1997, the President signed into law the National Capital Revitalization and Self-Government Improvement Act of 1997, under which the Federal Government undertook certain responsibilities and governmental functions befitting a State or county government. Also in 1997, the President signed into law tax incentives designed to spur economic growth in the District of Columbia.

It is the policy of this Administration, therefore, to build on the momentum of the accomplishments over the last 5 years by formally establishing the Federal D.C. Interagency Task Force to further assist the District of Columbia in achieving financial stability, economic growth, and improvement in management and service delivery.

Sec. 2. *Establishment of the Federal Interagency Task Force on the District of Columbia.*

(a) There is established the ''Federal Interagency Task Force on the District of Columbia'' (Task Force).

(b) The Task Force shall be composed of the following members:

(1) The Attorney General;

(2) The Secretary of Housing and Urban Development;

(3) The Secretary of Health and Human Services;

(4) The Secretary of Labor;

(5) The Secretary of Transportation;

(6) The Secretary of the Treasury;

(7) The Administrator of General Services;

(8) The Secretary of Education;

(9) The Secretary of the Interior;

(10) The Administrator of the Environmental Protection Agency;

(11) The Secretary of Commerce;

(12) The Secretary of Agriculture;

(13) The Director of the Office of Management and Budget;

(14) The Administrator of the Small Business Administration;

(15) The Commissioner of the Social Security;

(16) The Secretary of Energy;

(17) The Director of the Office of Personnel Management; and

(18) Such other members as the Director of the Office of Management and Budget may provide (including the Director of the Court Services and Offender Supervision Agency, which office is located in the Department of Justice.)

(c) The Task Force shall be chaired by the Director of the Office of Management and Budget (Director). The Director may appoint an Assistant Director or other senior official to assist in the management of the Task Force.

(d) The Office of Management and Budget shall provide administrative support for the Task Force. To the extent permitted by law, other executive departments and agencies may provide such staff, resources, and information as may be required in carrying out the provisions of this order.

(e) The Director shall develop, review, modify, and, as appropriate, implement program recommendations, in cooperation with the appropriate elected Federal and local officials and agencies, to promote long-term financial stability, economic growth, and opportunity for self-government for the District of Columbia.

(f) To the extent permitted by law, the Task Force staff shall communicate with Federal and local elected officials as early in program planning cycles as reasonably feasible, to develop and explain specific Federal and local plans and program actions.

Sec. 3. *Purpose.* The purpose of the Interagency Task Force will be to coordinate and better leverage Administration efforts and initiatives for the District of Columbia in concert with local and regional initiatives to improve the long-term financial stability of the Nation's Capital and to improve self-governance. The Director's designee shall serve as liaison between the executive branch and the executive, legislative, and judicial branches of government of the District of Columbia, as well as the private sector.

Sec. 4. *Responsibilities.* To the extent permitted by law, the Interagency Task Force shall:

(a) formulate and recommend interagency compacts and cooperative agreements between Federal agencies and the District of Columbia;

(b) develop, on a continuing basis, a comprehensive and coordinated plan to establish priorities to promote long-term financial stability, economic growth, and opportunity for self-government for the District of Columbia;

(c) provide for an understanding by the public of the needs and assets of the District of Columbia;

(d) support District efforts to encourage economic growth in the District of Columbia;

(e) serve as the focal point and coordinating unit for Federal programs, technical assistance, and other support for the District of Columbia; and

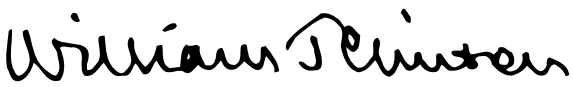
(f) provide a forum for consideration of problems within the District of Columbia and propose and effectuate solutions.

Sec. 5. *Assistance to Economically Distressed Areas.* Members of the Task Force, to the extent permitted by law and within existing budgetary resources, shall provide targeted assistance to economically distressed areas within the District of Columbia and to projects that require economic development

assistance. To the extent permitted by law, members of the Task Force shall also participate in comprehensive neighborhood revitalization initiatives requiring Federal assistance, including programs organized by the government of the District of Columbia, and collaborative efforts organized by private organizations, such as the Anacostia Best Practices initiative.

Sec. 6. *Local Accommodation.* To the extent permitted by law, the Federal Interagency Task Force shall make efforts to accommodate the concerns of local elected officials in proposing Federal technical or other assistance.

Sec. 7. *Judicial Review.* This order does not create any right or benefit, substantive or procedural, enforceable by law against the United States, its officers, its employees, or any other person.



THE WHITE HOUSE,
January 15, 2001.

[FR Doc. 01–1813
Filed 1–18–01; 8:45 am]
Billing code 3195–01–P

Presidential Documents

Executive Order 13190 of Janaury 15, 2001

President's Commission on Educational Resource Equity

By the authority vested in me as President by the Constitution and the laws of the United States of America, including the Federal Advisory Committee Act, as amended (5 U.S.C. App.), it is hereby ordered as follows:

Section 1. *Policy.* A quality education is essential to the success of every child in the 21st century and to the continued strength and prosperity of our Nation. Our Nation has embraced the goal of promoting high educational standards for all children and increasing accountability in education. Although we know it is crucial that all children have access to the educational resources and opportunity necessary to achieve high standards, long-standing gaps in access to educational resources exist, including disparities based on race and ethnicity. These gaps limit the ability of individuals, as well as our Nation, to reach their full potential. Therefore, it is the policy of this Administration that our Nation undertake appropriate steps to understand fully the current status of resource equity in education and to identify and implement strategies at the local, State, and national levels that will ensure that all students have a full and equal opportunity to succeed.

Sec. 2. *Establishment.* To carry out this policy, there is established the ''President's Commission on Educational Resource Equity'' (Commission). The Commission shall be composed of not more than 13 members appointed by the President from the public and private sectors. The members may include current and former Federal, State, and local government officials, corporate and foundation leaders, recognized education and civil rights experts, educational practitioners, and others with experience and expertise in educational resource equity. The President shall designate from among the Commission members such official or officials to be chairperson or chairpersons, as he shall deem appropriate.

Sec. 3. *Duties and Commission Report.* (a) The Commission shall collect and review information about the current status of gaps in the availability of educational resources, including the underlying causes and effects of such resource gaps. The Commission shall, as appropriate, invite experts and communities to provide information and guidance in furtherance of their duties.

(b) Not later than August 31, 2001, the Commission shall prepare and submit a report for the President and the Congress on the issue of resource equity in education. The report shall include, but not be limited to:

(i) An analysis of the status of resource equity in education with regard to such factors as finances, staff, facilities, instructional programs, and support services, taking into account, as appropriate, differences in costs and needs for different students and communities;

(ii) An analysis of how resource gaps in education affect the success of individuals and our Nation;

(iii) An examination of the effectiveness of targeted Federal resources toward disadvantaged students and low-income schools as compared with the provision of State and local resources toward disadvantaged students and low-income schools;

(iv) A summary of best practices with regard to overcoming gaps in the availability of educational resources; and

(v) Short- and long-term recommendations for educational policy makers, including local, State, and Federal officials, to achieve resource equity in education.

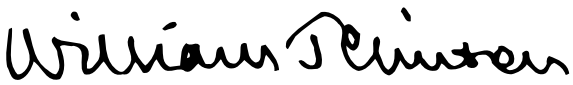
Sec. 4. *Administration, Compensation, and Termination.* (a) The Department of Education shall, to the extent permitted by law, provide administrative support and funding for the Commission.

(b) Members of the Commission shall serve without compensation, but while engaged in the work of the Commission, members appointed from among private citizens of the United States shall be allowed travel expenses, including per diem in lieu of subsistence, as authorized by law for persons serving intermittently in the Government service (5 U.S.C. 5701-5707) to the extent funds are available for such purposes.

(c) The functions of the President under the Federal Advisory Committee Act, as amended, except that of reporting to the Congress, that are applicable to the Commission, shall be performed by the Department of Education in accordance with the guidelines that have been issued by the Administrator of General Services.

(d) The chairperson (or chairpersons) may from time to time prescribe such rules, procedures, and policies relating to the activities of the Commission as are not inconsistent with law or with the provisions of this order.

(e) The Commission shall terminate 30 days after submitting its final report, unless extended by the President.



THE WHITE HOUSE,
January 15, 2001.

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Rules and Regulations

Federal Register
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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

NUCLEAR REGULATORY COMMISSION

10 CFR Part 50

RIN 3150–AG11

Consideration of Potassium Iodide in Emergency Plans

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its emergency planning regulations governing the domestic licensing of production and utilization facilities. The final rule requires that consideration be given to including potassium iodide (KI) as a protective measure for the general public that would supplement sheltering and evacuation. KI would help prevent thyroid cancers in the unlikely event of a major release of radioactivity from a nuclear power plant. The final rule responds to petitions for rulemaking (PRM 50–63 and PRM 50–63A) submitted by Mr. Peter G. Crane concerning the use of KI in emergency plans.

EFFECTIVE DATES: April 19, 2001.

FOR FURTHER INFORMATION CONTACT: Michael T. Jamgochian, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. Telephone: (301) 415–3224. Internet: MTJ1@nrc.gov.

SUPPLEMENTARY INFORMATION: Section 50.47 of the Commission's regulations establishes requirements for emergency plans for nuclear power reactors to provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency. Section 50.47(b) contains 16 planning standards, and in particular, § 50.47(b)(10) requires that emergency plans include ''a range of protective actions'' for the plume exposure pathway emergency planning zone (EPZ) for emergency workers and the public. This provision does not identify specific protective actions that must be included in these emergency plans.

The Petitioner's Requested Amendment to the NRC Regulations

On November 27, 1995 (60 FR 58256), the NRC published a document announcing the receipt of a petition for rulemaking (PRM 50–63) filed by Mr. Peter G. Crane on his own behalf and requested public comment on the suggested action. In the original petition (PRM 50–63), submitted on September 9, 1995, the petitioner requested that 10 CFR part 50 be amended to include language taken from FEMA's Federal Radiological Emergency Response Plan of September 1994. The petitioner requested that the NRC amend its regulations concerning emergency planning to include a requirement that emergency planning protective actions include the prophylactic use of potassium iodide (KI), which the petitioner stated prevents thyroid cancer after nuclear accidents.

The petitioner proposed that section 50.47(b)(10) be amended to read as follows:

> (10) A range of protective actions *including sheltering, evacuation and prophylactic use of iodine* have been developed for the plume exposure pathway EPZ [emergency planning zone] for emergency workers and the public.
>
> Guidelines for the choice of protective actions during an emergency, consistent with Federal guidelines, are developed and in place, and protective actions for the ingestion exposure pathway EPZ appropriate to the locale have been developed.

In the September 9, 1995, petition (PRM 50–63), the petitioner stated that he believes that if his proposed rule change is adopted, the plan will become an accurate description of emergency preparedness for radiological emergencies; the recommendation of the Kemeny Commission to stockpile KI will at last be implemented; and the United States will be in compliance with the International Basic Safety Standards.

On November 11, 1997, the petitioner submitted a revision to his original petition (PRM 50–63A). In the revised petition, the petitioner requested that 10 CFR 50.47(b) be amended to read: (10) ''A range of protective actions have been developed for the plume exposure EPZ for emergency workers and the public. In developing this range of actions, consideration has been given to evacuation, sheltering, and the prophylactic use of potassium iodide (KI), as appropriate. Guidelines for the choice of protective actions during an emergency, consistent with Federal guidelines, are developed and in place, and protective actions for the ingestion exposure pathway EPZ appropriate to the locale have been developed.''

The petitioner also provided a marked-up version of the NRC staff's proposed Federal Radiological Preparedness Coordinating Committee (FRPCC) **Federal Register** document concerning a revision to the Federal policy relating to the use of KI by the general public. The NRC published a document announcing the receipt of the amended petition on December 17, 1997, (62 FR 66038) and requested public comment on the amended petition.

As part of the petitioner's comments on the proposed rule, the petitioner also stated that his original petition was incorporated by reference and resubmitted because the amended petition was based in part upon the June 30, 1997, Commission decision to fund State supplies for those States that request it.

The petitioner also requested in PRM 50–63 that the NRC, either on its own or jointly with other agencies, issue a policy statement declaring that KI stockpiling is a sensible and prudent measure necessary to assure that the drug will be available in the event of a major accident. The petitioner believes that this statement would clarify that KI can be used in conjunction with evacuation and sheltering to maximize protection to the public.

Commission Action Concerning the Petitions

By staff requirements memorandum (SRM) dated June 26, 1998, to SECY 98–061, ''Staff Options for Resolving a Petition for Rulemaking (PRM 50–63 and 50–63A) Relating to Re-evaluation of the Policy Regarding the use of Potassium Iodide (KI) by the General Public after a Severe Accident at a Nuclear Power Plant,'' the Commission decided to grant the revised petition for rulemaking (PRM 50–63A). The Commission also directed that the

preamble for the proposed rule include a statement to the effect that State and local decision makers, provided with proper information, may find that the use of KI as a protective supplement is reasonable and prudent for specific local conditions.

By SRM dated April 22, 1999, to SECY 98–264, ''Proposed Amendments to 10 CFR 50.47; Granting of Petitions for Rulemaking (PRM 50–63 and 50–63A) Relating to a Re-evaluation of Policy on the Use of Potassium Iodide (KI) After a Severe Accident at a Nuclear Power Plant,'' the Commission voted to approve publication in the **Federal Register** of a [7590–01-P] proposed rule that would grant in part both the original petition (PRM 50–63) and the revised petition for rulemaking (PRM 50–63A). The proposed rule was published for public comment on June 14, 1999 (64 FR 31737). That notice provides greater detail concerning the basis for the petition and the NRC's rationale for the proposed rule language put forth for comment.

Other Activities Related to the Rulemaking on KI

In its decision on June 30, 1997, the Commission endorsed the Federal offer to fund the purchase of KI for States at their request. On June 26, 1998, in a decision on this rulemaking petition, the Commission again noted that the Federal government (most likely the NRC) is prepared to fund the purchase of a stockpile of KI for the States, upon request.[1] However, in its April 22, 1999, SRM, the Commission decided: (1) Not to fund State stockpiles of KI; (2) to direct the NRC staff to work with FEMA to establish and maintain regional KI stockpiles; and (3) to support NRC funding of the purchase and resupply of the regional KI stockpiles to the extent that this cannot be covered by FEMA under its initiatives. The Commission determined that notwithstanding the June 30, 1997, and June 26, 1998, intention that ''most likely the NRC'' would fund the purchase of State stockpiles of KI, NRC was not prepared to fund State stockpiles of KI absent Congressional funding specifically for this purpose.

The Federal Radiological Preparedness Coordinating Committee (FRPCC) is responsible to coordinate all Federal responsibilities for assisting state and local governments in emergency planning and preparedness for peacetime radiological emergencies. Federal agencies which participate in the FRPCC include (among others): the Federal Emergency Management Agency (FEMA), NRC, the Environmental Protection Agency (EPA), and the Department of Health and Human Services (HHS). The 1985 Federal Policy recommends the stockpiling or distribution of KI during emergencies for emergency workers and institutionalized persons, but does not recommend requiring pre-distribution or stockpiling for the general public. In parallel with petitioning the NRC for rulemaking, Mr. Crane requested that the FRPCC policy be reconsidered. In early 1996, the FRPCC convened a subcommittee on Potassium Iodide. The subcommittee recommended the following to the FRPCC regarding the Federal KI policy: (1) Without changing the Federal policy that it is the State's prerogative to make its own decisions on whether to use KI, the Federal Government (NRC through FEMA), should fund the purchase of a stockpile for a State that, hereafter, decides to incorporate KI as a protective measure for the general public; (2) the language in the 1985 policy should be softened to be more flexible and balanced, as for instance, rewording it to state ''it [potassium iodide for use by the general public] is not required, but may be selected as a protective measure at the option of the State or, in some cases, local governments;'' and (3) local jurisdictions that wish to use KI should consult with the State to determine if the arrangements are appropriate. If local governments have the authority or secure the approval to incorporate KI as a protective measure for the general public, they would need to include such a measure in their emergency plans.

On June 16, 1997, the NRC staff forwarded to the Commission a staff version of the FRPCC-proposed Policy Regarding Use of Potassium Iodide After a Severe Accident at a Nuclear Power Plant. In its SRM of June 30, 1997, the Commission endorsed the Federal offer to fund the purchase of KI for States. On June 26, 1998, the Commission directed that the FRPCC proposed Policy be modified to include a statement to the effect that State and local decision makers, provided with proper information, may find the use of KI as a protective supplement is reasonable and prudent for specific local conditions. As noted above, the Commission also reiterated its endorsement of the Federal offer to fund KI stockpiles for States. Subsequently, on April 22, 1999, the Commission directed the staff to amend the draft FRN on the Federal KI Policy to conform to the Commission decision on the petitions for rulemaking, and the decision not to fund State KI stockpiles.

On April 29, 1999, the Director of FEMA, Mr. James Lee Witt, forwarded a letter to the Commission commenting on the issue of funding of stockpiles of KI for States. The letter objected to the Commission's ''unilateral'' decision on funding, and also noted ''FEMA has always opposed the notion that Federal regional stockpiles of KI would be effective [and believes that] regional stockpiles would complicate, not strengthen radiological emergency preparedness.'' FEMA believes that if a State opts to use KI as a supplemental protective measure, the NRC should provide the funds for such a purchase.

The NRC responded to Mr. Witt's letter on June 15, 1999. This letter noted the Commission's decision not to fund state stockpiles of KI as well as the reasons underlying that decision. The letter also referred to the Commission's direction to ''the NRC staff to work with FEMA staff to establish and maintain regional KI stockpiles to be used in the event that local stockpiles prove to be insufficient, or when a state without a stockpile elects to use KI on an ad hoc basis in the case of a nuclear emergency.'' The letter expressed confidence that the staffs, working together would successfully resolve the KI supply issue. The status of the stockpile and funding issues are discussed later in this notice. NRC is working closely with the other Federal agencies to determine appropriate changes to the 1985 policy. A decision regarding policy changes will be reached after the conclusion of this rulemaking.

In accordance with a Memorandum of Understanding between NRC and FEMA, NRC sent draft versions of this **Federal Register** notice to FEMA for its review and comment. FEMA responded by letter dated January 12, 2000. That letter reiterated their previous comments opposing regional stockpiles and instead favoring NRC funding of State stockpiles. The letter also noted that the development of regional stockpiles of KI had not progressed.

As discussed in the public comment evaluation, the Commission, as part of its decision to grant in full the amended rulemaking petition, has withdrawn its support for the funding of regional KI stockpiles and has reinstated its offer to provide for NRC funding of State or, in some cases, local stockpiles. The Commission agrees to fund a State's

[1] This was in contrast to previous Commission statements, such as those made when the Commission amended its emergency planning regulations (45 FR 55402) on November 3, 1980, wherein the Commission stated that any direct funding of State or local governments solely for emergency preparedness purposes by the Federal government would come through the Federal Emergency Management Agency (FEMA).

stockpile of KI, subject to various restrictions and limitations (see Staff Requirements Memorandum for the Affirmation Session on December 22, 2000). NRC intends to work closely with FEMA and the other Federal agencies in FRPCC to finalize the draft Federal Policy to replace the 1985 Federal Policy. A decision regarding changes to the draft policy will be reached after the conclusion of this rulemaking. The substance of the specific comments attached to the FEMA letter is addressed by the issues in the public comment evaluation.

On September 30, 1998, the Commission also directed the staff to withdraw its guidance document, NUREG–1633 and substantially revise it, in a number of respects, including an improved discussion on how the practical problems in KI stockpiling, distribution and use are handled by States and other nations who use KI as a supplement. To accomplish this task, the NRC formed a KI Core Group, consisting of representatives from those States that have KI as a supplemental protective action, the Conference of Radiation Control Program Directors, the National Emergency Management Association, the U.S. Food and Drug Administration (FDA), EPA and FEMA. The revised draft guidance document, NUREG–1633, ''Assessment of the Use of KI as a Supplemental Protective Action During Severe Reactor Accidents'', Rev. 2 is expected to be issued for comment following receipt of the FDA's draft revised position on exposure action levels and proper dosage of KI which was issued for public comment on January 4, 2001 (66 FR 801).

In addition, the NRC plans to develop a public information brochure concerning the use of KI by the general public following completion of the final NUREG.

Public Comment Evaluation

On November 27, 1995 (60 FR 58256), the NRC announced the receipt of the original petition for rulemaking (PRM 50–63), and requested public comment on the suggested rule amendment. A total of 65 comment letters were received.[2] Letters in favor of granting the petition came from 5 environmental groups, 22 members of the public (including 1 from the petitioner), and the American Thyroid Association. Letters opposed to the petition came from 20 utilities, 9 State governmental agencies, 2 utility interest organizations, a letter signed by 12 health physicists, 2 State university medical centers and 1 member of the public.

On December 17, 1997 (62 FR 66038), the Commission published a request for public comment on the amended petition (PRM 50–63A) in the **Federal Register**. In response to several requests, the comment period was extended until February 17, 1998, by a **Federal Register** notice published on January 21, 1998 (63 FR 3052). A total of 86 comment letters were received. The letters in favor of granting the petition came from 8 public interest groups, 48 members of the public (including 3 from the petitioner), 3 physicians, 2 U.S. Senators, one State Representative, FEMA, the American Thyroid Association, a KI manufacturer, and the US Pharmacopeia Convention. Fourteen utilities, 3 State government agencies, 1 utility interest association, and 2 members of the public opposed the petition for rulemaking. A detailed analysis of the issues raised by the public comments with the response to those issues was published in the June 14, 1999, proposed rule **Federal Register** notice.

On June 14, 1999 (64 FR 31737), the Commission published a proposed rule in the **Federal Register**, based on the revised petition for rulemaking (PRM 50–63A) and requested public comment by September 14, 1999. A total of 77 comment letters were received.[3] The letters in favor of the proposed rulemaking and the revised petition for rulemaking originated from a United States Senator; a member of the U.S. House of Representatives; 3 State agencies; 4 public interest groups; 10 members of the public (including two from the petitioner); and one letter with 529 signatures. Letters that opposed the proposed rulemaking came from 14 utilities; 13 State or local government agencies; 1 utility interest association; one letter from the Conference of Radiation Control Program Directors Standards committee representing 5 committee members; a letter from the National Emergency Management Association representing emergency management directors in 50 states; a law firm representing 15 utilities; and a former Assistant Secretary of Nuclear Energy at DOE. The FEMA letter of April 29, 1999, was submitted before the rule was published and discussed KI stockpiles. Another 24 letters requested the Commission to grant the original petition (PRM 50–63) by *requiring* the use of KI rather than the *consideration* of KI in emergency planning. These letters originated from members of the public as well as public interest groups. As part of the petitioner's comment letter dated August 17, 1999, on the proposed rule the petitioner stated that, in light of the Commission's decision not to fund state stockpiles of KI, the Commission should consider his original petition (PRM 50–63) to be incorporated by reference and resubmitted. He also requested the Commission to grant the petition as originally submitted.

The following discussion addresses the significant comments and issues raised in the three public comment periods for the original and amended petitions for rulemaking and the proposed rule.

Issue A: Should KI Be Considered as a Supplemental Protective Action to Evacuation and Sheltering

Several commenters on the proposed rule state that the rulemaking would not add significant public health and safety benefit beyond the current emergency plans, because evacuation and sheltering are the best means to protect the public in the event of a radiological emergency. According to these commenters, evacuation and sheltering are more effective at dose reduction because they reduce dose to all organs, not just to the thyroid.

Other comments express the view that the Chernobyl experience (including use of KI in Poland) shows that (1) thyroid cancer is a major result of reactor accidents, (2) the exposure can continue for days and thus the institution of KI blocking at any time is beneficial, (3) deployment of KI is safe, and (4) shelf life is extremely long. These commenters note that EPA Manual [Manual of Protective Action Guides and Protective Actions for Nuclear Incidents, EPA–400–R–92–001 (May 1992)] quotes the FDA as stating that potassium iodide ''will have substantial benefit even if it is taken 3 or 4 hours after acute exposure.'' Thus, these commenters believe that the advantage of having a supply of KI on hand outweighs moderate cost and that KI should be a supplemental protective action. Further, these commenters note that just because there may be other radionuclides to which people are exposed is not a reason to deny them the availability of KI.

Commenters who favor the use of KI as a supplemental protective action conclude that evacuation and sheltering alone may not be sufficient safety actions in the event that evacuation is not feasible. They state that natural

[2] Two letters that were received in response to the notice did not address the issues in the petition and are not discussed further.

[3] Three of the letters (those from FEMA, the senator and the congressional representative) were not submitted during the comment period in response to the notice, but are being treated as comment letters for purposes of this discussion.

disasters could occur that would make evacuation difficult and time consuming at best, as for instance, earthquakes, hurricanes, blizzards, and ice storms. According to these commenters, a point against strong reliance upon evacuation is the evacuation routes themselves. As an example, a commenter cites the area around the Seabrook Nuclear Plant, noting that during the summer tourist season especially, it can be predicted that evacuees will be forced to wait in traffic for great lengths of time. This commenter believes that if KI were predistributed, instances of cancer, hypothyroidism and other thyroid disorders might be avoided.

Response. The Commission recognizes evacuation to be the most effective protective measure to be taken in the event of a radiological emergency because it protects the whole body (including the thyroid and other organs) from all radionuclides and all exposure pathways. The Commission recognizes that there may be situations when evacuation is not feasible or is delayed. In-place sheltering is an effective protective action in such a situation. However, it is important to note that the issue is not evacuation or sheltering *versus* KI. Rather, it is evacuation or sheltering *with* KI versus evacuation or sheltering *without* KI. The use of KI is intended to supplement, not to replace, other protective measures. This amendment represents no change in the NRC's view that the primary and most desirable protective action in a radiological emergency is evacuation of the population before any exposure to radiation occurs. Depending on the circumstances, KI may offer additional protection for one radiation-sensitive organ, the thyroid, if used in conjunction with evacuation and sheltering. In developing the range of public protective actions for severe accidents at commercial nuclear power plants, evacuation and in-place sheltering provide adequate protection for the general public but the use of KI can be a reasonable and prudent supplement. Therefore, it seems reasonable, while continuing to recognize the role of the State and local governments in matters of emergency planning, to require explicitly that emergency planners consider the use of KI.

Issue B: Is There a Need for New Regulation

Commenters in favor of the proposed rule note that a host of countries—France, Germany, Belarus, Russia, Switzerland, Austria, the Czech Republic, Japan, Great Britain, Sweden, Slovakia, and others—protect themselves with stockpiles of KI. These commenters point to soaring rates of thyroid cancer appearing in children in the Soviet Union who were exposed to the Chernobyl nuclear accident and who received too little potassium iodide, and too late. Thus, these commenters support the view that there is new information that suggests the need for consideration by State and local governments. In addition, many of these commenters would go further than the proposed rule language and require the use of KI, not just its consideration.

In contrast to the above, letters from some state and local governments, and from utilities, say that the State and local governments have already considered the use of KI. They believe that the petitioner has not provided any compelling reasons why additional Federal requirements are needed or how they would benefit the health and safety of the public. These State and local government commenters reject the view that the States have not had access to sufficient technical information regarding potassium iodide, and that without accurate and current information on KI—including the Chernobyl experience and the consensus of international experts—States cannot make an informed judgment. They conclude that this assertion is without merit, as there has been no shortage of information related to the use of potassium iodide available to State radiological emergency planners, and oppose the implication that State and local governments, absent Federal actions, are incapable of making informed decisions regarding the protection of their citizens during a radiological emergency. One commenter stated that by issuing this rule, the Commission is ignoring the views of States where KI has been stockpiled or pre-distributed, and where experience shows the system is ineffective.

The commenters opposing the proposed rule on this basis also note that reliance on the Chernobyl experience discounts the vast technical, political, and socio-economic differences between the United States and Eastern European countries at the time of the Chernobyl accident. The efficacy of any protective measure will depend on a large number of factors, including but not limited to: the type of reactor involved; accident sequences and timing; source term; timeliness of notification; the manner in which protective action decisions are made and transmitted to the public; the mobility of the public; and the receptiveness of the general public to official instructions. These commenters believe that the above factors have already been considered by State and local governments in the development of existing emergency response plans.

Response. The Commission did not intend to imply that States are not capable of making informed decisions regarding the protection of their citizens during a radiological emergency. In fact, the final rule calls on offsite authorities to make their own decision on this matter. Additionally, the Commission recognizes that most State and local governments have already considered the use of KI in the event of an emergency as part of their planning. Nevertheless, the Commission believes it appropriate to provide information that may be of aid to offsite authorities in their consideration of this matter. Offsite authorities may, of course, use this information as they see fit.

Several States have welcomed the NRC's efforts in developing information relating to the benefits and risks associated with using KI as a supplemental protective measure for the general public. This information is intended to supplement and update information already available on this subject, including experience from State and foreign governments that have made KI available to the public. As noted earlier, this information will be in a revised NUREG–1633, which is scheduled for publication for comment after the FDA issues its draft guidance and in an information brochure.

The Commission finds that KI is a reasonable, prudent, and inexpensive supplement to evacuation and sheltering for specific local conditions. Through its decision to require that the use of KI be ''considered'' (rather than being required), the Commission is acknowledging that the efficacy of any protective measure will depend upon a number of factors, including those noted by the commenter, that can vary not only between countries but in individual States. Thus, the Commission concluded that decisions on the use of KI need to be resolved on a State-by-State basis. As part of this consideration, State and local governments can weigh all relevant factors.

Issue C: The Importance of Information in the Decisionmaking Process Concerning the Public Use of KI

In the proposed rule, the Commission noted that NUREG–1633 was being revised to provide information about experience in the United States and abroad with distribution of KI, and that an information brochure was also being prepared. According to some commenters, distribution of information on the benefits and risks associated with

the use of KI should not be limited to people living within nuclear power plant emergency planning zones. Further, commenters note that a comprehensive public information program outlining the potential range of benefits and risks of using KI and how to employ it most effectively in the event of a radiological emergency would be necessary to allow personal decisionmaking. Making the information and the KI itself available directly to members of the public provides them with the ability to decide for themselves how best to take advantage of the benefits associated with the use of KI as supplementary protection. One vehicle currently used for disseminating regular preparedness information which could be used to provide information on KI is the public information brochures and calendars already required to be distributed annually within each emergency planning zone. In this commenter's view, making information and KI available provides the greatest level of protection for the greatest number of people.

Some State government organizations were concerned that making provisions for KI might give the public a false sense of security that they are fully protected, and that the public might not evacuate. Thus, these organizations believe that there is a need for public information concerning the supplemental role that the use of KI could play.

Several of the commenters stated that it is desirable that the NRC would work with other appropriate Federal agencies to develop and promulgate clear and necessary guidance on the subject, similar to the guidance on sheltering and evacuation. These commenters also believe that the final decision should lie at the discretion of the State and local governments. A few commenters expressed the view that the rule puts the burden of assessment on States who have fewer technical resources than the NRC, the EPA or the FDA.

One commenter thought that the decisionmaking about stockpiling KI must include rigorous assessments to ensure sufficient quantities of KI will be available for distribution to members of the public, in both the plume exposure pathway and the ingestion exposure pathway.

Response. The Commission recognizes that once a State decides to include KI as a protective measure for the general public, it would be up to the State to decide how and when to conduct an educational program on the benefits and risks associated with using KI and to supply KI for appropriate distribution to the general public. Additionally, the Commission agrees that more detailed guidance on the use of KI would be useful in assisting States to assess the merits of stockpiling KI for the general public, including logistics, amounts and public information needs. The Commission has formed a KI ''Core Group'' consisting of representatives of State, local, and Federal agencies whose responsibility is to develop clear guidance relating to the use of KI. This guidance (NUREG–1633, Rev. 2) should be published for comment after FDA issues its draft guidance, which was issued for public comment on January 4, 2001 (66 FR 801). The NRC is continuing to work with other Federal agencies through the FRPCC to coordinate government policies concerning radiation protection and emergency planning. Further, a public information brochure to be published later will assist States and individuals in making an informed decision on KI.

Issue D: Making KI Available to the General Public

A range of comments were submitted concerning ways by which KI could be made available to the general public in the event of a radiological emergency. Many commenters simply asked NRC to ''make KI available'' without further detail. In the proposed rule, the NRC discussed Federal stockpiles of KI as part of Federal response to terrorist acts. One commenter indicated that expanding this supply may be the best approach. Another commenter stated that the public is not interested in stockpiles, but instead wants information to make their own decisions. Of those comments related to specific methods of availability, these can be generally grouped into individual availability, State stockpiles in the vicinity of nuclear power plants, or regional stockpiles.

Individual Availability

One State submitted, as part of its comments, a report that discussed a plan they have developed that would allow citizens to gain access to KI in advance of an accident. The plan calls for the State to secure agreements with KI manufacturers to sell the medication directly to individuals or retail outlets, and to urge local pharmacies to stock KI as an over-the-counter drug. Information concerning KI availability and use would be included in the annual emergency information mailings prepared by nuclear power plant staffs and distributed to every property owner within the emergency planning zones. The State concluded that this method would allow individuals to make their own decisions about the use of KI. This State noted that one can envision this activity being conducted in conjunction with existing programs designed to remind and encourage family members to periodically check home first aid kits, smoke detectors, spare batteries for flashlights and radios, and other items that they might employ for their comfort and protection in the event of any emergency. In addition, one commenter noted that KI is now available via the Internet from at least two vendors at an affordable price. (See also comments above in issue C about decisionmaking.)

State Stockpiles

A number of commenters believe that KI should be stockpiled in schools, fire houses or reception centers near nuclear power plants. These commenters state that this is the advice of the experts, for instance the World Health Organization and Dr. Jean Temeck, from FDA. These commenters believe that the young are the most vulnerable; and, in the words of Dr. Temeck, ''in an emergency you want to get it to the children as quickly as possible and the teacher is right there on the spot. * * * You do not need to be medically trained to give KI. A permission slip to administer KI can be sent out by the school at the beginning of each year.'' Further, it makes sense to these commenters that this time-critical medicine be available nearby, such as in a local school, hospital, or fire-station. Thus, these commenters believe that State stockpiles are appropriate because regional stockpiles will not adequately protect the public since KI must be taken prior to exposure, or very shortly thereafter (within about six hours), to be an effective blocking agent.

Regional Stockpiles

A number of commenters, including emergency preparedness and response officials and FEMA, are concerned about the regional stockpiling and distribution process and its potential for reducing the effectiveness of measures which will provide much greater protection to the public. In their view, the complex logistics of storage and distribution of regional stockpiles far outweigh the usefulness of such a stockpile and that regional stockpiles of potassium iodide would complicate, not strengthen radiological emergency preparedness. These commenters believe regional stockpiling has disadvantages as compared to State stockpiling. The administration of KI is time-critical and regional stockpiling means critical time will be spent transporting the drug from a regional stockpile to the area where it is needed. For these reasons, they believe that

regional stockpiles should supplement, not substitute for State stockpiles.

Response. If a State decides to use KI as a supplemental protective measure, the Commission agrees that the State should focus on the early administration of KI to children. A decision to make KI available to the general public will require some planning by the State for its own supplies of KI and methods of distribution. Such planning (for implementation of protective actions) is a normal part of a State's emergency planning activities. As noted earlier, the NRC plans to issue a guidance document (NUREG–1633) to assist the States. The Commission recognizes the logistical challenges associated with the distribution of KI to the general public. For this reason, the staff intends to include a discussion of experience with KI distribution in the United States and abroad in the guidance document NUREG–1633.

There are different approaches that a State can use in incorporating KI as a supplemental protective measure for the general public. One approach is that mentioned by a commenter to distribute information about the over-the-counter availability of KI. Making KI available over the counter would provide members of the public with the opportunity to decide for themselves if they wanted to store and use KI. In fact, some KI manufacturers have indicated that they would make KI available to any person who requests it, at a fee. This approach would minimize the need for State stockpiles or predistribution and would put KI in the hands of the public before an accident occurs, rather than attempting to distribute the KI from stockpiles after an emergency is declared.

The concerns about the effectiveness of regional stockpiles for rapid deployment of KI to the public are also acknowledged. FEMA has stated that in its view, regional stockpiles will not enhance local radiological emergency preparedness because of complex logistics. The Commission agrees. As part of its decision on this final rule, the Commission has decided to provide funding for a supply of KI for States that request such funding through FEMA and to discontinue support of regional stockpiles. The Commission believes that in light of logistic difficulties, it is doubtful that regional stockpiles of KI could be effectively employed in the unlikely event of a radiological emergency at a commercial nuclear power plant.

Issue E: Requiring versus Considering Use of KI

Several commenters thought that the proposed rule should be modified to require the use of KI, not just the consideration by State and local officials. These commenters believe, for instance, that the tragic comedy of errors surrounding attempts to distribute KI in the wake of the Three Mile Island partial core melt accident only serves to highlight the need for pre-distribution. The health of our children is too important to leave their protection to the consideration of states. These commenters ask that if the U.S. system is adequate, why do other industrialized nations believe that sheltering and evacuation alone are insufficient? Some of these commenters want all commercial reactor licensees to distribute KI to all individuals within the EPZ and to make KI available to anyone within a 50-mile radius of the reactor upon request. These commenters believe that the prophylactic use of KI for the general public should be a *mandatory* emergency planning requirement and should not be merely an optional consideration, because, if given the choice, many States may not adequately protect their citizens. Another reason cited for wanting NRC to require KI is that ''without a federal mandate for stockpiling KI, the nuclear industry will simply shift its fight against the policy to the State and local levels.''

Response. Because the Commission believes that current emergency planning and protective measures—evacuation and sheltering—are adequate and protective of public health and safety, the Commission will not *require* use of KI by the general public. Rather, the Commission recognizes the *supplemental* value of KI and the prerogative of the State to decide on the appropriateness of the use of KI by its citizens. The Commission believes the final rule together with the Commission's decision to provide funding for the purchase of a State's supply of KI strikes a proper balance between encouraging (but not requiring) the offsite authorities to take advantage of the benefits of KI and acknowledging the offsite authorities' role in such matters.

The use of KI is intended to supplement, not to replace, other protective measures. This rule change thus represents no alteration in the NRC's view that the primary and most desirable protective action in a radiological emergency is evacuation of the population before any exposure to radiation occurs. The Commission recognizes that there may be situations when evacuation is not feasible or is delayed. In-place sheltering is an effective protective action in such a situation. Depending on the circumstances, KI may offer additional protection to one radiation-sensitive organ, the thyroid, if used in conjunction with evacuation and sheltering. In addition, the Commission notes that issues surrounding the prophylactic use of KI following such accidents do not lend themselves to across-the-board solutions. Therefore, the Commission has chosen to leave this decision to State and local emergency response planners, who may find that KI should be a supplementary protective measure, rather than to mandate its use. Additionally, the Commission's amendment to require explicitly that planners consider the use of KI, rather than require the use of KI, recognizes the important role of the States and local governments in matters of emergency planning and the use of medicinal protective measures by their citizens.

Issue F: Funding

Some commenters, including FEMA, state that the recent decision of the Commissioners *not* to fund the purchase of KI is an unfortunate reversal to the goal of providing supplementary protection for the general public. Thus, citing the Chernobyl accident, they urge the Commission to reconsider its position in light of the proven usefulness of KI in preventing childhood thyroid cancer. One State commenter was concerned that after two years of efforts made toward implementing this supplementary protection, the Commission's recent actions undermine that State's effort. While understanding the Commission's financial concerns leading to this decision, this commenter proposed that the Commission could approach Congress for a supplemental appropriation.

Another commenter stated that the Commission's withdrawal of the offer to pay for State KI stockpiles sends a message that KI preparedness is not important, and that States who were considering plans to establish stockpiles have dropped such plans. Further, some commenters believe that the NRC reversal of position regarding funding of KI for States that elect to stockpile it adversely affects the implementation of the policy proposed by the Federal Radiological Preparedness Coordinating Committee (FRPCC). [That draft policy currently provides that if a State chooses to add KI as a supplement to its evacuation and sheltering protective

actions, the State will inform FEMA, which will forward the request to the NRC for payment.] Another commenter noted that the Kemeny Commission supported stockpiling KI, and that the Commission should fulfill an earlier NRC commitment to do so.

Several States expressed the view that the requirement that use of KI be considered is an unfunded State mandate and is contrary to an Executive Order of 8/5/99.

A number of commenters stated that they thought the utilities should pay for supplies of KI in the vicinity of the power plants. Some utilities expressed concern that the rulemaking might result in requests to the utilities from State and local organizations for such funding.

Response. The Commission decision not to fund State stockpiles has been reversed as the result of public comment on this rulemaking. Promulgation of this final rule underscores the Commission's views on the importance of emergency preparedness, including consideration of the use of KI. The Commission has decided to fund State and, in some cases, local stockpiles of KI, subject to certain restrictions and limitations (see Staff Requirements Memorandum for the Affirmation Session on December 22, 2000). The Commission believes that in light of logistical difficulties, it is doubtful that regional stockpiles of KI could be effectively employed in the unlikely event of a radiological emergency at a commercial nuclear power plant. The Commission's offer to fund the purchase of a supply of KI for a State choosing to use KI prophylaxis as a supplemental protective measure retains the FRPCC's proposal that the State remain responsible for all other funding connected with the incorporation of KI, such as preparing guidelines for its stockpiling, maintenance, distribution and use, and for all other ancillary costs.

The Commission agrees that, in the past, licensees may have found it in their own self interest to assist State and local governments by providing resources for emergency planning needs. The Commission expects that those States who decide to use KI for the general public will make suitable arrangements to fund costs other than the initial purchase of a supply of KI. After funding the initial purchases of KI, the Commission may consider extending the program to fund stockpile replenishment, but has made no commitments in this regard. As with other aspects of offsite emergency planning, the NRC will not require licensees to fund State activities, but the States can, of course, act in cooperation and coordination with licensees.

As to the issues whether the rule constitutes an ''unfunded State mandate'' or is contrary to an Executive Order of August 5, 1999, the Nuclear Regulatory Commission, as an independent regulatory agency, is not subject to the requirements of Title II of the Unfunded Mandates Reform Act of 1995 or Executive Order 13132, ''Federalism,'' August 5, 1999.

Issue G: Whether This Rulemaking Is a Backfit

A commenter representing nuclear utilities raised a concern that if licensees would be required to expend significant resources in considering the use of KI in emergency plans, then the proposed rule is clearly a backfit and a backfitting analysis should be performed. Thus, the commenter requested that the NRC either limit the specific actions which would be required to be taken by licensees to demonstrate that the adequate consideration required by the proposed rule has been implemented, or the required backfitting analysis should be conducted and a suitably revised proposed rule should be published for comment.

Response. This notice contains a ''Backfit Analysis'' section, which notes that the Commission concludes that the rule imposes no new requirements on licensees, nor does it alter procedures at nuclear facilities. Rather, it is directed to States or local governments, the entities with the responsibility to determine the appropriateness of the use of KI for their citizens, calling upon the governments to consider KI as one of the elements of their offsite emergency planning. The final rule imposes no binding requirement for State or local governments to alter emergency plans and procedures.

Furthermore, the basic standard that emergency planning must include consideration of a range of protective actions is already set forth in the existing § 50.47(b)(10). Once again, the rule does not impose new requirements on nuclear power plant licensees who are the intended beneficiaries of the Backfit Rule provisions. Therefore, no backfit is involved.

Issue H: State Liabilities in Providing KI for the General Public

State and local government organizations raised concerns about legal implications should a member of the general public be given KI at their directive or recommendation and the individual has an extreme allergic reaction. Commenters note that the **Federal Register** notice does not address legal issues for States who decide to adopt KI and for States who do not decide to adopt or administer KI to the public. Further, if the NRC decides to require stockpiling of KI for the general public, the commenters ask whether NRC has considered what liability may arise from any adverse health effects. Another concern was about who would assume liability if the KI was used prior to a Governor ordering its use.

Response. These comments focus principally on concerns that State and local governments involved in distribution and administration of KI may be liable in tort if an individual receiving the KI has a significant adverse medical reaction to the KI. As stated in the proposed rule FR notice, the question of whether a State or locality might be liable for involvement with administration of KI to the general public can only be answered by reference to the laws and precedents of particular States. The NRC presumes that this would be part of the ''consideration'' that States and localities will undertake as a result of promulgation of this rule. To the extent that commenters are raising the potential for Federal government liability for the promulgation of this proposed rule, the proposed rule FRN notes NRC views that whether the Commission may be subject to tort liability through the implementation of a KI program depends upon a number of factors. However, it would appear that a Commission decision to require State and local emergency planning officials to consider stockpiling KI for public distribution should be subject to the ''discretionary function'' exception to the Federal Tort Claims Act. 28 USC 2671, *et seq.*, which protects the Federal Government from liability. The Commission's offer to fund State stockpiles would similarly be subject to the ''discretionary function'' exception. The Commission has directed the staff to ensure that NRC funding for KI is accompanied by appropriate disclaimers to ensure that the NRC and any of its employees are not to be held responsible for any activity connected with transporting, storing, distributing, administering, using, or determining proper doses of KI for adults and children.

Issue I: FDA Input on KI

A few commenters thought that the dosage and intervention levels should be lowered from the values in the existing FDA guidance. For instance, they conclude that NRC should require using KI prophylaxis at one rem projected dose exposure not at the

current 25 rem. It was noted that Poland uses a 5 rem intervention level. The concern of these commenters is that continued use of the old guidance subjects children to greater risk than necessary.

Response. The FDA is the Federal agency responsible for decisions about appropriate thresholds and dosages for use of KI. Existing FDA guidance related to the use of KI on dosage intervention levels is contained in a June 29, 1982 notice (47 FR 28158). As stated therein, ''FDA concludes in the final recommendations that risks from the short-term use of relatively low doses of potassium iodide for thyroid blocking in a radiation emergency are outweighed by the risks of radioiodine-induced thyroid nodules or cancer at a projected dose to the thyroid gland of 25 rem.'' That notice also provides recommended dosages for adults and children. New FDA guidance was published in the **Federal Register** for public comment on January 4, 2001 (66 FR 801). The Commission will incorporate it into its guidance documents.

Issue J: Original Petition Versus Revised Petition

A few commenters state that in the proposed rule, the Commission claims to have granted the alternative submitted in the amended petition, but did not actually do so. In their view, the amended petition contained the combination of three elements— the requirement to consider KI stockpiling, the unequivocal recommendation that States establish stockpiles, and the offer of Federally-funded State stockpiles. Since the promise of funding removed a major impediment to States adopting a pro-KI policy, the commenters believe that the petitioner felt that amending his petition to require only ''consideration'' of the use of KI would likely result in State decisions favorable to using KI. In their view, the amended PRM was premised on the now-withdrawn NRC offer of Federally-funded State stockpiles of KI, and therefore it would be entirely appropriate for the petitioner to rescind his amendment to PRM 50–63 and to insist that the NRC adopt what was requested in his original petition.

Response. The Commission agrees with this comment. Since the Commission has decided to reinstate its offer to fund a supply of KI for State or, in some cases, local governments that choose to incorporate KI prophylaxis in their emergency plans, the Commission believes that it is granting the amended petition (PRM–50–63A) in all respects.

Issue K: Meaning of ''Consideration''

Several commenters stated that the proposed rule is vague in that it did not define ''consideration.'' They believe that the rule should clarify that the KI ''consideration'' within the context of radiological emergency planning and preparedness needs to be performed only once by the responsible State agency, which would provide written notice of the consideration to the Commission. Thereafter, no further ''consideration'' should be required unless the State determines there is reason to reconsider its position and that the ''consideration'' process is not subject to continuing oversight or recurring evaluation by the NRC, or any other federal agency.

Another commenter questioned whether a State that considered the issue in the early 1980s, and rejected the use of KI, could now claim that the Commission's current proposal has already been fulfilled. Reliance upon the earlier consideration would violate the intent of the petitioner's proposal.

Another commenter questioned whether the following scenario would be considered acceptable and in compliance with the rule: a State considered the use of KI, but found the licensee unwilling to pay for it, so the State decided that although use of KI might be a good idea, it couldn't afford it.

Response. The Commission would expect that a State's ''consideration'' would involve at least an internal review of this notice and brief deliberation on the State's position on the use of KI by the general public. In NRC's experience, States periodically review their emergency plans and preparedness, typically on an exercise frequency basis, to ensure that plans are up to date and account for local changed circumstances. For those States that conduct such periodic reviews, the Commission would expect the States to undertake their ''consideration'' of the use of KI during the first periodic review conducted by the State of offsite emergency plans and preparedness following the effective date of this rule amendment and issuance of revised NUREG–1633 guidance. For those States that do not routinely conduct periodic reviews, the Commission would expect the States to undertake their ''consideration'' of the use of KI on the same frequency as periodic emergency preparedness exercises following the effective date of this rule amendment and issuance of guidance. The rule does not require States to provide written notice of their ''consideration.'' The Commission expects that States will inform FEMA and the NRC of the results of their consideration.

Additionally, the Commission agrees that the ''consideration'' process is not subject to continuing oversight or recurring evaluation by the NRC or any other Federal agency.

By issuing this rule, the Commission is stating its conclusion that consideration of the use of KI that might have been performed many years ago, needs to be reexamined in light of new information. Thus reliance upon such earlier evaluations would not be consistent with the rule requirement.

Issue L: Federal Distribution of KI

One commenter noted that the Commission's proposed rule would seem to support the same techniques used for forced KI distribution that were dictated by governments in Eastern Europe during the Chernobyl accident. The commenter urged the Commission to consider whether this posture would be endorsed by any government, be it Federal, State, or local. This commenter believes the NRC staff ignores the testimony of those States where KI is stockpiled or pre-distributed for the public and where experience shows the system is ineffective. Additionally, a commenter thought that the proposed rule is predicated on the false assumption that even if States decide not to stockpile KI for the general public, they will have access to Federal reserves of the drug. By the Commission's own admission, such reserves have yet to be established nor has the funding mechanism to support such reserves been identified. The proposal suggests that states ''consider'' the availability of resources that do not exist.

Likewise, a commenter stated that the proposed rule implies that even when a State decides as a matter of public policy against distribution of KI for the general population, the Federal government will develop plans to override that decision. The purpose of such plans is unclear in the context of the proposed rule. Once a State has given due consideration to the use of KI stockpiling as a supplemental protective action and determined it to be unwarranted, the commenter seeks the basis on which the Commission proposes to develop a contingency plan.

Response. The Commission has never endorsed ''forced KI distribution.'' Under this final rule the use of KI continues to be a State option. Moreover, revised NUREG–1633 will discuss the benefits and risks associated with using KI and the U.S. and foreign experience with public distribution. While the Commission has always

recognized that distribution at the time of an accident will present difficulties if there has been no advance planning, the Commission believes that the States will take the distribution matters into account when they consider the use of KI for the general public under this rule.

The Commission has decided to withdraw its decision to provide funding for regional Federal KI stockpiles. However, it should be noted that Commission efforts in this regard were not intended to ''override'' a State decision not to use KI during an emergency; rather, they were intended to make KI available in the event that a particular State changed its views and decided to use KI in an actual emergency, and had nowhere else to go for KI. The Commission believes that in light of logistical difficulties, it is doubtful that regional stockpiles of KI could be effectively employed in the unlikely event of a radiological emergency at a commercial nuclear power plant.

Issue M: Importance of Emergency Planning

A few commenters feel that safe siting and Design-Engineered features alone do not optimize protection of the public-health and safety and that the Commission should not rely upon probabilistic risk assessments to obviate the need for stockpiling and predistribution of KI. Another commenter is concerned that the premature aging of reactor components, the economics of utility restructuring, and the long-term storage of high-level waste at reactor sites all contribute to the need for KI stockpiling.

Response: The Commission agrees with the importance of emergency planning to complement site and design features and stated so in the August 19, 1980, **Federal Register** Notice (45 FR 55402) which codified the NRC's emergency planning regulations following the Three Mile Island accident: ''The Commission's final rules are based on the significance of adequate emergency planning and preparedness to ensure adequate protection of the public health and safety. It is clear * * * that onsite and offsite emergency preparedness as well as proper siting and engineered design features are needed to protect the health and safety of the public. As the Commission reacted to the accident at Three Mile Island, it became clear that the protection provided by siting and engineered design features must be bolstered by the ability to take protective measures during the course of an accident.''

The Commission did not rely upon probabilistic risk assessments in developing this final regulation on consideration of the use of KI.

The Commission interprets the third comment to relate to factors that the commenter believes could increase the likelihood of an accident and which, in the commenter's view, heighten the importance of emergency planning. The Commission's regulations recognize the importance of emergency planning by requiring development of a range of protective actions, which include sheltering and evacuation and, by this rulemaking, consideration of the use of KI for the general public.

Issue N: Cost of KI and Shelf-Life

One commenter feels that the NRC has exaggerated the estimated cost of KI, ignoring comments that point to the availability of inexpensive and long-lasting KI. This commenter thinks that market forces are likely to bring down the cost of KI and that savings in the NRC budget could be effected without diminishing the safety of America's children.

The U.S. Pharmacopeia wrote in its comment letter that the long-term viability of the drug was tested and it was found that 11 years after manufacture and eight years after the expiration date, the tablets were assayed at 99.1% of the labeled content of KI. The petitioner expressed the view that since the U.S. is currently engaged in a $15 million study of radiation-caused thyroid disease in the Ukraine, it was hard to understand why the government was not willing to spend a fraction of that amount to prevent radiation caused thyroid disease at home.

Response. Cost estimates used in past documents were based upon information available at those times. NRC presently estimates the cost of KI to be about 18 to 20 cents per tablet if purchased in bulk, with a shelf life of 7 to 10 years. As a result, the Commission finds that KI is a reasonable, prudent and inexpensive supplement to evacuation and sheltering for the general public for specific local conditions.

As noted earlier, the Commission has decided to offer to provide funding for a supply of KI for State or, in some cases, local governments that choose to incorporate KI prophylaxis in their emergency plans.

Issue O: Safety of KI

Commenters believe that there is new information available from Poland and Belarus regarding use of KI following a radioactive release. They state that there were no reported serious adverse reactions. Specifically, 18 million individuals received prophylactic KI with overall toxicity of 2.5% (mostly nausea) but with only a fraction of 1% having serious side-effects.[4] Commenters state that this experience has been recognized by other countries who are stockpiling KI for use by the general public. This data has led some commenters to say that just because there are other lethal radionuclides to which people may be exposed, why deny them the availability of KI, which can counteract the deadly effects of radioactive iodine. Every drug has contraindications and the potential for allergic reactions. In an emergency as dire as a reactor accident where people risk illness and death, a possible adverse reaction to KI seems relatively minimal, and people absolutely should have the choice of making an informed decision and assuming possible risk.

Response. The Commission did consider the experience with mass distribution of KI during the Chernobyl radiological emergency (although the record on that distribution is not complete). That experience is still being investigated and evaluated by public health authorities worldwide. When the appropriate health agencies have established the applicability of the Polish experience to the United States, the findings will be followed in NRC guidance. The NRC acknowledges that KI is a reasonable, prudent, and inexpensive supplement to evacuation and sheltering for specific local conditions. The Commission guidance on emergency planning has long taken KI into consideration (see NUREG–0654/FEMA–REP–1, ''Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants,'' Rev. 1, p. 63, items e and f). The FDA has approved KI as an over-the-counter medication and has found it effective and safe as discussed in the response to issue I.

Commission Decision on the Petitions for Rulemaking

Based on the foregoing, and as noted herein, the action by the Commission to approve this final rule grants in part and denies in part the original petition (PRM 50–63) and grants in all respects the amended petition (PRM 50–63A). The rule change, which requires ''consideration'' of the use of KI, is responsive to the amended petition. Further, including in this **Federal Register** notice for the final rule, a

[4] Comment letter from the Massachusetts Coalition To Stockpile KI dated September 10, 1999.

statement that ''KI is a reasonable, prudent, inexpensive supplement to evacuation and sheltering for specific local conditions,'' is also responsive to both petitions. This statement does not use the petitioner's exact language but is responsive to the petitioner's request. The Commission's final position on funding of State stockpiles grants that part of the original and amended petition to include a statement of such support in the Statement of Considerations for the rule. However, the final rulemaking would deny that part of the original petition requesting that the Commission amend 10 CFR 50.47(b)(10) to *require* that the range of protective actions developed for the plume exposure pathway EPZ include sheltering, evacuation, and the prophylactic use of iodine.

The Commission has found that ''[I]n developing the range of actions for severe accidents at nuclear power plants, evacuation and sheltering provide adequate protection for the general public.'' (Proposed Rule, 64 FR at 31745). In addition, the Commission notes that issues surrounding the prophylactic use of KI following such accidents do not lend themselves to across-the-board solutions. Therefore, the Commission has chosen to leave such decisions to State and local emergency response planners to determine whether their emergency plans should include the use of KI as a supplementary protective measure for the general public. The Commission's decision is implemented through this final rule that changes 10 CFR 50.47(b)(10). This final rule completes NRC action on PRM 50–63 and PRM 50–63A.

Rationale for the Commission Decision

The Commission has considered the KI policy question on numerous occasions since 1984. The history of the Commission deliberations shows that reaching consensus on this policy question has been an elusive goal. An important reason for this historical lack of consensus is that this policy question is not a clear-cut one. Individual Commissioners, past and present, have differed in their views with respect to the relative importance to be given to factors bearing on the KI issue. These honest differences have led to divided Commission views on how to resolve the policy question. The Commission agrees that its historical difficulty in reaching consensus on the KI policy question underscores the reality that this policy question is not a simple one, is not one that is easily resolved and, as a result, has been the subject of protracted deliberation.

After considering all public comments received, the information available in the literature, 20 years of experience gained in evaluating licensee emergency preparedness plans, and the arguments presented by the petitioner, the Commission has decided to amend 10 CFR 50.47(b)(10), by adding a sentence similar to the one suggested in the revised petition. Specifically the following sentence is inserted in § 50.47(b)(10), after the first sentence: ''In developing this range of actions, consideration has been given to evacuation, sheltering, and, as a supplement to these, the prophylactic use of potassium iodide (KI), as appropriate.''

The Commission finds that KI is a reasonable, prudent and inexpensive supplement to evacuation and sheltering for specific local conditions. The Commission's guidance on emergency planning has long taken KI into consideration (NUREG–0654/FEMA–REP–1, Rev. 1, p. 63, items e and f). However, since the last revision of that guidance, there has been experience with the mass distribution of KI during an international radiological emergency, and though the record on that distribution is not complete, the indications thus far are that mass distribution is effective in preventing thyroid cancer and causes few threatening side effects. Moreover, many nations in Europe and elsewhere—nations as different in their circumstances, politics, and regulatory structures as France, Canada, and Japan—have stockpiled KI and planned for its use. So have some U.S. States. The World Health Organization and the International Atomic Energy Agency recommend its use. Therefore, in order to achieve greater assurance that KI will receive due attention by planners, it is reasonable to take a further small step and, continuing to recognize the important role of the States and local governments in matters of offsite emergency planning, explicitly require that planners consider the use of KI.

The amendment should not be taken to imply that the NRC believes that the present generation of nuclear power plants is any less safe than previously thought. On the contrary, present indications are that nuclear power plant safety has significantly improved since the current emergency planning requirements were put in place after the Three Mile Island-2 accident in 1979.

The use of KI is intended to supplement, not to replace, other protective measures. This amendment does not change the NRC's view that the primary and most desirable protective action in a radiological emergency is evacuation of the population before any exposure to radiation occurs. The Commission recognizes that there may be situations when evacuation is not feasible or is delayed. In-place sheltering is an effective protective action in such a situation. Depending on the circumstances, KI may offer additional protection to one radiation-sensitive organ, the thyroid, if used in conjunction with evacuation and sheltering. In developing the range of public protective actions for severe accidents at commercial nuclear power plants, evacuation and in-place sheltering provide adequate protection for the general public. In appropriate circumstances, KI can provide additional protection. In addition, the Commission notes that issues surrounding the prophylactic use of KI following such accidents do not lend themselves to across-the-board solutions. Therefore, the Commission has chosen to leave such decisions to State and local emergency response planners, who may find that KI should be a supplementary protective measure.

The NRC recognizes that any decision to use KI as a supplemental protective measure for the general public presents issues of how best to position and distribute the medicine, to ensure: (1) That optimal distribution takes place in an emergency, with first priority given to protecting children; (2) that persons with known allergies to iodine not take it; and (3) that members of the public understand that KI is not a substitute for measures that protect the whole body. To date, these issues have been addressed in different ways in the numerous countries that currently use KI as a protective measure for their citizens. The NRC is working with States and other Federal agencies to develop guidance on these and other issues relating to the use of KI. The NRC believes that these implementation issues can be solved, given the level of expertise in the relevant Federal and State agencies, and the experience of numerous nations that have built KI into their emergency plans.

Commission Decision on Funding of State Stockpiles or Supplies of KI

The **Federal Register** notice for the proposed rule (64 FR 31737) stated the Commission's then-held position only to support funding of regional stockpiles or other supplies of KI as opposed to funding of State stockpiling of KI. As described above, in its deliberations on this final rule, the Commission has withdrawn its support for funding of regional KI stockpiles and has reinstated its offer to provide NRC funding of State or, in some cases, local stockpiles,

subject to various restrictions and limitations (see Staff Requirements Memorandum for the Affirmation Session on December 22, 2000).

In doing this, the Commission has responded to comments from FEMA and other commenters. The Commission is supporting the 1996 FRPCC's Ad Hoc Subcommittee on Potassium Iodide recommendation that the Federal government (NRC through FEMA) should fund the purchase of State, or in some cases local, KI stockpiles. The Commission recognizes that this policy contradicts the Commission's historical policy that funding for State and local emergency planning is the responsibility of those governments often working with licensees. The Commission is making this exception to the long-standing policy on the basis of the FRPCC's recommendation and recent petitions received. The Commission has determined that for a State that has decided to stockpile KI, NRC funding for purchase of KI for use by that State during a radiological emergency would directly contribute to fulfilling NRC's regulatory mission. The Commission also recognizes that any State choosing to incorporate KI prophylaxis as a supplemental protective action in its emergency planning will face costs, other than the cost of the purchase of KI. Consistent with the long-standing policy, these ancillary costs will remain the responsibility of the State government. Depending on how the State incorporates KI prophylaxis in its emergency plans, the ancillary costs could significantly exceed the cost of the purchase of the KI supply.

Metric Policy

On October 7, 1992, the Commission published its final Policy Statement on Metrication. According to that policy, after January 7, 1993, all new regulations and major amendments to existing regulations were to be presented in dual units. The amendment to the regulations contains no units.

National Technology Transfer and Advancement Act

The National Technology Transfer and Advancement Act of 1995, Pub. L. 104–113, requires that Federal agencies use technical standards developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this final rule, the NRC is amending its emergency planning regulations to require that consideration be given to including potassium iodide as a protective measure for the general public that would supplement sheltering and evacuation in the event of a severe reactor accident. This action does not constitute the establishment of a consensus standard that contains generally applicable requirements to which the provisions of the Act apply.

Environmental Assessment and Finding of No Significant Impact for Completing Action on the Petitions for Rulemaking Relating to the Use of Potassium Iodide (KI) for the General Public

I. Introduction

On September 9, 1995, a petition for rulemaking (PRM 50–63) was filed with the NRC by Mr. Peter Crane. The petitioner requested that the NRC amend its emergency planning regulations to require that emergency plans specify a range of protective actions to include sheltering, evacuation, and the prophylactic use of KI.

In SECY–97–245, dated October 23, 1997, the NRC staff provided three options for the Commission's consideration in order to resolve PRM 50–63.

On November 5, 1997, the Commission was briefed by the NRC staff, the Federal Emergency Management Agency (FEMA), and the petitioner regarding the options available for resolving the petition for rulemaking. During the meeting, the Commission invited the petitioner to submit a modification to his petition in order to address views he discussed during the meeting.

On November 11, 1997, the petitioner submitted a revision to his petition PRM 50–63A, that requested two things:

1. A statement clearly recommending stockpiling of KI as a ''reasonable and prudent'' measure, and

2. A proposed rule change to 10 CFR 50.47(b)(10) which would be accomplished by inserting the following sentence after the first sentence: ''In developing this range of actions, consideration has been given to evacuation, sheltering, and the prophylactic use of potassium iodide (KI), as appropriate.''

On June 26, 1998, the Commission disagreed with the NRC staff's recommendation in SECY–98–061 dated March 31, 1998, ''Staff Options for Resolving a Petition for Rulemaking (PRM 50–63 and 50–63A) Relating to a Re-evaluation of the Policy Regarding the use of Potassium Iodide (KI) by the General Public after a Severe Accident at a Nuclear Power Plant,'' to deny the revised petition for rulemaking (PRM 50–63A) and directed the NRC staff to grant the petition by revising 10 CFR 50.47 (b)(10). This final rule responds to this directive.

Alternatives were essentially considered in previous documents. In SECY–97–124 (June 16, 1997), ''Proposed Federal Policy Regarding Use of Potassium Iodide after a Severe Accident at a Nuclear Power Plant,'' the NRC staff identified three options, one of which contained three sub-options, concerning a proposed change in the Federal policy regarding the use of potassium iodide (KI) as a protective measure for the general public during severe reactor accidents.

On April 22, 1999, the Commission voted to approve publication in the **Federal Register** of a proposed rule that would grant the revised petition for rulemaking (PRM 50–63A). The proposed rule was published on June 14, 1999 (64 FR 31737). In the petitioner's comment letter on the proposed rule, he stated that in light of the Commission decision not to fund State stockpiles of KI, the Commission should consider his original petition (PRM 50–63) to be incorporated by reference and resubmitted in his comment letter. He also requested the Commission to grant the petition as originally submitted. The Commission, by undertaking this final rulemaking, is denying in part the original petition for rulemaking (PRM 50–63), which would *require* the use of KI for the general public. In so doing, the Commission has decided to continue to recognize the important role of the State by explicitly requiring that planners *consider* (PRM 50–63A) the use of KI for the general public. The Commission is granting in all respects the amended petition, including reinstating its support for funding State stockpiles of KI.

II. Need for Action

In SECY–97–245, the NRC staff proposed options for resolving the original petition for rulemaking. In an SRM on SECY–98–061, the Commission directed the NRC staff to proceed with the rulemaking. In so doing, the Commission found that KI is a reasonable, prudent, and inexpensive supplement to evacuation and sheltering for specific local conditions. The Commission's guidance on emergency planning has long taken KI into consideration (NUREG–0654/FEMA–REP–1, Rev. 1, p. 63 items e and f). However, since the last revision of that guidance, there has been experience with the mass distribution of KI during an international radiological emergency. Although the record on that distribution is not complete, the indications thus far are that mass distribution is effective in

preventing thyroid cancer and causes few threatening side effects. Therefore, in order to achieve greater assurance that KI will receive due attention by planners, it seems reasonable, while continuing to recognize the important role of the States in matters of offsite emergency planning, to explicitly require that planners consider the use of KI. The rule is needed to ensure that the States are aware of and take into consideration the costs, risks, and benefits of KI in their decision making process in order to optimize emergency planning for the public health and safety.

III. Environmental Impact of the Final Action

The environmental impacts of the final action and its alternative (deny the petitions in their entirety and take no action) are considered negligible by the NRC staff, given that the final action would only add the sentence: ''In developing this range of actions, consideration has been given to evacuation, sheltering, and the prophylactic use of potassium iodide (KI), as appropriate.'' The NRC staff is not aware of any environmental impacts as a result of this final action.

IV. Alternative to the Final Action

The alternative to the final action at this time is to deny the petitions and take no action with respect to the use of KI by the public. Should this no-action alternative be pursued, the NRC staff is not aware of any resulting environmental impact.

V. Agencies and Persons Consulted

Cognizant personnel from the States, FEMA, and FDA were consulted, as was the petitioner, as part of this rulemaking activity.

VI. Finding of No Significant Environmental Impact: Availability

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51, that the amendment is not a major Federal action significantly affecting the quality of human environment and; therefore, an environmental impact statement is not required. This amendment will require that consideration be given to evacuation, sheltering, and as a supplement to these, the prophylactic use of KI. This action will not have a significant impact upon the environment.

Paperwork Reduction Act Statement

This final rule does not contain a new or amended information collection requirement subject to the Paperwork Reduction Act of 1995 (44 U.S.C 3501 *et seq.*). Existing requirements were approved by the Office of Management and Budget (OMB) approval numbers 3150–0009 and 3150–0011.

Public Protection Notification

If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

Regulatory Analysis of the Final Rulemaking Completing Action on Petitions for Rulemaking (PRM 50–63) and (PRM 50–63A) Relating to the Use of Potassium Iodide (KI)

On September 9, 1995, a petition for rulemaking (PRM 50–63) was filed with the NRC by Mr. Peter Crane. The petitioner requested that the NRC amend its emergency planning regulations to require that emergency plans specify a range of protective actions to include sheltering, evacuation, and the prophylactic use of KI.

In SECY–97–245, dated October 23, 1997, the NRC staff provided three options for the Commission's consideration to resolve PRM 50–63.

On November 5, 1997, the Commission was briefed by the NRC staff, the Federal Emergency Management Agency (FEMA), and the petitioner regarding the options available for resolving the petition for rulemaking. During the meeting, the Commission invited the petitioner to submit a modification to his petition in order to address views he discussed during the meeting.

On November 11, 1997, the petitioner submitted a revision to his petition (PRM 50–63A), which requested two things:

A statement clearly recommending stockpiling of KI as a ''reasonable and prudent'' measure; and

A proposed rule change to 10 CFR 50.47(b)(10) which would be accomplished by inserting the following sentence after the first sentence: ''In developing this range of actions, consideration has been given to evacuation, sheltering, and the prophylactic use of potassium iodide (KI), as appropriate.''

In the petitioner's comment letter on the proposed rule, he stated that in light of the Commission decision not to fund State stockpiles of KI, the Commission should consider his original petition (PRM 50–63) to be incorporated by reference and resubmitted in his comment letter. He also requested the Commission to grant the petition as originally submitted. The Commission, by undertaking this rulemaking, is granting the amended petition and is granting in part and denying in part the original petition. The Commission is denying that portion of the original petition for rulemaking (PRM 50–63), which would *require* the use of KI for the general public. In so doing, the Commission has decided to continue to recognize the important role of the State in matters of emergency planning by explicitly requiring that planners *consider* (PRM 50–63A) the use of KI for the general public.

In SECY–97–245, the NRC staff proposed options for resolving the original petition for rulemaking. By SRM dated June 26, 1998, on SECY–97–245, ''Staff Options for Resolving a Petition for Rulemaking (PRM 50–63) Relating to a Re-evaluation of the Policy Regarding use of Potassium Iodide (KI) after a Severe Accident at a Nuclear Power Plant,'' the Commission directed the NRC staff to revise 10 CFR 50.47(b)(10). This final rule responds to this directive.

Alternatives were essentially considered in previous documents. In SECY–97–124 dated June 16, 1997, ''Proposed Federal Policy Regarding Use of Potassium Iodide after a Severe Accident at a Nuclear Power Plant,'' the NRC staff identified three options, one of which contained three sub-options, concerning a proposed change in the Federal policy regarding the use of potassium iodide (KI) as a protective measure for the general public during severe reactor accidents. Given that the Commission considered the options and directed the NRC staff to grant the amended petition, the only alternatives considered here are the Commission-approved option and the baseline, no-action alternative.

The final rule does not ''require'' any action of licensees. States are to ''consider'' the use of KI along with evacuation and sheltering as protective actions. It is estimated that no more than 30 States will need to make this consideration. The rule does not impose any substantive requirements on States to actually stockpile or plan for the use of KI. Therefore, States would not accrue the costs associated with such actions. However, the Commission recognizes that consideration of using KI as a supplemental protective measure may result in some State expenditures. The NRC staff estimates that the labor needed by the States could range from a staff-week, to half of a staff-year. The latter would be the case if a State decided to hold hearings on the issue.

If one assumes an average hourly salary of $70 (this estimate includes benefits, prorated secretarial and managerial assistance, but not overhead), the range of estimates would be from $2800 to $63,000 per State. Using a base of 30 States, the range of impacts for the States to make the KI consideration is from $84,000 to $1.9 million.

The Commission notes that when it amended its emergency planning regulations on November 3, 1980, the regulatory standards for emergency planning were a restatement of basic joint NRC-FEMA guidance to licensees and to State and local governments incorporated in NUREG–0654; FEMA–REP–1, ''Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants for Interim Use and Comment.'' This guidance was cited in the regulation and addresses the use of radioprotective drugs by the general public, including quantities, storage, and means of distribution and State and local plans for decision making with respect to their use. The Commission removed the citations of the guidance from the regulation in 1987, but the guidance has continued in use for planning purposes by States and licensees and by the Federal agencies for evaluating emergency plans. As a result, it is believed that all of the 30 affected States have at some point considered the use of KI. A few of the 30 affected States have made the decision to stockpile KI. Thus, in practical terms, the projected costs will occur only in those States that have not previously elected to stockpile KI and choose stockpiling in light of the Chernobyl accident, recent international practice, and the NRC requirement to consider the use of KI.

It is difficult to estimate the benefit of a State's consideration to use KI for the general public. However, we believe the benefit of such an action by the States is summed up by the petitioner who stated that the decision to use KI for the general public should turn on whether, given the consequences of being without KI in a major accident, the drug is a prudent measure; not on whether it will necessarily pay for itself over time. As the petitioner further noted, ''KI represents a kind of catastrophic-coverage insurance policy offering protection for events which, while they occur only rarely, can have such enormous consequences that it is sensible to take special precautions, especially where, as here, the cost of such additional precautions is relatively low.''

Nonetheless, the Commission notes that this rule will introduce another element in the context of emergency planning requirements for which licensees are ultimately responsible. Licensees have the obligation to confirm that offsite authorities have considered the use of KI as a supplemental protective action for the general public. While this ultimate responsibility could have practical implications, with some associated burdens, the extent is considered minimal when viewed in the overall licensee burden of complying with all of the existing emergency planning requirements.

Additionally, the rule does not articulate any implementation date or inspection criteria.

As stated above, this analysis focuses on the rule being codified as the result of petitions for rulemaking and on the Commission direction to grant the amended petition in all respects and to grant in part the original petition.

This constitutes the regulatory analysis for this action.

Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission hereby certifies that this rule will not have a significant economic impact on a substantial number of small entities. This final rule would affect only States and indirectly licensees of nuclear power plants. These States and licensees do not fall within the scope of the definition of ''small entities'' set forth in the Regulatory Flexibility Act, 5 U.S.C. 601, or the size standards adopted by the NRC (10 CFR 2.810).

Compatibility of Agreement State Regulations

Under the ''Policy Statement on Adequacy and Compatibility of Agreement State Programs'' that was approved by the Commission on June 30, 1997, and published in the **Federal Register** on September 3, 1997 (62 FR 46517), Part 50 is classified as compatibility Category ''NRC.'' The NRC program elements in this category are those that relate directly to areas of regulation reserved to the NRC by the Atomic Energy Act or provisions of Title 10 of the Code of Federal Regulations.

Plain Language

The President's Memorandum dated June 1, 1998, entitled ''Plain Language in Government Writing,'' directed that the government's writing be in plain language. This memorandum was published June 10, 1998 (63 FR 31883). In complying with this directive, editorial changes have been made in the final revisions to improve the organization and readability of the existing language of the paragraphs being revised. These types of changes are not discussed further in this notice.

Backfit Analysis

The definition of backfit, as set forth in 10 CFR 50.109(a)(1), is clearly directed at obligations imposed upon licensees (and applicants) and their facilities and procedures. Section 50.109(a)(1) defines a backfit as:

> * * * the modification of or addition to systems, structures, components, or design of a facility; or the design approval or manufacturing license for a facility; or the procedures or organization required to design, construct or operate a facility, any of which may result from a new or amended provision in the Commission rules or the imposition of a regulatory staff position interpreting the Commission rules that is either new or different from a previously applicable staff position * * *

Section 50.109 is replete with references to ''facilities'' and ''licensees,'' which in their totality make clear that the rule is intended to apply to actions taken with respect to nuclear power plant licensees and the facilities they operate. *See* § 50.109(a)(7), ''If there are two or more ways to achieve compliance with a license or the rules or orders of the Commission, or with written *licensee* commitments * * * then ordinarily the applicant or *licensee* is free to choose the way that best suits its purposes [emphasis added].'' This focus on licensees and their facilities is further confirmed by the Statement of Considerations accompanying the backfit rule (53 FR 20603; June 6, 1988), where the Commission stated that backfitting ''means measures which are intended to improve the safety of nuclear power reactors * * *.'' (53 FR at 20604). The nine factors to be considered under 10 CFR 50.109(c) further make clear that the rule is aimed at requirements applicable to licensees and facilities. These include: ''(2) General description of the activity that would be required by the *licensee* or *applicant* in order to complete the backfit; * * * (5) Installation and continuing costs associated with the backfit, including the cost of *facility* downtime or the cost of construction delay; [and] (6) The potential safety impact of changes in plant or operational complexity. * * * [emphasis added].''

The final rule imposes no new requirements on licensees, nor does it alter procedures at nuclear facilities. Rather, it is directed to State or local governments, the entities with the important role to determine the appropriateness of the use of KI for their citizens, calling on these governments to

''consider'' KI as one of the elements of their offsite emergency planning. However, the rule imposes no binding requirement to alter plans and procedures on State or local governments. Furthermore, the basic standard that emergency planning must include consideration of a range of protective actions is already set forth in the existing wording of § 50.47(b)(10). On this basis, the final rule does not impose new substantive requirements on *anyone*. After consideration of these factors, no backfit is involved and no backfit analysis as defined in § 50.109 is required.

Commission precedent also makes clear that the amendment does not constitute a backfit. The Commission's position was stated explicitly in 1987, when the last major change took place in emergency planning regulations (52 FR 42078; November 3, 1987). The Commission's final rule involving the ''Evaluation of the Adequacy of Off-Site Emergency Planning for Nuclear Power Plants at the Operating License Review Stage Where State and Local Governments Decline to Participate in Off-Site Emergency Planning'' stated that the emergency planning rule change in question ''does not impose any new requirements on production or utilization facilities; it only provides an alternative method to meet the Commission's emergency planning regulations. The amendment therefore is not a backfit under 10 CFR 50.109 and a backfit analysis is not required'' (52 FR 42084). Likewise, when the Commission altered its emergency planning requirements in 1987 to change the timing for full participation emergency exercises (a change that, as a practical matter, could be expected to result in licensees' modifying emergency preparedness-related procedures to accommodate exercise frequency changes), it stated: ''The final rule does not modify or add to systems, structures, components or design of a facility; the design approval or manufacturing license for a facility; or the procedures or organization required to design, construct, or operate a facility. Accordingly, no backfit analysis pursuant to 10 CFR 50.109 is required for this final rule'' (52 FR 16828; May 6, 1987). The final emergency planning rule change is of a similar nature and similarly does not involve a backfit.

It has been argued by at least one commenter on the petition for rulemaking that, although licensees are not directly burdened by the final rule, they would be indirectly burdened because they would feel called upon to explain the new policy to their customers. By this logic, almost any Commission action that led an NRC licensee to issue a press release could be considered a backfit. Such a position is unsound law and policy. Here, the burden of public information on licensees or applicants, if any, appears *de minimis*. It plainly does not rise to the level of the type of concrete burden contemplated by the Commission when it enacted the backfit rule. It might also be argued that, if a State or local government were to decide to stockpile and use KI for the general public, it would undertake interactions with the affected licensee to coordinate offsite emergency planning. Although this could result in some voluntary action by the licensee to coordinate its planning, the final rule itself does not impose any requirement or burden on the licensee. Accordingly, the Commission concludes that the final rule would not impose any backfits as defined in 10 CFR 50.109.

Nonetheless, the Commission notes that this rule will introduce another element in the context of the emergency planning requirements that licensees are ultimately responsible for, whereby licensees have the obligation to confirm that offsite authorities have considered the use of KI as a supplemental protective action for the general public. That ultimate responsibility could have practical implications, with some associated burdens, the extent of which is considered minimal when viewed in the overall licensee burden of complying with all of the existing emergency planning requirements.

Small Business Regulatory Enforcement Fairness Act

In accordance with the Small Business Regulatory Enforcement Fairness Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of OMB.

List of Subjects in 10 CFR Part 50

Antitrust, Classified information, Criminal penalties, Fire protection, Intergovernmental relations, Nuclear power plants and reactors, Radiation protection, Reporting and recordkeeping requirements.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act for 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 552 and 553, the NRC is adopting the following amendment to 10 CFR part 50.

PART 50—DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES

1. The authority citation for 10 CFR part 50 continues to read as follows:

Authority: Secs. 102, 103, 104, 105, 161, 182, 183, 186, 189, 68 Stat. 936, 938, 948, 953, 954, 955, 956, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2132, 2133, 2134, 2135, 2201, 2232, 2233, 2239, 2282); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended 1244, 1246, (42 U.S.C. 5841, 5842, 5846).

Section 50.7 also issued under Pub. Law 95–601, sec. 10, 92 Stat. 2951, as amended by Pub. Law 102–486, sec. 2902, 106 Stat. 3123, (42 U.S.C. 5851). Sections 50.10 also issued under secs. 101, 185, 68 Stat. 936, 955, as amended (42 U.S.C. 2131, 2235); sec. 102, Pub. Law 91–190, 83 Stat. 853 (42 U.S.C. 4332). Section 50.13, 50.54(dd), and 50.103 also issued under sec. 108, 68 Stat. 939, as amended (42 U.S.C. 2138). Sections 50.23, 50.35, 50.55, and 50.56 also issued under sec. 185, 68 Stat. 955 (42 U.S.C. 2235). Sections 50.33a, 50.55a and Appendix Q also issued under sec. 102, Pub. Law 91–190, 83 Stat. 853 (42 U.S.C. 4332). Sections 50.34 and 50.54 also issued under Pub. Law 97–415, 96 Stat. 2073 (42 U.S.C. 2239). Section 50.78 also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Sections 50.80, 50.81 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Appendix F also issued under sec. 187, 68 Stat. 955 (42 U.S.C. 2237).

2. In § 50.47, paragraph (b)(10) is revised to read as follows:

§ 50.47 Emergency plans.

* * * * *

(b) * * *

(10) A range of protective actions has been developed for the plume exposure pathway EPZ for emergency workers and the public. In developing this range of actions, consideration has been given to evacuation, sheltering, and, as a supplement to these, the prophylactic use of potassium iodide (KI), as appropriate. Guidelines for the choice of protective actions during an emergency, consistent with Federal guidance, are developed and in place, and protective actions for the ingestion exposure pathway EPZ appropriate to the locale have been developed.

* * * * *

Dated at Rockville, Maryland, this 9th day of January, 2001.

For the Nuclear Regulatory Commission.

Annette Vietti-Cook,

Secretary of the Commission.

[FR Doc. 01–1156 Filed 1–18–01; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 150

RIN 3150–AG60

Termination of Section 274i Agreement Between the State of Louisiana and the Nuclear Regulatory Commission

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is revising its regulations to remove the reference to an inspection agreement, referred to as the 274i Agreement, with the State of Louisiana. The inspection agreement entered into pursuant to section 274i of the Atomic Energy Act allowed the State of Louisiana to perform inspections or other functions in offshore waters adjacent to Louisiana on behalf of the NRC. This reference is located in the reciprocity regulations in 10 CFR 150.20. Under section 150.20(c), certain general licensees are not required to file with the NRC if the licensee provides timely notification of its offshore activities to the Agreement State that issued the specific license, and that State is listed in 150.20(d) as agreeing to perform inspections for NRC under a 274i agreement. Louisiana is the only Agreement State listed in the regulation. This action responds to a request from the Governor of Louisiana to terminate the agreement. The NRC agreed that the 274i inspection agreement is no longer needed and should be terminated. Therefore, the NRC is revising the regulations by deleting 150.20 (c) and (d) in their entirety. In the event NRC enters into a 274i inspection agreement with an Agreement State in the future, the provisions of 150.20(c) and (d), which were promulgated following notice and comment rulemaking, will be reinstated via direct final rulemaking.

DATES: The final rule is effective January 19, 2001.

FOR FURTHER INFORMATION CONTACT: Stephanie P. Bush-Goddard, Ph.D., Office of Nuclear Material Safety and Safeguards, telephone (301) 415–6257, e-mail, SPB@nrc.gov, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

Background

In 1967, the State of Louisiana and the United States Atomic Energy Commission (now the U.S. Nuclear Regulatory Commission) entered into an agreement pursuant to section 274b of the Atomic Energy Act of 1954, as amended, to discontinue the Commission's regulatory responsibilities over the use and possession of certain types of radioactive material in Louisiana. The State of Louisiana, in turn, assumed authority (formerly exercised by the NRC) over these regulatory activities. This agreement was noticed in the **Federal Register** on May 3, 1967 (32 FR 6806). The discontinuance of the Commission's authority became effective May 1, 1967 and, at the same time, established Louisiana as an Agreement State. Additionally, on May 3, 1967 (32 FR 6807), the Commission published in the **Federal Register** a notice of an agreement between the State of Louisiana and the Commission that permitted the State to perform inspections or other functions in offshore waters adjacent to Louisiana on behalf of the Commission. This inspection agreement, entered into pursuant to section 274i of the Act, did not expand the State's regulatory authority but rather specifically authorized the State to conduct inspection activities and other functions on the Commission's behalf.

The NRC received a letter from Louisiana Governor M. J. ''Mike'' Foster, Jr., dated March 22, 2000, which requested termination of the section 274i agreement. The Governor stated that the termination would become effective 30 days from receipt of the letter. The request was filed in accordance with section 6 of the inspection agreement, which states: ''* * * This Agreement shall become effective on May 1, 1967, and shall remain in effect so long as the 274b Agreement remains in effect unless sooner terminated by either party on 30 days' prior written notice.''

Governor Foster noted that difficulties arranging transportation and a lack of financial and personnel resources made it burdensome to conduct field activities for the NRC. The State concluded that the section 274i inspection agreement was no longer needed and should be terminated.

Effective April 26, 2000, the inspection agreement with the State of Louisiana and the NRC was terminated. Beginning April 26, 2000, the NRC, not the State, began conducting inspections of NRC-licensed activities in offshore waters adjacent to Louisiana. In this final rule, the NRC is issuing a conforming amendment to its reciprocity regulations in 10 CFR 150.20 (c) and (d). These sections provide that a licensee is not required to fulfill certain NRC reporting requirements for licensed activities performed in certain offshore waters. Under section 150.20 (c), certain general licensees are not required to file with the NRC if the licensee provides timely notification of its offshore activities to the Agreement State that issued the specific license, and that State is listed in 150.20(d) as agreeing to perform inspections for NRC under a 274i agreement. Louisiana was the only Agreement State listed in the regulation because it was the only State which had entered into such an agreement with the NRC.

In a letter to Governor Foster acknowledging termination of the 274i Agreement, the NRC indicated it would remove from the regulation only the specific reference to the NRC's inspection agreement with Louisiana in section 150.20(d). However, to promote clarity in the regulations, these sections will be removed in their entirety. In the event NRC enters into a 274i inspection agreement with an Agreement State in the future, the provisions of 150.20(c) and (d), which were promulgated following notice and comment rulemaking, will be reinstated via direct final rulemaking. In a separate communication, the NRC will provide guidance to Louisiana licensees on the impacts that the termination of this agreement will have on the notification and fee requirements for activities conducted in offshore waters.

However, termination of the section 274i inspection agreement does not in any way affect the existing agreement between the Commission and the State of Louisiana entered into pursuant to section 274b of the Act. Accordingly, termination of the inspection agreement does not affect Louisiana's status as an Agreement State.

Procedural Background

This amendment involves a conforming change to NRC's regulations to reflect the fact that the State of Louisiana has terminated the section 274i inspection agreement. Accordingly, the NRC finds that, pursuant to 5 U.S.C. 553(b)(B), notice and comment is unnecessary. These amendments are effective upon publication in the **Federal Register**. Good cause exists to dispense with the usual 30-day delay in the effective date, because these amendments are of a minor and administrative nature, conforming the NRC's regulations as a result of the April 26, 2000 termination of the 274i agreement with the State of Louisiana.

Agreement State Compatibility

Under the ''Policy Statement on Adequacy and Compatibility of Agreement State Programs'' approved by the Commission on June 30, 1997, and

published in the **Federal Register** on September 3, 1997 (62 FR 46517), this rule is classified as compatibility Category ''NRC.'' Compatibility is not required for Category ''NRC'' regulations. The NRC program elements in this category are those that relate directly to areas of regulation reserved to the NRC by the Atomic Energy Act of 1954, as amended (AEA), or the provisions of Title 10 of the Code of Federal Regulations. Although an Agreement State may not adopt program elements reserved to NRC, it may wish to inform its licensees of certain requirements via a mechanism that is consistent with the particular State's administrative procedure laws, but does not confer regulatory authority on the State.

Voluntary Consensus Standards

The National Technology Transfer Act of 1995 (Public Law 104–113) requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this final rule, the NRC is revising its regulations to remove the reference to an inspection agreement, referred to as the 274i Agreement, with the State of Louisiana. The inspection agreement entered into pursuant to section 274i of the Atomic Energy Act allowed the State of Louisiana to perform inspections or other functions in offshore waters adjacent to Louisiana on behalf of the NRC. This reference is located in the reciprocity regulations in 10 CFR 150.20. Under section 150.20(c), certain general licensees are not required to file with the NRC if the licensee provides timely notification of its offshore activities to the Agreement State that issued the specific license, and that State is listed in 150.20(d) as agreeing to perform inspections for NRC under a 274i agreement. Louisiana is the only Agreement State listed in the regulation. This action responds to a request from the Governor of Louisiana to terminate the agreement. The NRC agreed that the 274i inspection agreement is no longer needed and should be terminated. Therefore, the NRC is revising the regulations by deleting 150.20 (c) and (d) in their entirety. In the event NRC enters into a 274i inspection agreement with an Agreement State in the future, the provisions of 150.20 (c) and (d), which were promulgated following notice and comment rulemaking, will be reinstated via direct final rulemaking. This action does not constitute the establishment of a standard that establishes generally-applicable requirements.

Environmental Impact: Categorical Exclusion

The NRC has determined that this final rule is the type of action described in categorical exclusion 10 CFR 51.22(c)(2). Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this final rule.

Paperwork Reduction Act Statement

This final rule does not contain a new or amended information collection requirement subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Existing requirements were approved by the Office of Management and Budget, Approval Number 3150–0032.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, collection of information unless it displays a currently valid OMB control number.

Regulatory Analysis

These minor amendments impose no new restrictions or requirements, and therefore, have no significant impact. Accordingly, a regulatory analysis is considered not necessary and has not been prepared.

Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Commission certifies that this rule will not have a significant economic impact on a substantial number of small entities. This administrative rule is being revised to remove the reference to an inspection agreement, referred to as the 274i Agreement, with the State of Louisiana. The inspection agreement entered into pursuant to section 274i of the Atomic Energy Act allowed the State of Louisiana to perform inspections or other functions in offshore waters adjacent to Louisiana on behalf of the NRC. This reference is located in the reciprocity regulations in 10 CFR 150.20. Under section 150.20(c), certain general licensees are not required to file with the NRC if the licensee provides timely notification of its offshore activities to the Agreement State that issued the specific license, and that State is listed in 150.20(d) as agreeing to perform inspections for NRC under a 274i agreement. Louisiana is the only Agreement State listed in the regulation. This action responds to a request from the Governor of Louisiana to terminate the agreement. The NRC agreed that the 274i inspection agreement is no longer needed and should be terminated. Therefore, the NRC is revising the regulations by deleting 150.20(c) and (d) in their entirety. In the event NRC enters into a 274i inspection agreement with an Agreement State in the future, the provisions of 150.20(c) and (d), which were promulgated following notice and comment rulemaking, will be reinstated via direct final rulemaking.

Backfit Analysis

The NRC has determined that the backfit rule does not apply to this final rule because this amendment does not involve any provisions that would impose backfits as defined in 10 CFR Chapter 1. Therefore, a backfit analysis is not required for this final rule.

Small Business Regulatory Enforcement Fairness Act

In accordance with the Small Business Regulatory Enforcement Fairness Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs, Office of Management and Budget.

List of Subjects in 10 CFR Part 150

Criminal penalties, Hazardous materials transportation, Intergovernmental relations, Nuclear materials, Reporting and recordkeeping requirements, Security measures.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553, the NRC is adopting the following amendments to 10 CFR part 150.

PART 150—EXEMPTIONS AND CONTINUED REGULATORY AUTHORITY IN AGREEMENT STATES AND IN OFFSHORE WATERS UNDER SECTION 274

1. The authority citation for part 150 continues to read as follows:

Authority: Sec. 161, 68 Stat. 948, as amended, sec. 274, 73 Stat. 688 (42 U.S.C. 2201, 2021); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841). Sections 150.3, 150.15, 150.15a, 150.31, 150.32 also issued under secs. 11e(2), 81, 68 Stat. 923, 935, as amended, secs. 83, 84, 92 Stat. 3033, 3039 (42 U.S.C. 2014e(2), 2111, 2113, 2114). Section 150.14 also issued under sec. 53, 68 Stat. 930, as amended (42 U.S.C. 2073). Section 150.15 also issued under secs. 135, 141, Pub. Law 97–425, 96 Stat. 2232, 2241 (42 U.S.C. 10155, 10161). Section 150.17a also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Section 150.30 also issued under sec 234, 83 Stat. 444 (42 U.S.C. 2282).

§ 150.20 [Amended]

2. In § 150.20, paragraph (b)(1), first sentence, remove the words ''Except as specified in paragraph (c) of this section, shall'', add in their place ''shall'' and remove paragraphs (c) and (d).

Dated at Rockville, Maryland, this 28th day of December, 2000.

For the Nuclear Regulatory Commission.

Patricia G. Norry,

Acting Executive Director for Operations.

[FR Doc. 01–1079 Filed 1–18–01; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF COMMERCE

Bureau of Export Administration

15 CFR Parts 740, 742, and 748

[Docket No. 010112014–1014–01]

RIN 0694–AC41

Implementation of Presidential Announcement of January 10, 2001: Revisions to License Exception CTP

AGENCY: Bureau of Export Administration, Commerce.

ACTION: Final rule.

SUMMARY: The Bureau of Export Administration (BXA) is amending the Export Administration Regulations (EAR) by revising License Exception CTP to reflect rapid technological advances in computing capability. This rule implements the President's sixth revision to U.S. export controls on high performance computers (HPCs), announced January 10, 2001. License Exception CTP is revised by removing Computer Tier 2 and merging its countries into Computer Tier 1. All HPCs continue to be eligible for export to a Computer Tier 1 country under License Exception CTP. Additionally, HPCs with CTP up to 85,000 MTOPS can be exported to Computer Tier 3 countries under License Exception CTP, and beginning March 20, 2001, exporters will no longer be required to submit National Defense Authorization Act (NDAA) advance notifications for HPCs with CTP exceeding 85,000 MTOPS. The NDAA advance notification will not be required for these computers, because exporters will be submitting a license for exports to Computer Tier 3 countries of HPCs with CTP exceeding 85,000 MTOPS. This rule also moves Lithuania from Computer Tier 3 to Computer Tier 1, effective May 19, 2001. The President's action will promote our national security, enhance the effectiveness of our export control system and ease unnecessary regulatory burdens on both government and industry.

DATES: This rule is effective January 19, 2001.

FOR FURTHER INFORMATION CONTACT: Tanya Hodge Mottley in the Office of Strategic Trade and Foreign Policy Controls, Bureau of Export Administration, at (202) 482–1837.

SUPPLEMENTARY INFORMATION:

Background

On January 10, 2001, the President announced significant changes to U.S. export control policy for HPCs. The new policy continues the Administration's commitment, as announced on July 1, 1999, to review and update its HPC policy every six months in order to reflect rapid advancements in computer hardware, as well as identify any risk posed by HPC exports to certain end-users and countries. This policy strengthens America's high tech competitiveness, while maintaining export controls to protect U.S. national security.

The Administration, in consultation with the national security community and industry, has determined that additional adjustments are warranted. Effective immediately, all countries in Computer Tier 2 have been moved to Computer Tier 1. Computer Tier 2 has been deleted. Those countries formerly in Computer Tier 2 do not pose proliferation or security threats to the United States.

This rule implements the Administration's decision to increase License Exception CTP eligibility for HPC exports to countries in Computer Tier 3 by raising the CTP level to 85,000 MTOPS, to reflect the widespread availability of computers, including high performance computing capability attained by clustering numerous lower level personal computers together.

Effective March 20, 2001, this rule raises the advance notification requirement level for HPC exports to Computer Tier 3 countries from 28,000 to 85,000 MTOPS. As required by the NDAA, changes in the advance notification level for HPC exports to Tier 3 destinations are only effective 60 days following the President's submission of a report to Congress. In addition, this rule revises the support documentation requirements for computers exported to the People's Republic of China.

This rule removes Lithuania from Computer Tier 3 and places it in Computer Tier 1. However, due to the requirements in the 1998 National Defense Authorization Act (NDAA), removing Lithuania from Computer Tier 3 is not effective until 120 days after the Congress receives a report justifying such a removal.

This rule revises the Export Administration Regulations by modifying computer exports under License Exception CTP, as follows:

1. Moving all Computer Tier 2 countries to Computer Tier 1;
2. Raising the CTP limit for computers eligible for License Exception CTP for exports and reexports to Computer Tier 3 destinations from ''28,000 MTOPS'' to ''85,000 MTOPS'';
3. Moving Lithuania to Tier 1 as of May 19, 2001;
4. Revising the CTP range for which NDAA notification is required for computers exported or reexported to Computer Tier 3 countries;
5. Revising the CTP level of computers for which PRC End-User Certificates are required as support documentation for export under License Exception CTP; and
6. Revising the CTP level of the computers that require post shipment verification reports for exports to Computer Tier 3 countries.

Rulemaking Requirements

1. This final rule has been determined to be not significant for purposes of Executive Order 12866.

2. Notwithstanding any other provision of law, no person is required to respond to nor be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. This regulation involves collections previously approved by the Office of Management and Budget under control numbers 0694–0088, ''Multi-Purpose Application,'' which carries a burden hour estimate of 45 minutes per manual submission and 40 minutes per electronic submission. Miscellaneous and recordkeeping activities account for 12 minutes per submission. Information is also collected under OMB control number 0694–0107, ''National Defense Authorization Act,'' Advance Notifications and Post-Shipment Verification Reports, which carries a burden hour estimate of 15 minutes per report. This rule also involves collections of information under OMB control number 0694–0073, ''Export Controls of High Performance Computers'' and OMB control number 0694–0093, ''Import Certificates and End-User Certificates.''

3. This rule does not contain policies with Federalism implications as that

term is defined in Executive Order 13132.

4. The provisions of the Administrative Procedure Act requiring notice of proposed rule making, the opportunity for public participation, and a delay in effective date, are inapplicable because this regulation involves a military or foreign affairs function of the United States (see 5 U.S.C. 553(a)(1)). Further, no other law requires that a notice of proposed rule making and an opportunity for public comment be given for this rule. Because a notice of proposed rule making and opportunities for public comment are not required to be given for this rule by 5 U.S.C. 553, or by any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, are inapplicable.

Therefore, this regulation is issued in final form. Although there is no formal comment period, public comments on this regulation are welcome on a continuing basis. Comments should be submitted to Office of Exporter Services, Bureau of Export Administration, Department of Commerce, P.O. Box 273, Washington, DC 20044.

List of Subjects

15 CFR Parts 740 and 748

Administrative practice and procedure, Exports, Foreign trade, Reporting and record keeping requirements.

15 CFR Part 742

Exports, Foreign trade.

Accordingly, parts 740, 742 and 748 of the Export Administration Regulations (15 CFR Parts 730–799) are amended as follows:

1. The authority citation for 15 CFR Part 740 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; Pub. L. No. 106–508; 50 U.S.C. 1701 *et seq.*; E.O. 12924, 59 FR 43437, 3 CFR, 1994 Comp., p. 917; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; Notice of August 3, 2000 (65 FR 48347, August 8, 2000).

2. The authority citation for 15 CFR Part 742 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; Pub. L. No. 106–508; Pub.L. No. 106–398; 50 U.S.C. 1701 *et seq.*; 18 U.S.C. 2510 *et seq.*; 22 U.S.C. 3201 *et seq.*; 42 U.S.C. 2139a; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12924, 59 FR 43437, 3 CFR, 1994 Comp., p. 917; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; Notice of November 10, 1999, 64 FR 61767, 3 CFR, 1999 Comp., p. 318; Notice of August 3, 2000 (65 FR 48347, August 8, 2000).

3. The authority citation for part 748 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; Pub. L. No. 106–508; 50 U.S.C. 1701 *et seq.*; E.O. 12924, 59 FR 43437, 3 CFR, 1994 Comp., p. 917; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; Notice of August 3, 2000 (65 FR 48347, August 8, 2000).

PART 740—[AMENDED]

4. Part 740 is amended by revising section 740.7, to read as follows:

§ 740.7 Computers (CTP).

(a) *Scope.* License Exception CTP authorizes exports and reexports of computers and specially designed components therefor, exported or reexported separately or as part of a system for consumption in Computer Tier countries as provided by this section. (Related equipment controlled under 4A003.d and .g is authorized under this License Exception, only when exported or reexported with these computers as part of a system.) You may not use this License Exception to export or reexport items that you know will be used to enhance the CTP beyond the eligibility limit allowed to your country of destination. When evaluating your computer to determine License Exception CTP eligibility, use the CTP parameter to the exclusion of other technical parameters for computers classified under ECCN 4A003.a, .b and .c, *except* of parameters specified as Missile Technology (MT) concerns or 4A003.e (equipment performing analog-to-digital conversions exceeding the limits in ECCN 3A001.a.5.a). This License Exception does not authorize the export or reexport of graphic accelerators or coprocessors, or of computers controlled for MT reasons.

(b) *Computer Tier 1.* (1) *Eligible countries.* The countries that are eligible to receive exports under this License Exception include Antigua and Barbuda, Argentina, Australia, Austria, Bahamas, Barbados, Bangladesh, Belgium, Belize, Benin, Bhutan, Bolivia, Botswana, Brazil, Brunei, Burkina Faso, Burma, Burundi, Cameroon, Cape Verde, Central African Republic, Chad, Czech Republic, Chile, Colombia, Congo, Costa Rica, Cote d'Ivoire, Cyprus, Denmark, Dominica, Dominican Republic, Ecuador, El Salvador, Equatorial Guinea, Eritrea, Estonia, Ethiopia, Fiji, Gabon, Finland, France, Gambia (The), Germany, Ghana, Greece, Grenada, Guatemala, Guinea, Guinea-Bissau, Guyana, Haiti, Honduras, Hong Kong, Hungary, Iceland, Indonesia, Ireland, Italy, Jamaica, Japan, Kenya, Kiribati, Korea (Republic of), Lesotho, Liberia, Liechtenstein, Luxembourg, Madagascar, Malawi, Malaysia, Maldives, Mali, Malta, Marshall Islands, Mauritius, Mexico, Micronesia (Federated States of), Monaco, Mozambique, Namibia, Nauru, Nepal, Netherlands, New Zealand, Nicaragua, Niger, Nigeria, Norway, Palau, Panama, Papua New Guinea, Paraguay, Peru, Philippines, Poland, Portugal, Romania, Rwanda, St. Kitts & Nevis, St. Lucia, St. Vincent and Grenadines, Sao Tome & Principe, San Marino, Senegal, Seychelles, Sierra Leone, Singapore, Slovakia, Slovenia, Solomon Islands, Somalia, South Africa, Spain, Sri Lanka, Surinam, Swaziland, Sweden, Switzerland, Taiwan, Tanzania, Togo, Tonga, Thailand, Trinidad and Tobago, Turkey, Tuvalu, Uganda, United Kingdom, Uruguay, Vatican City, Venezuela, Western Sahara, Western Samoa, Zaire, Zambia, and Zimbabwe. As of May 19, 2001, Lithuania is a Computer Tier 1 country.

(2) *Eligible computers.* The computers eligible for License Exception CTP to Tier 1 destinations are those having a Composite Theoretical Performance (CTP) greater than 6,500 Millions of Theoretical Operations Per Second (MTOPS).

(c) [Reserved]

(d) *Computer Tier 3.* (1) *Eligible countries.* The countries that are eligible to receive exports and reexports under this License Exception are Afghanistan, Albania, Algeria, Andorra, Angola, Armenia, Azerbaijan, Bahrain, Belarus, Bosnia & Herzegovina, Bulgaria, Cambodia, China (People's Republic of), Comoros, Croatia, Djibouti, Egypt, Georgia, India, Israel, Jordan, Kazakhstan, Kosovo (Serbian province of), Kuwait, Kyrgyzstan, Laos, Latvia, Lebanon, Lithuania, Macau, Macedonia (The Former Yugoslav Republic of), Mauritania, Moldova, Mongolia, Montenegro, Morocco, Oman, Pakistan, Qatar, Russia, Saudi Arabia, Serbia, Tajikistan, Tunisia, Turkmenistan, Ukraine, United Arab Emirates, Uzbekistan, Vanuatu, Vietnam, and Yemen. As of May 19, 2001, Lithuania is moved to Computer Tier 1.

(2) *Eligible computers.* The computers eligible for License Exception CTP to Tier 3 destinations are those having a CTP greater than 6,500 MTOPS, but less than or equal to 85,000 MTOPS, subject to the restrictions in paragraph (d)(3) of this section.

(3) *Eligible exports.* Only exports and reexports to permitted end-users and end-uses located in countries in Computer Tier 3. License Exception CTP does not authorize exports and reexports to Computer Tier 3 for nuclear, chemical, biological, or missile end-users and end-uses and military

end-users and end-uses subject to license requirements under § 744.2, § 744.3, § 744.4, § 744.5, and § 744.12 of the EAR. Such exports and reexports will continue to require a license and will be considered on a case-by-case basis. Retransfers to these end-users and end-uses in eligible countries are strictly prohibited without prior authorization.

(4) *Supporting documentation.* Exporters are required to obtain a People's Republic of China (PRC) End-User Certificate before exporting computers described by paragraph (d)(2) of this section to the PRC, regardless of value. (See § 748.10(b)(3) of the EAR for information on obtaining the PRC End-User Certificate.) Exporters are required to provide the PRC End-User Certificate Number to BXA as part of their post-shipment report (see paragraph (d)(5)(v) of this section). When providing the PRC End-User Certificate Number to BXA, you must identify the transaction in the post shipment report to which that PRC End-User Certificate Number applies. The original PRC End-User Certificate shall be retained in the exporter's files in accordance with the recordkeeping provisions of § 762.2 of the EAR.

(5) *NDAA notification.* (i) *General requirement and procedures.* The National Defense Authorization Act (NDAA) of FY98 (Public Law 105–85, 111 Stat. 1629), enacted on November 18, 1997 requires advance notification of certain exports and reexports of computers to Computer Tier 3 countries. For each such transaction destined to Computer Tier 3, prior to using License Exception CTP, you must first notify BXA by submitting a completed Multipurpose Application Form (BXA–748P). The Multipurpose Application Form must be completed including all information required for a license application according to the instructions described in Supplement No. 1 to part 748 of the EAR, with two exceptions. You (the applicant as listed in Block 14) shall in Block 5 (Type of Application) mark the box ''Other.'' This designator will permit BXA to route the NDAA notice into a special processing procedure. (Blocks 6 and 7, regarding support documentation, may be left blank.) BXA will not initiate the registration of an NDAA notice unless all information on the Multipurpose Application form is complete.

(A) *Prior to February 26, 2001*, advance notification is required for all exports and reexports of computers with a CTP greater than 12,500 but less than or equal to 85,000 MTOPS to Computer Tier 3 destinations. You must also provide a notice using this procedure prior to exporting or reexporting items that you know will be used to enhance the CTP of a previously exported or reexported computer beyond 12,500 MTOPS, but less than or equal to 85,000 MTOPS.

(B) *Beginning on February 26, 2001 but prior to March 20, 2001*, advanced notification is required for export and reexport of computers with a CTP greater than 28,000 MTOPS, but less than or equal to 85,000 MTOPS to Computer Tier 3 destinations. You must also provide a notice using this procedure prior to exporting or reexporting items that you know will be used to enhance the CTP of a previously exported or reexported computer beyond 28,000 MTOPS, but less than or equal to 85,000 MTOPS.

(ii) *Action by BXA.* Within 24 hours of the registration of the NDAA notice, BXA will refer the notice for interagency review. Registration is defined as the point at which the notice is entered into BXA's electronic system.

(iii) *Review by other departments or agencies.* The Departments of Defense, Energy, and State have the authority to review the NDAA notice. Objections by any department or agency must be received by the Secretary of Commerce within nine days of the referral. Unlike the provisions described in § 750.4(b) of the EAR, there are no provisions for stopping the processing time of the NDAA notice. If, within 10 days after the date of registration, any reviewing agency provides a written objection to the export or reexport of a computer, License Exception CTP may not be used. In such cases, you will be notified that a license is required for the export or reexport. The NDAA notice will then be processed by BXA as a license application in accordance to the provisions described in § 750.4 of the EAR, and the licensing policies set forth in the Export Administration Regulations. Its NDAA notice number will be changed to a license application number. BXA may at this time request additional information to properly review the license application. If BXA confirms that no objection has been raised within the 10-day period (as described in paragraph (d)(5)(iv) of this section), you may proceed with the transaction on the eleventh day following date of registration. (Note that the fact that you have been advised to proceed with the transaction does not exempt you from other licensing requirements under the EAR, such as those based on knowledge of a prohibited end-use or end-user as referenced in general prohibition five (part 736 of the EAR) and set forth in part 744 of the EAR.)

(iv) *Status of pending advance notification requests.* You must contact BXA's System for Tracking Export License Applications (''STELA'') at (202) 482–2752. (See § 750.5 of the EAR for procedures to access information on STELA.) STELA will provide the date of registration of the NDAA notice. If no departments or agencies raise objections within the 10-day period, STELA will provide you on the eleventh day following date of registration with confirmation that no objections have been raised and you may proceed with the transaction. BXA will subsequently issue written confirmation to you. If a license is required, STELA will notify you that an objection has been raised and a license is required. The NDAA notice will be processed as a license application. In addition, BXA may provide notice of an objection by telephone, fax, courier service, or other means.

(v) *Post-shipment verification.* This section outlines special post-shipment reporting requirements for exporters of certain computers to destinations in Computer Tier 3. Post-shipment reports must be submitted in accordance with the provisions of this paragraph (d)(5)(v), and all relevant records of such exports must be kept in accordance with part 762 of the EAR.

(A) Exporters must file post-shipment reports for computer exports, as well as exports of items used to enhance previously exported or reexported computers, according to the following schedule:

(*1*) For exports occurring prior to February 26, 2001, where the CTP is greater than 12,500 MTOPS; and

(*2*) For exports on or after February 26, 2001, but prior to March 20, 2001, where the CTP is greater than 28,000 MTOPS.

(B) *Information that must be included in each post-shipment report.* No later than the last day of the month following the month in which the export takes place, the exporter must submit the following information to BXA at the address listed in paragraph (d)(5)(v)(C) of this section:

(*1*) Exporter name, address, and telephone number;

(*2*) NDAA notification number;

(*3*) Date of export;

(*4*) End-user name, point of contact, address, telephone number;

(*5*) Carrier;

(*6*) Air waybill or bill of lading number;

(*7*) Commodity description, quantities—listed by model numbers, serial numbers, and CTP level in MTOPS; and

(*8*) Certification line for exporters to sign and date. The exporter must certify that the information contained in the report is accurate to the best of his or her knowledge.

Note to paragraph (d)(5)(v)(B) of this section: For exports authorized under License Exception CTP to the People's Republic of China (PRC), you must submit the PRC End-User Certificate Number identifying the transaction for which the End-User Certificate Number applies.

(C) *Mailing address.* A copy of the post-shipment report[s] required under paragraph (d)(5)(v) of this section shall be delivered to one of the following addresses. Note that BXA will not accept reports sent C.O.D.

(*1*) For deliveries by U.S. postal service: U.S. Department of Commerce, Bureau of Export Administration, P.O. Box 273, Washington, D.C. 20044, Attn: Office of Enforcement Analysis HPC Team, Room 4065.

(*2*) For courier deliveries: U.S. Department of Commerce, Office of Enforcement Analysis HPC Team, 14th Street and Constitution Ave., NW, Room 4065, Washington, DC 20230.

(e) *Restrictions.* (1) *Access by certain foreign nationals.* Computers eligible for License Exception CTP may not be accessed either physically or computationally by nationals of Cuba, Iran, Iraq, Libya, North Korea, Sudan or Syria, except commercial consignees described in Supplement No. 3 to part 742 of the EAR are prohibited only from giving such nationals user-accessible programmability.

(2) *Reexport and retransfers.* Computers eligible for License Exception CTP may not be reexported/retransferred without prior authorization from BXA i.e., a license, a permissive reexport, another License Exception, or ''No License Required''. This restriction must be conveyed to the consignee, via the Destination Control Statement, see § 758.6 of the EAR. Additionally, the end-use and end-user restrictions in paragraph (d)(3) of this section must be conveyed to any consignee in Computer Tier 3.

(f) *Reporting requirements.* In addition to the reporting requirements set forth in paragraph (d) of this section, see § 743.1 of the EAR for additional reporting requirements of certain items under License Exception CTP.

PART 742—[AMENDED]

5. Section 742.12 is amended by removing the second sentence in paragraph (d); revising paragraph (a); removing and reserving paragraph (b)(2); and revising paragraph (b)(3) to read as follows:

§ 742.12 High performance computers.

(a) *License and recordkeeping requirements.* (1) This section contains special provisions for exports, reexports, and certain intra-country transfers of high performance computers, including software, and technology. This section affects the following ECCNs: 4A001; 4A002; 4A003; 4D001; 4D002; and 4E001. Licenses are required under this section for ECCN's having an ''XP'' under ''Reason for Control'' when License Exception CTP is not available (see § 740.7 of the EAR). License requirements reflected in this section are based on particular destinations, end-users, or end-uses. For the calculation of CTP, see the Technical Note that follows the Advisory Notes for Category 4 in the Commerce Control List. Note that License Exception CTP contains restrictions on access by nationals of certain countries, and on reexports and transfers of computers.

(2) In recognition of the strategic and proliferation significance of high performance computers, a license is required for the export or reexport of high performance computers to destinations, end-users, and end-uses, as specified in this section and on the CCL. These license requirements supplement requirements that apply for other control reasons, such as nuclear nonproliferation provided in section 742.3 of the EAR. The license requirements described in this section 742.12 are not reflected on the Country Chart (Supplement No. 1 to part 738 of the EAR). Three Computer Country Tiers have been established for the purposes of these controls. Countries included in Computer Tiers 1 and 3 are listed in License Exception CTP in section 740.7 of the EAR. As of January 19, 2001 there is no longer a Computer Tier 2, and countries that were in Tier 2 are incorporated into Computer Tier 1. Computer Tier 4 consists of Cuba, Iran, Iraq, Libya, North Korea, Sudan, and Syria.

(3) Exporters must keep accurate records of each export to countries not included in Country Group A:1 (see Supplement No. 1 to part 740 of the EAR) of a computer with a CTP greater than 6,500 MTOPS. These records must be submitted semiannually to BXA and must contain the information as described in § 743.1 of the EAR.

(b) * * *

(1) * * *

(2) [Reserved]

(3) Computer Tier 3. (i) *License requirement.* (A) A license is required to export or reexport computers to countries in Computer Tier 3 to nuclear, chemical, biological, or missile end-users and end-uses and military end-users and end-uses subject to license requirements under § 744.2, § 744.3, § 744.4, § 744.5, and § 744.12 of the EAR in Computer Tier 3 countries.

(B) A license is required to export or reexport computers with a CTP greater than 85,000 MTOPS to a country in Computer Tier 3.

(C) Prior to February 26, 2001, a license may be required to export or reexport computers with a CTP greater than 12,500 MTOPS to countries in Computer Tier 3 pursuant to the NDAA (see § 740.7(d)(5) of the EAR). Beginning on February 26, 2001 but prior to March 20, 2001, a license may be required to export or reexport computers with a CTP greater than 28,000 MTOPS but less than or equal to 85,000 MTOPS to countries in Computer Tier 3 pursuant to the NDAA.

(ii) *Licensing policy for nuclear, chemical, biological, or missile end-users and end-uses and military end-users and end-uses.* License applications for exports and reexports to nuclear, chemical, biological, or missile end-users and end-uses and military end-users and end-uses subject to license requirements under § 744.2, § 744.3, § 744.4, § 744.5, and § 744.12 of the EAR in countries in Computer Tier 3 will be reviewed on a case-by-case basis using the following criteria:

(A) The presence and activities of countries and end-users of national security and proliferation concern and the relationships that exist between the government of the importing country and such countries and end-users;

(B) The ultimate consignee's participation in, or support of, any of the following:

(*1*) Activities that involve national security concerns; or

(*2*) Nuclear, chemical, biological or missile proliferation activities described in part 744 of the EAR;

(C) The extent to which the importing country is involved in nuclear, chemical, biological, or missile proliferation activities described in part 744 of the EAR;

(D) The end-user, whether the end-use is single-purpose or multiple-purpose.

(iii) *Licensing policy for other end-users and end-uses.* License applications for exports and reexports to other end-uses and end-users located in Computer Tier 3 countries will generally be approved, except there is a presumption of denial for all applications for exports and reexports of computers having a CTP greater than 6,500 MTOPS destined to Indian and Pakistani entities determined to be

involved in nuclear, missile, or military activities included in Supplement No. 4 to part 744 (Entity List). All license applications for exports and reexports to India and Pakistan not meeting these criteria for presumption of denial will be considered on a case-by-case basis under other licensing policies set forth in the EAR applicable to such computers.

(iv) *Post-shipment verification.* This section outlines special post-shipment reporting requirements for exporters of certain computers to destinations in Computer Tier 3. Post-shipment reports must be submitted in accordance with the provisions of this paragraph (b)(3)(iv), and all relevant records of such exports must be kept in accordance with part 762 of the EAR.

(A) Exporters must file post-shipment reports for computer exports, as well as exports of items used to enhance previously exported or reexported computers, according to the following schedule:

(*1*) For exports occurring prior to February 26, 2001, where the CTP is greater than 12,500 MTOPS;

(*2*) For exports on or after February 26, 2001, but before March 20, 2001 where the CTP is greater than 28,000 MTOPS; and

(*3*) For exports on or after March 20, 2001 where the CTP is greater than 85,000 MTOPS.

(B) *Information that must be included in each post-shipment report.* No later than the last day of the month following the month in which the export takes place, the exporter must submit the following information to BXA at the address listed in paragraph (b)(3)(iv)(C) of this section:

(*1*) Exporter name, address, and telephone number;

(*2*) License number;

(*3*) Date of export;

(*4*) End-user name, point of contact, address, telephone number;

(*5*) Carrier;

(*6*) Air waybill or bill of lading number;

(*7*) Commodity description, quantities—listed by model numbers, serial numbers, and CTP level in MTOPS; and

(*8*) Certification line for exporters to sign and date. The exporter must certify that the information contained in the report is accurate to the best of his or her knowledge.

(C) *Mailing address.* A copy of the post-shipment report[s] required under paragraph (b)(3)(iv)(A) of this section shall be delivered to one of the following addresses. Note that BXA will not accept reports sent C.O.D.

(*1*) For deliveries by U.S. postal service: U.S. Department of Commerce, Bureau of Export Administration, P.O. Box 273, Washington, D.C. 20044, Attn: Office of Enforcement Analysis HPC Team, Room 4065.

(*2*) For courier deliveries: U.S. Department of Commerce, Office of Enforcement Analysis HPC Team, 14th Street and Constitution Ave., NW, Room 4065, Washington, DC 20230.

* * * * *

PART 748—[AMENDED]

6. Section 748.10 is amended by revising paragraph (b)(3) as follows:

§ 748.10 Import and end-user certificates.

* * * * *

(b) * * *

(3) Your transaction involves an export to the People's Republic of China (PRC) of a computer. You must obtain a PRC End-User Certificate, regardless of dollar value, as follows:

(i) For exports of computers as described by § 740.7(d)(2) of the EAR, regardless of value, to the People's Republic of China. (See paragraph (c) of this section for information on obtaining the PRC End-User Certificate.) Exporters are required to obtain a PRC End-User Certificate before exporting computers to the PRC. In addition, exporters are required to provide the PRC End-User Certificate Number to BXA as part of their post-shipment report (see § 740.7(d)(5)(v) of the EAR). When providing the PRC End-User Certificate Number to BXA, you must identify the transaction in the post shipment report to which that PRC End-User Certificate Number applies. The original PRC End-User Certificate shall be retained in the exporter's files in accordance with the recordkeeping provisions of § 762.2 of the EAR.

(ii) For exports of computers that require license applications.

* * * * *

Dated: January 16, 2001.

Matthew S. Borman,

Acting Deputy Assistant Secretary for Export Administration.

[FR Doc. 01–1623 Filed 1–16–01; 4:49 pm]

BILLING CODE 3510–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 207, 807, and 1271

[Docket No. 97N–484R]

Human Cells, Tissues, and Cellular and Tissue-Based Products; Establishment Registration and Listing

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to require human cells, tissue, and cellular and tissue-based product establishments to register with the agency and list their human cells, tissues, and cellular and tissue-based products. FDA is also amending the registration and listing regulations that currently apply to human cells, tissues, and cellular and tissue-based products regulated as drugs, devices, and/or biological products. These actions are being taken to establish a unified registration and listing program for human cells, tissues, and cellular and tissue-based products.

DATES: The regulation is effective April 4, 2001, except for 21 CFR 207.20(f), 807.20(d), and 1271.3(d)(2), which are effective on January 21, 2003.

FOR FURTHER INFORMATION CONTACT: Valerie A. Butler, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Introduction

We, FDA, are putting in place a comprehensive new system of regulation for human cells, tissues, and cellular and tissue-based products. The goal of the new approach is to improve protection of the public health without imposing unnecessary restrictions on research, development, or the availability of new products. Under the new system, the regulation of different types of human cells, tissues, and cellular and tissue-based products will be commensurate with the public health risks presented, enabling us to use our resources more effectively. Consolidating the regulation of human cells, tissues, and cellular and tissue-based products into one regulatory program is expected to lead to increased consistency and greater efficiency. Together, these planned improvements will increase the safety of human cells,

tissues, and cellular and tissue-based products, and public confidence in their safety, while encouraging the development of new products.

A. Background

In 1997, we announced our regulatory plans for human cells, tissues, and cellular and tissue-based products in two documents:

• ''A Proposed Approach to the Regulation of Cellular and Tissue-Based Products'' (62 FR 9721, March 4, 1997) and

• ''Reinventing the Regulation of Human Tissue'' (Ref. 1).

The proposed approach described a comprehensive plan for regulating human cells, tissues, and cellular and tissue-based products that would include establishment registration and product listing, donor-suitability requirements, good tissue practice regulations, and other requirements. Under this tiered, risk-based approach, we proposed to exert only the type of government regulation necessary to protect the public health. To accomplish this goal, we planned to issue new regulations under the communicable disease provisions of the Public Health Service Act (the PHS Act). Some human cellular and tissue-based products would be regulated only under these new regulations, while other human cellular and tissue-based products would also be regulated as drugs, devices, and/or biological drugs. We requested written comments on the proposed approach and, on March 17, 1997, held a public meeting (62 FR 9721).

Since 1997, we have published three proposed rules to implement the proposed approach. In 1998, as a first step toward accomplishing these goals, we published the proposed rule, ''Establishment Registration and Listing for Manufacturers of Human Cellular and Tissue-Based Products'' (63 FR 26744, May 14, 1998) (the ''registration proposed rule''). That rule proposed to require cell and tissue establishments to register with us and submit a list of their human cellular and tissue-based products. We also proposed modifications to current registration and listing requirements for drugs and devices under which cell and tissue establishments already regulated under the Federal Food, Drug, and Cosmetic Act (the act) and/or section 351 of the PHS Act (42 U.S.C 262) would register and list following the new procedures.

In addition to the registration proposed rule, we published two more proposed rules:

• Suitability Determination for Donors of Human Cellular and Tissue-Based Products (64 FR 52696, September 30, 1999) (the ''donor-suitability proposed rule''); and

• Current Good Tissue Practice for Manufacturers of Human Cellular and Tissue-Based Products; Inspection and Enforcement (66 FR 1508, January 8, 2000) (the ''GTP proposed rule'').

Together, these three rules when finalized would establish a comprehensive regulatory program for human cellular and tissue-based products, to be contained in part 1271 (21 CFR part 1271).

In the three proposed rules, we used the term ''human cellular and tissue-based products.'' In this final rule, we have changed the term to ''human cells, tissues, and cellular and tissue-based products'' (abbreviated ''HCT/P's''). This change in terminology is a clarification and does not affect the scope of the definition, which continues to encompass an array of articles containing or consisting of human cells or tissues, and intended for implantation, transplantation, infusion, or transfer into human recipients, including investigational products. The definition of ''human cells, tissues, or cellular or tissue-based product'' is intended to cover HCT/P's at all stages of their manufacture, from recovery through distribution. Some examples of HCT/P's include skin, tendons, bone, heart valves, corneas, hematopoietic stem cells, manipulated autologous chondrocytes, epithelial cells on a synthetic matrix, and semen or other reproductive tissue.

B. Implementation of the New Regulations

We had intended to finalize the registration proposed rule with the two other rules that would make up part 1271 in its entirety, and to implement all three rules together. However, we are now making the registration rule final, with staggered effective dates, before finalizing the two remaining portions of part 1271. We are taking this action because of recent concerns raised about the safety of tissue, which have led us to believe that accelerating the collection of basic information about the rapidly growing tissue industry is vital. This medical sector has grown rapidly, with a need for clearer standards and improved accountability. The Department of Health and Human Services met in mid-2000 with representatives of key tissue-related organizations, who supported finalization of this regulation as quickly as possible, instead of awaiting simultaneous publication with the other tissue regulations. For these reasons, we are going to begin collecting registration and listing information, while continuing to develop the remainder of the final rules that will complete part 1271, and we have changed the effective date of this rule from the proposed 180 days to 75 days after the date of publication in the **Federal Register**. As part of completing the rulemaking for part 1271, we would make any necessary conforming amendments to this regulation to make it consistent with any changes made in the remainder of the rulemaking process, and we would revoke part 1270.

Establishments that engage in the recovery, screening, testing, processing, storage, or distribution of human tissue intended for transplantation currently regulated under section 361 of the PHS Act (42 U.S.C. 264) and the regulations in part 1270 (21 CFR part 1270) (''Human Tissue Intended for Transplantation'') will be required to begin registering with the agency and listing their HCT/P's within 30 days after the effective date of this final rule. The effective date for all other human cells, tissues, and cellular and tissue-based products (as described in § 1271.3(d)(2)) is 2 years after publication, by which time we expect to have completed rulemaking for all the subparts of part 1271. (Some establishments that are not required to register and list until the second effective date have expressed a desire to submit registration and listing forms as soon as possible. In response, FDA is prepared to accept registration and listing forms submitted in advance of the second effective date. However, FDA is not soliciting this information.) Once the entire rulemaking is complete, the new regulatory approach would apply to a broad range of human cells, tissues, and cellular and tissue-based products, including reproductive cells and tissue; hematopoietic stem cells; and tissues and cells regulated as devices, drugs, and/or biological products.

Staggering the effective dates of this regulation permits us to begin collecting important registration and listing information soon from those establishments currently regulated under part 1270, while continuing to proceed through rulemaking to develop the remainder of part 1271. We believe that this action may prevent an unintentional gap in the regulation of certain currently regulated HCT/P's, permit an orderly implementation process, and avoid duplicative information collection. If we instead implemented the regulation immediately for all HCT/P's, this action could have the effect of shifting the regulation of certain products (e.g., HCT/P's currently regulated as devices

that meet the criteria set out in § 1271.10 for regulation solely under section 361 of the PHS Act) into the new regulatory system before standards and enforcement provisions are in place. Staggering the effective dates also helps permit an orderly implementation process. Establishments that manufacture cells and tissues that will be regulated for the first time under new part 1271 may require more time than those currently regulated to implement the provisions of this final rule. However, we also recognize that unanticipated delays in completing the rulemaking for the remainder of part 1271 could occur. Should the rulemaking proceedings be delayed past the 2-year timeframe, we will consider whether to maintain the 2-year effective date for the HCT/P's described in § 1271.3(d)(2) or whether to extend that date for some or all of those HCT/P's.

C. Legal Authority

We are issuing this final rule under the authority of section 361 of the PHS Act. Under section 361 of the PHS Act, we may make and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases between the States or from foreign countries into the States. (See sec. 1, Reorg. Plan No. 3 of 1966 at 42 U.S.C. 202 for delegation of section 361 of the PHS Act authority from the Surgeon General to the Secretary, Health and Human Services; see 21 CFR 5.10(a)(4) for delegation from the Secretary to FDA.) Intrastate transactions may also be regulated under section 361 of the PHS Act. (See *Louisiana* v. *Mathews,* 427 F. Supp. 174, 176 (E.D. La. 1977).)

HCT/P's are derivatives of the human body and thus pose a potential risk of transmitting infectious disease. We have determined that some HCT/P's may be effectively regulated solely by controlling the infectious disease risks they present. The regulation now being finalized forms the foundation for a regulatory program that will further the goal of preventing the transmission of communicable disease. To begin implementing this regulatory program, we are publishing the registration final rule, with staggered effective dates so that those HCT/P establishments not currently subject to regulation under section 361 of the PHS Act will have adequate preparation time and FDA can continue working towards finalizing the remainder of the program.

For this regulatory system to be effective in preventing the spread of disease, we must obtain basic information about the human cell and tissue industry and its HCT/P's. The information to be submitted in compliance with the registration and listing requirements in subpart B will provide baseline data on establishments that will be subject to part 1271. This information from the registration rule will assist us in reacting swiftly to newly discovered or understood risks by alerting members of the industry to our concerns and, when appropriate, by conducting establishment inspections. Without this information, we would not be able to effectively monitor compliance with the proposed donor-suitability, GTP, and other regulations that make up the rest of the regulatory program.

Authority for enforcement of section 361 of the PHS Act is provided by section 368 of the PHS Act (42 U.S.C. 271). Under section 368(a) of the PHS Act, any person who violates a regulation prescribed under section 361 of the PHS Act may be punished by imprisonment for up to 1 year. Individuals may also be punished for violating such a regulation by a fine of up to $100,000 if death has not resulted from the violation or up to $250,000 if death has resulted (18 U.S.C. 3559 and 3571(c)). In addition, Federal District Courts have jurisdiction to enjoin individuals and organizations from violating regulations implementing section 361 of the PHS Act. The regulations that we have proposed specific to enforcement appear in the GTP proposed rule.

HCT/P's that do not meet FDA's criteria set forth in part 1271 for regulation solely under section 361 of the PHS Act are regulated as drugs, devices, and/or biological products under the act and/or section 351 of the PHS Act, and their manufacturers are required to register with the agency under section 510 of the act (21 U.S.C. 360). Regulations implementing section 510 of the act are found in parts 207 and 807 (21 CFR parts 207 and 807), among other parts. In order to consolidate our data base on the cell and tissue industry and thus to improve our oversight functions, we are amending parts 207 and 807 to require registering establishments to follow the procedures set out in part 1271; these amendments are effective in 2 years, when we project the remaining two proposed tissue rules will be ready for implementation. Section 510 of the act remains the authority for the substantive registration requirement for products subject to parts 207 and 807. Because harmonizing the registration and listing procedures applicable to the various HCT/P's is intended to further the goal of preventing the spread of communicable disease, we are relying on the additional authority of section 361 of the PHS Act for the proposed amendments to parts 207 and 807.

II. Highlights of the Final Rule

A. Plain Language

On June 1, 1998, President Clinton directed Federal agencies to begin using ''plain language'' in regulations and other documents. The goal of the plain language initiative is to publish government documents that are easier to understand.

In response to this initiative, we have written the registration regulation in plain language. We have

- Written the regulation in question-and-answer format,
- Reorganized some regulatory sections for greater clarity, and
- Followed other plain-language conventions, such as using ''must'' instead of ''shall.''

The resulting codified language is easier to read and understand than the proposed regulation. These editorial changes are for clarity only and do not change the substance of the requirements.

B. Framework of the Final Regulation and Part 1271

When final, new part 1271 will be made up of six subparts. This final regulation contains subpart A (general provisions pertaining to the scope and applicability of part 1271; definitions); and subpart B (registration and listing procedures). The donor-suitability proposed rule contains subpart C of part 1271; and the GTP proposed rule contains subparts D, E, and F.

Section 1271.10, in subpart A, sets out the criteria that form the foundation of our tiered, risk-based approach to regulating HCT/P's. HCT/P's that meet these criteria are subject only to regulation under section 361 of the PHS Act. When all the proposed rules that will make up part 1271 become effective, these HCT/P's would be subject to the regulations in part 1271, and no premarket submissions would be required. (We sometimes refer to these HCT/P's as ''361 HCT/P's.'' This term replaces ''section 361 products,'' which was used in the registration proposed rule.) HCT/P's that do not meet the criteria for regulation as 361 HCT/P's will be regulated as drugs, devices, and/or biological products.

In September 1999, in the donor-suitability proposed rule, we modified proposed §§ 1271.1, 1271.3(e), 1271.10, and 1271.20 as they appeared in the registration proposed rule, and we added new § 1271.15. We made some of these changes to clarify our meaning.

We made other changes so that the provisions on scope and applicability contained in subpart A would apply not only to the registration procedures in subpart B but more generally to the rest of the requirements in part 1271. These changes obviated the need for the addition, in later rulemaking, of new sections dealing with scope and applicability and were consistent with our original regulatory intent, as set out in the proposed approach.

We received comments on the registration proposed rule, and we received additional comments on subparts A and B of part 1271 in response to the donor-suitability proposed rule. To the extent possible we address these comments in this final rule; however, we recognize that additional discussion may be necessary as issues arise in the remaining rules that will makeup part 1271.

C. Staggered Effective Dates

In order to accomplish the goal of staggering the effective dates of the registration and listing regulation for different types of HCT/P's, we have divided the definition of ''HCT/P'' in § 1271.3(d) into two paragraphs. Paragraph (d)(1) of § 1271.3 identifies the subgroup of human tissues defined in part 1270. Paragraph (d)(2) provides the broader definition of HCT/P based on proposed § 1271.3(e). The definition of the subgroup in paragraph (d)(1) incorporates the definition of ''human tissue'' set out in § 1270.3(j) and thus identifies those tissues that are currently regulated under part 1270, including, for example, such tissues as corneas, bone, and skin. This represents the subgroup of human cells, tissues, and cellular and tissue-based products for which this final rule will first go into effect. Paragraph (d)(2) of § 1271.3 provides the broader definition of HCT/P and includes those HCT/P's described in paragraph (d)(1) as well as such additional HCT/P's as reproductive cells and tissues, hematopoietic stem cells, and cells and tissues currently regulated as drugs, devices, and/or biological products. The definition in paragraph (d)(2) of § 1271.3 will eventually replace paragraph (d)(1), as described below.

The effective date of § 1271.3(d)(1) is 75 days after the publication of this rule. The entire definition of HCT/P in § 1271.3(d)(2) is effective 2 years after the publication of this final rule in the **Federal Register**. The effect of this action is to make this final regulation applicable first to those HCT/P's currently regulated under part 1270, and later to the complete range of HCT/P's defined in § 1271.3(d)(2). When all of the regulations that make up part 1271 are final and have superseded part 1270, we will revoke § 1271(d)(1) and renumber (d)(2) as a conforming amendment. At that time the new regulatory framework contained in part 1271 will be instituted as a whole.

D. Other Highlights of This Final Rule

This final rule contains other changes from the proposed rule. Among these changes are the following:

- We have broadened ''family-related allogeneic use,'' as used in proposed § 1271.10, to include first-degree and second-degree blood relatives.
- We have modified the definition of ''homologous use.''
- We have replaced the phrase ''combined with or modified by the addition of a drug or a device'' in § 1271.10 with new language.
- We have deleted the phrase ''pending scheduled'' from the exception in § 1271.15(d) for establishments that only receive or store HCT/P's.
- We have added an exception for establishments that only recovers reproductive cells or tissues for immediate transfer into a sexually intimate partner of the cell or tissue donor. (§ 1271.15(e)).

III. Comments on the Proposed Rule and FDA's Responses

We received 28 comments on the proposed rule as it was published in 1998. We received over 400 comments on the donor-suitability proposed rule; many of these raised issues related to subparts A and B of part 1271.

A. General Comments

(Comment 1) Many comments expressed general approval of the rule. One comment stated that the proposed rule addresses the public health needs for regulation in this area, helping to assure an adequate supply of safe and functional products without imposing unnecessary regulatory burdens or inhibitions to progress. Another comment, in support of registration, noted the importance of establishing a known data base of the industry. Another comment stated that creation of an official inventory of establishments subject to FDA regulation is important to determine the actual level of compliance and to develop reliable estimates of the cost of enforcement.

We acknowledge and appreciate these supportive comments. The new regulation on registration and listing will increase our knowledge and understanding of the HCT/P industry and will enable us to monitor industry developments and communicate with industry members. This final rule will enhance our compliance efforts in protecting the public from the spread of communicable diseases, when the remaining tissue regulations become effective.

(Comment 2) Some comments objected to the development of a comprehensive regulatory system. One of these comments objected that the approach is based on potential, not actual, concerns, is more applicable to new products than to such tissues as corneal tissue offered for transplant, and is unnecessary in light of quality assurance programs established by professional organizations.

We believe that this new regulatory program for HCT/P's, when it is in place, will be superior to the confusing patchwork of requirements that it will replace. We have created a simple registration system with uniform requirements for all HCT/P's and a one-page registration and listing form. The procedures in subpart B of part 1271 will be followed by all HCT/P establishments, along with those in proposed subparts C and D of part 1271. Together, they are intended to establish a communicable disease prevention program necessary to protect the public health.

In developing and issuing the registration rule, we have recognized that, because all HCT/P's are derived from the human body, they share certain common characteristics, among other things the ability to transmit infectious diseases. Thus, basic requirements such as registration, communicable disease screening and testing, and GTP's may reasonably be applied to all HCT/P's. However, we have also recognized that within the larger group of HCT/P's, certain products may present a greater degree of risk, and that these HCT/P's should be subject to additional premarket requirements.

With this tiered, risk-based approach, we will be putting in place a set of baseline requirements for all HCT/P's, while recognizing that different HCT/P's may present different concerns. As the comment points out, some concerns may be more applicable to new products than to such tissues as corneal tissue offered for transplant. We have identified criteria corresponding to the types of reduced risks that certain products may present. HCT/P's that do not meet all of these criteria will be regulated under the act and/or section 351 of the PHS Act (subject to subsequent effective dates). On the other hand, most HCT/P's, including cadaveric corneas, will be regulated solely under the communicable disease authority of section 361 of the PHS Act

and the regulations that will make up part 1271.

When implemented, the registration, donor-suitability, and GTP regulations are intended to reduce the risk of transmission of communicable disease by HCT/P's. The donor-suitability proposed rule incorporates and expands upon many of the requirements for human tissue intended for transplantation in part 1270. The part 1270 requirements were put into place to prevent the transmission of human immunodeficiency virus and hepatitis through the transplantation of tissue from domestic and foreign sources, ''Human Tissue Intended for Transplantation,'' final rule (62 FR 40429, July 29, 1997).

Registration and listing are crucial components of a regulatory program to increase the safety of HCT/P's. Indeed, the United States General Accounting Office (GAO) has urged the agency to put a program in place in response to the potential transmission of infectious diseases from cell and tissue donors to recipients, GAO, ''Human Tissue Banks, FDA Taking Steps to Improve Safety, but Some Concerns Remain'' (December 1997).

We recognize the importance of voluntary quality assurance programs, and we respect the efforts and accomplishments of professional organizations. We have considered the efforts of professional organizations, and we will continue to do so as we implement the new regulations. However, not all HCT/P establishments belong to or are accredited by such groups, and voluntary programs are not enforceable.

(Comment 3) Another comment stated that we should finalize the registration rule as soon as possible, without waiting for the other rules.

We agree that there are benefits to publishing the registration final rule in advance of the other final rules, and we are doing so. However, as discussed earlier in this document, we are staggering the regulation's effective dates. Under this approach, we will be able to promptly begin receiving registration and listing information for HCT/P's currently subject to part 1270.

(Comment 4) One comment asserted that we should identify those tissues and entities subject to part 1271 that are not currently subject to part 1270, and initiate rulemaking to broaden the coverage of the substantive regulations codified in part 1270.

Rather than broaden the scope of the regulations in part 1270, we have earlier noted that we intend to replace part 1270 with the new regulations in part 1271 (donor-suitability proposed rule, 64 FR 52697). Revocation of part 1270 will occur at the time the GTP final rule becomes effective. We have earlier made clear (64 FR 52697 to 52698) that the new rules in part 1271, when complete, will be broader in scope than those in part 1270, will impose additional testing and screening requirements, and will cover more establishments and HCT/P's (e.g., hematopoietic stem cells, reproductive tissue). Thus, it is not necessary to initiate rulemaking to broaden the coverage of the regulations in part 1270.

(Comment 5) One comment asked the agency to clarify if it intends to require registered organizations to pass along any information the agency disseminates. Another comment counseled against depending on a secondary dissemination system, from those required to register to those with whom they interact who are not required to register, to get educational information to all of the tissue community.

We are not imposing a specific information-dissemination requirement at this time. The only members of the tissue community who would be subject to the rules in part 1271 and who are not required to register are those individuals who recover cells or tissue under contract, agreement, or other arrangement with a registered establishment, but who perform no other manufacturing step (except for sending the cells or tissue to the registered establishment). These individuals would be subject to the other requirements that will be contained in part 1271, when complete, and the establishments for whom they perform their services would be responsible for their work. (This exception is discussed in greater detail below.) Therefore, we believe that if we distribute information to registered establishments, we will be reaching the whole of the affected tissue community.

(Comment 6) One comment expressed concern that the proposed rule failed to identify the party ultimately responsible for the tissue or for the decisions required in the process of determining donor and tissue suitability.

We have addressed the question of responsibility in the GTP proposed rule.

(Comment 7) Several comments raised the issue of dispute resolution, particularly with respect to questions about homologous use and minimal manipulation. One of these comments urged us to develop and follow a process for resolving disputes in a prompt and efficient manner. One comment recommended that the Tissue Reference Group (TRG) serve as the forum for resolving any disagreements that arise with regard to the application of definitions.

We recognize that, as we implement this new regulation, there will be areas in which additional guidance may be desirable or interpretations may differ. To help answer questions about how a particular HCT/P will be regulated, the agency developed the TRG. If an establishment is not sure how its HCT/P may be regulated, it should contact the TRG.

The TRG provides a single reference point and makes recommendations to the Center Directors regarding regulation of specific HCT/P's, e.g., regulation solely under section 361 of the PHS Act or additionally under the act and/or section 351 of PHS Act. The TRG is composed of: (1) Three representatives from the Center for Biologics Evaluation and Research (CBER), including the product jurisdictional officer; (2) three representatives from the Center for Devices and Radiological Health (CDRH), including the product jurisdictional officer; and (3) a liaison from the agency's Office of the Chief Mediator and Ombudsman (OCMO), a nonvoting member. Other FDA staff attend the TRG meetings as needed to discuss issues related to products in their area of expertise. Further information about the TRG can be found on CBER's website at http://www.fda.gov/cber/tissue/trg.htm.

In some cases, a product regulated under the act will fall under the jurisdiction of more than one agency component, e.g., a combination device and biological product. Where the agency component with primary jurisdiction is unclear or in dispute, a sponsor may request designation from the product jurisdiction officer, who is the FDA Ombudsman, as detailed in 21 CFR part 3. In addition, the OCMO can assist in resolving disputes with the agency that may arise from decisions made by the Center Directors regarding the regulation of HCT/P's, after consideration of TRG recommendations, as described above.

In addition, we recognize that further public discussion of how tissue regulation would be applied to certain categories of human cells, tissues, and cellular and tissue-based products may be warranted due to the complexity or sensitivity of the issues. For example, we held a public meeting on August 2, 2000, to discuss how proposed definitions for ''minimally manipulated'' and ''homologous use'' should be applied to human bone allograft products (65 FR 44485, July 18, 2000). We intend to provide further opportunities for public discussion of

how the regulatory approach should be applied to other HCT/P's. We anticipate that there may be additional needs for discussion through public meetings, public hearings, or guidance as we implement the new regulations.

(Comment 8) One comment asserted that we have published no document describing the TRG's current composition, authoritative status, procedures, whether its decisions are or will be made public, or how industry is expected to communicate with the group. The comment also suggested that we should consider making the TRG's policy decisions routinely available to the public.

We appreciate these comments and are committed to working on the issues raised. Among other things, the TRG is looking into mechanisms for increasing the transparency of its functions, while still protecting confidential information. Information about the TRG can be found on CBER's website at http://www.fda.gov/cber/tissue/trg.htm.

(Comment 9) Several comments asserted that we are proposing to regulate the practice of medicine, especially with respect to reproductive tissue and hematopoietic stem cells.

We disagree with this comment. This final rule sets out registration and listing requirements for establishments that recover, process, store, label, package, or distribute HCT/P's, or screen or test cell and tissue donors. HCT/P's, including hematopoietic stem cells and reproductive tissues, fall within our jurisdiction. Some HCT/P's will be regulated under the act and/or the PHS Act, while other HCT/P's will be effectively regulated solely by regulations issued under our authority to prevent the spread of communicable disease. We are not attempting to govern practitioners' use of HCT/P's, but rather to ensure that HCT/P's that would be used by practitioners in their treatment of patients are in compliance with applicable regulations, including regulations designed to prevent the transmission or spread of communicable disease.

(Comment 10) We received several comments on our proposed regulation of hematopoietic stem cells. One comment supported the proposal that all establishments involved with hematopoietic stem cell therapy register with FDA. Two comments asserted that the proposed regulation would jeopardize patient treatment, impede the development of new therapies, and increase the costs of treatment. One comment asserted that we lack the legal authority to regulate intrastate hematopoietic stem cell transplants. Another comment argued that clinical research involving the use of blood or bone marrow transplantation for treatment of human diseases, but not involving an investigational drug or device, should not require an investigational new drug application or investigational device exemption. This comment further requested the development of simplified procedures for evaluating those investigational devices or cellular biologic products that are more than minimally manipulated. Two comments argued that there is no need for FDA regulation as industry standards suffice and FDA requirements would be duplicative.

We believe that it is necessary to bring the regulation of hematopoietic stem cells in line with the regulation of other HCT/P's, and that we possess the legal authority to take this action. Like other HCT/P's, hematopoietic stem cells may transmit communicable diseases; thus, the basic communicable disease prevention requirements that will be contained in part 1271, including these registration and listing requirements, are as relevant to these cells as to any other HCT/P's. Intrastate activities involving hematopoietic stem cells, as well as other HCT/P's, can be regulated to prevent the interstate spread of communicable diseases under section 361 of the PHS Act. (See *Louisiana* v. *Mathews*, 427 F. Supp. 174, 176 (E.D. La. 1977).) The GAO has cited the lack of regulation of hematopoietic stem cells as a significant gap in our oversight, and urged us to proceed with implementing new regulations that would cover hematopoietic stem cells. We are now closing that gap.

Although we applaud the development of industry standards noted by the comments received, such standards are not followed by all HCT/P establishments. Moreover, voluntary standards differ significantly from enforceable regulations. We cannot take enforcement actions to ensure compliance with voluntary industry standards and thus would be limited in our ability to protect the public health if we relied on such standards alone. Establishments that comply with industry standards, however, should have little trouble adapting their practices to the new requirements. Thus, any additional burden should be minimal.

Rather than require data submission from each hematopoietic stem cell establishment, we have considered the development of standards for certain stem cell products. On January 20, 1998 (63 FR 2985), we published a notice in the **Federal Register** requesting the submission of proposed standards and supporting data relating to certain stem cell products by January 20, 2000, entitled ''Request for Proposed Standards for Unrelated Allogeneic Peripheral and Placental/Umbilical Cord Blood Hematopoietic Stem/Progenitor Cell Products.'' Later, we extended the deadline for submitting data to July 17, 2000 (65 FR 20825, April 18, 2000).

(Comment 11) One comment generally agreed with our proposal to require registration for certain reproductive tissue, but requested several clarifications and exceptions. Several comments questioned the need for the regulation of reproductive cells and tissues, citing current oversight from professional organizations, other Federal agencies, and States. Comments opposed registration for programs involved in egg donation, egg retrieval, semen processing, semen evaluation, or in vitro fertilization (IVF) in assisted reproductive technologies. One comment asserted that a large number of medical practitioners who perform inseminations would not be included in this new regulation, lessening their effectiveness. Another comment asserted that programs that manufacture tissue culture products for the growth of oocytes and sperm for sale should be required to register, but IVF programs making culture medium for their own uses should be exempt.

We stand by our decision to extend regulatory requirements to reproductive cells and tissue. Currently, FDA does not have regulations in place to address the infectious disease risk of donating, processing, and storing reproductive cells and tissue. Because there has been no registration or listing requirement, we have not had accurate information about the industry. We agree with the GAO that extending regulation to reproductive cells and tissues will remedy a significant gap in oversight.

Although we recognize the value of professional efforts to self-regulate, and of regulatory efforts of other agencies and the States, we disagree that these piecemeal, often voluntary, efforts are adequate. Nor will the new regulations in part 1271 be duplicative. State regulation varies from State to State and does not consistently address our concerns about the transmission of communicable disease. The model certification program for embryo laboratories developed by the Centers for Disease Control and Prevention (CDC) is a voluntary program that States may or may not choose to adopt; its primary focus is not on preventing the transmission of communicable disease. No State has yet adopted CDC's model certification program. Membership in professional societies is voluntary.

Moreover, many establishments do not report to the Society for Assisted Reproductive Technology. The Clinical Laboratories Improvement Amendment of 1988 (CLIA) covers clinical laboratory testing, including certain procedures performed in embryo laboratories; however, as discussed later in this document, CLIA certification is not equivalent to the requirements we are putting in place.

We disagree that establishments that only deal with egg donation, retrieval, semen processing, or IVF should be exempt from the new regulations. These activities are vital to the handling of reproductive tissues. Performing these activities appropriately in order to prevent cross-contamination and mix-ups requires proper recordkeeping, storage practices, and accountability. Moreover, registration of these establishments is consistent with agency practice in other areas; e.g., establishments where only blood donation or processing occurs are required to register.

As discussed later in this document, however, this final rule contains a new exception for certain reproductive tissue establishments that perform only certain limited activities that raise limited communicable disease concerns. Under the exception, an establishment that only recovers reproductive cells or tissue for immediate transfer into a sexually intimate partner of the cell or tissue donor is not required to comply with the requirements that will be contained in part 1271, including registration and listing.

With respect to the comment about tissue culture media, these products are not considered HCT/P's. Rather, embryo culture media and other such products are regulated as medical devices by FDA, and establishments that manufacture embryo culture media are subject to the device regulations.

(Comment 12) Several comments responded to our discussion of regulating dura mater and human heart valve allografts as 361 HCT/P's rather than as devices, if they meet the criteria in § 1271.10 (63 FR 26744 at 26747). Three comments supported the regulation of heart valves as 361 HCT/P's. One comment suggested that, to prevent a regulatory ''open window,'' the regulatory change should not take place until GTP requirements are effective or other steps are taken. One comment asked whether the transfer of heart valves would be reflected in a codified regulation. A fourth comment supported regulating dura mater as a 361 HCT/P and strongly suggested that ''special controls'' be included in the GTP requirements. No comments objected to regulating heart valve allografts and dura mater as 361 HCT/P's.

We agree that we should avoid an ''open window'' where possible. Therefore, we have staggered effective dates for this rule to prevent such an outcome. We do not intend to begin regulating human heart valve allografts and dura mater that meet the criteria in § 1271.10 as 361 HCT/P's until the donor-suitability and GTP components of part 1271 become effective, or other appropriate steps have been taken. The GTP proposed rule contains special requirements for dura mater intended to address the communicable disease concerns about that product. Because § 1271.10 contains the criteria for regulation of HCT/P's as 361 HCT/P's, and we are now reiterating our view that heart valves meeting those criteria will not be regulated as devices, we do not intend to issue a separate regulation to change regulatory authority on that specific point.

(Comment 13) One comment suggested that we consider voluntary accreditation and inspection programs in implementing our regulatory strategy. The comment further requested that we accord ''deemed status'' to certain accredited facilities.

We are exploring various options for inspections and compliance actions to enforce the new regulations. Among other ideas, we are looking into those suggested by this comment, including the legal issues raised. At present, we have in place a tiered inspection approach to enforce the regulations in part 1270 that takes into consideration such factors as professional accreditation. We intend to provide a more detailed discussion of our regulatory intentions after consideration of comments to the GTP proposed rule.

(Comment 14) One comment noted that tissue recovery is frequently performed by organ procurement organizations, and that the requirements with regard to the prevention of infectious disease transmission are appropriately much less stringent for organ donation than are comparable requirements for tissues. The comment asserted that exempting these organizations from regulation would immeasurably weaken the public health protection provided by this regulation.

An organ procurement organization that also recovers cells or tissues in addition to organs is not exempt from these regulations, and must register with the agency and follow all other regulations applicable to its actions with respect to HCT/P's. An organ procurement establishment is not required to submit a list of the vascularized human organs for transplantation that it recovers, because these organs are not covered by the definition of HCT/P (see § 1271.3(d)(2)(i)). However, such an organization must list with the agency any HCT/P's that fall within the scope of part 1271 that the organization recovers or otherwise manufactures.

B. Comments on Subpart A of Part 1271: Definitions

We received comments on many of the proposed definitions in § 1271.3(a) through (h). We did not receive comments on the definitions of ''autologous'' and ''transfer.'' We address many of these comments below. Comments on the definitions of ''homologous use'' and ''minimal manipulation'' are addressed in section III.C of this document.

(Comment 15) The definition of *establishment* in proposed § 1271.3(b) reads as follows:

> *Establishment* means a place of business under one management, at one general physical location, that engages in the manufacture of human cellular or tissue-based products. The term includes, among others, facilities that engage in contract manufacturing services for a manufacturer of human cellular or tissue-based products. The term also includes any individual partnership, corporation, association, or other legal entity engaged in the manufacture of human cellular or tissue-based products, *except that an individual engaged solely in the procurement or recovery of cells or tissues or under contract to a registered establishment is not required to independently register* (emphasis added).

Comments raised issues about the proposed exception in the last sentence of the definition. Some comments asserted that individuals or organizations engaged solely in procurement under contract should be required to register. One comment pointed to the critical role in the suitability assessment of a cell and tissue donor that such organizations play. Another comment asserted that registration and listing should be applied to those who screen donors and that procurement of tissue that is not done in an aseptic manner places tissue recipients at risk. One comment expressed confusion about the exception and suggested that ''or under contract'' should read ''and under contract.'' This comment further suggested that individuals and other legal entities engaged solely in procurement or recovery be required to register unless contracted for that activity to a registered establishment.

Three comments argued for an expanded exception. One comment urged us to clarify that the ''under

contract to'' language can apply to other contracting individuals, not just to contractors engaged in procurement or recovery (e.g., sales representatives who distribute HCT/P's). Two other comments requested clarification that clinical laboratories who perform testing are excluded from the registration and listing requirements.

We have rewritten the exception and moved it to § 1271.15(f). The relevant language now states:

(f) You are not required to register or list your HCT/P's independently, but you must comply with all other applicable requirements in this part, if you are an individual under contract, agreement, or other arrangement with a registered establishment and engaged solely in recovering cells or tissues and sending the recovered cells or tissues to the registered establishment.

We believe this new language addresses many of the comments' concerns. We have replaced ''or under contract'' with ''and under contract, agreement, or other arrangement.'' In addition, because ''procurement'' and ''recovery'' refer to the same action—the removal of cells or tissue from a donor—we have decided that it is redundant and possibly confusing to use both words. Instead, the exception now uses the term ''recovery,'' the same term used in the definition of ''manufacture'' in § 1271.3(e). Therefore, the exception only applies to those individuals engaged solely in recovery of HCT/P's and who are under contract, agreement, or other arrangement with a registered establishment. We believe this is an appropriate way of easing the regulatory burden on individuals while ensuring the protection of the public health.

This exception does not extend to an individual who does more than recover tissue and send it to the contracting establishment. (Thus, for example, an individual engaged in any aspect of donor screening is not covered by the exception and must register.) Further, an individual who meets the terms of the exception would be excepted only from registration and listing requirements and would be required to comply with all other requirements to be contained in part 1271.

We are not extending the exception to ''other legal entities.'' Only individuals are covered. Examples of such individuals not required to register might include certain medical examiners, morticians, or physicians who recover hematopoietic stem cells or tissues (e.g., corneas, cord blood). Laboratories that perform donor testing are not excluded from registration, listing, or other requirements in part 1271.

(Comment 16) We proposed to define *family-related allogeneic use* in proposed § 1271.3(c) as ''the implantation, transplantation, infusion, or transfer of a human cellular or tissue-based product into a first-degree blood relative of the individual from whom cells or tissue comprising such product were removed.'' Under § 1271.10(d), as proposed, HCT/P's with a systemic effect that are for family-related allogeneic use would be regulated under section 361 of the PHS Act (provided that the HCT/P meets all other criteria set out in § 1271.10). This limited exception from the requirement for investigational use exemptions and premarketing submissions was first proposed in the proposed approach (62 FR 9721). In the registration proposed rule, we specifically requested further comments on the issue (63 FR 26744 at 26750).

We received approximately 13 comments on our proposed definition of ''family-related allogeneic use,'' most from individuals and organizations involved in hematopoietic stem cell transplantation. One comment praised the proposed definition as clearer and more consistent than that used in the proposed approach, but cautioned that our terminology might create confusion. Other comments argued that we should expand the definition to more distantly related family members. Several comments suggested that the term include all ancestral relations, siblings, and collateral relations to the fourth degree by blood, marriage, or adoption. Another comment objected to distinguishing between family-related donors and other donors, stating that the same principles apply in both situations. This comment argued that the clinical use of unrelated versus related allogeneic transplants falls within the practice of medicine and should not be regulated by FDA.

We have decided to change the term from ''family-related allogeneic use'' to ''allogeneic use in a first-degree or second-degree blood relative.'' Parents, children, and siblings are considered first-degree relatives. Aunts, uncles, nieces, nephews, first cousins, grandparents, and grandchildren are second-degree relatives. Relations by adoption or marriage are not included. Because we are using the phrase ''first-degree or second-degree blood relative'' in its ordinary sense, the final regulation does not contain a definition of this phrase.

Our decision to broaden the scope of related donors to include second-degree blood relatives, rather than just first-degree, is based upon several factors. In the absence of a human leukocyte antigen (HLA) identical sibling, the search for donors in extended families is occurring now to a very limited degree, but is likely to increase with the continuing advances in deoxyribonucleic acid technology. The likelihood of finding a donor with a haplotype identical to that of the recipient is greater among blood-related individuals than among unrelated individuals. Indeed, statistical methods have been proposed to measure this probability (Refs. 2 and 3).

In addition, for certain ethnic groups, it is extremely difficult to find an appropriate unrelated donor. Success at finding a match among the extended family can be equal to or even greater than the chance of finding a match using a single sibling search, if the haplotype is a common one within the patient's ethnic population, and the family members are of the same ethnic origin.

Registry outcome data for some hematologic malignancies suggest that peripheral blood and bone marrow transplant recipients may have a better survival rate when transplanted with hematopoietic stem cells from related donors. One possible reason is that a related donor is likely to share identical haplotypes with the patient (the genotypic level), whereas an unrelated donor is matched at the phenotypic level. Also, family donors may be better matched for minor histocompatability loci for which testing is not routinely performed.

We initially proposed a more limited exception. Having reviewed the comments on this issue, we believe there is some scientific merit in expanding the exception to second-degree blood relatives. This change is consistent with our goal of keeping regulatory burden to a minimum. The same scientific justification does not exist for expanding the exception to relatives by marriage or adoption, and is weaker for blood relatives beyond the second degree. In addition, the exception in § 1271.10(a)(4)(ii)(*b*) for allogeneic use in a first-degree or second-degree blood relative does not extend to those situations where the HCT/P is more than minimally manipulated, is advertised, labeled or otherwise objectively intended by the manufacturer for a nonhomologous use, or is combined with a drug or device (except as described in § 1271.10(a)(3)).

(Comment 17) One of the comments on ''family-related allogeneic use'' asserted that, in the context of reproductive medicine, the notion of appropriate use of family-related materials must include the close blood relatives of either partner. This

comment proposed that those facilities collecting or using reproductive tissues from sexually intimate partners or close relatives should not be required to register.

Later in this document, we address the question of registration for reproductive tissue facilities. The change in terminology from ''family-related allogeneic use'' to ''allogeneic use in first-degree or second-degree blood relatives'' does not affect the registration of reproductive tissue establishments.

(Comment 18) Several comments objected to the word ''product'' in the term *human cellular or tissue-based product*, defined in proposed § 1271.3(e). These comments asserted that human cells and tissues are donations, not goods manufactured for sale. Some comments argued that the use of the word ''product'' might have legal implications; e.g., subjecting eye banks to inappropriate product liability litigation. Comments also noted that the word ''product'' is inconsistent with terms used in the tissue and eye banking field. We also received an objection to describing embryos and germ cells as ''products.''

In choosing ''human cellular or tissue-based product,'' we were seeking a term that would describe everything that will be subject to the regulations in part 1271. We needed a term broad enough to cover both cells and tissues, and one that would include within its scope such diverse articles as unprocessed tissue, highly processed cells, and tissues that are combined with certain drugs or devices. Although we have considered removing the word ''product'' from the definition, we are concerned that another term (e.g., ''human cells and tissues'') would not be understood to include many of the highly manufactured products to which the regulations apply, or might be misconstrued to apply only to the cell or tissue component of such a product. Moreover, the term ''product'' is consistent with the language of the statutes under which we operate; for example, blood (which is also routinely donated) is a ''biological product'' under section 351 of the PHS Act. We do not believe that the use of the word ''product'' will affect the manner in which state laws apply to HCT/P's; our experience with the regulation of blood and blood products supports this view.

We recognize, however, that conceptual difficulties may arise in calling certain cells or tissues ''products.'' Thus, as noted earlier in this document, we have expanded the term to ''human cells, tissues, and cellular and tissue-based products,'' abbreviated as ''HCT/P's.'' We have made appropriate substitutions throughout the regulation. The definition itself has not changed, and the scope of the term remains the same.

Proposed § 1271.3(e) has been redesignated as § 1271.3(d)(2).

(Comment 19) One comment stated that the proposed rule leaves vague peripheral blood lymphocytes that are not cultured or manipulated, but are used for their immunological effects for the treatment of disease. According to the comment, the definition in proposed § 1271.3(e)(2) (final§ 1271.3(d)(2)(ii)) implies that these cells are subject to regulation under 21 CFR part 607. The comment recommends that these cells be specifically included in this proposal and not be considered mature blood cells subject to regulation under other sections of title 21 of the CFR.

We believe that the commenter is addressing donor lymphocytes (leukocytes) for infusion (DLI), which are the lymphocyte-rich cellular fractions obtained by leukapheresis of the peripheral blood of donors of bone marrow or peripheral blood hematopoietic stem/progenitor cells. Many DLI products are not further manipulated. These minimally manipulated products are administered to select patients to elicit a graft-versus-leukemia effect and to treat other transplant-associated complications.

DLI, regardless of the level of manipulation, meet the definition of HCT/P in this rule. FDA intends to regulate all DLI as HCT/P's, rather than as traditional blood products.

(Comment 20) One comment on proposed § 1271.3(e) requested clarification that an extract would not fall under the definition of human cellular or tissue-based product. The comment noted that the words ''any cell or tissue-based component of such a product'' may imply that an extract could fall within the definition.

We do not consider extracts to be HCT/P's. When we revised the definition of human cellular or tissue-based product in the donor-suitability proposed rule (64 FR 52696 at 52719), we deleted the phrase ''or any cell or tissue-based component of such a product.'' Moreover, we listed ''any secreted or extracted human products'' as an exception to the definition of HCT/P in proposed § 1271.3(e)(3). These changes are codified in this rule at § 1271.3(d)(2)(iii).

(Comment 21) One comment on proposed § 1271.3(e)(4) objected to the exclusion of bone marrow from the definition of HCT/P, since all three sources of hematopoietic stem cells (cord, peripheral blood, bone marrow) have the same risk of infectious disease transmission.

Minimally manipulated bone marrow falls under the purview of the Health Resources and Services Administration (section 379 of the PHS Act (42 U.S.C. 274(k)). For this reason, we have excepted it from the definition of HCT/P's, and thus from the scope of this regulation issued under section 361 of the PHS Act authority.

The exception for bone marrow in final § 1271.3(d)(2)(iv) extends only to ''minimally manipulated bone marrow for homologous use and not combined with a drug or a device (except for a sterilizing, preserving, or storage agent, if the addition of the agent does not raise new clinical safety concerns with respect to the bone marrow).'' Bone marrow would meet the definition of an HCT/P if it is: More than minimally manipulated; advertised, labeled, or otherwise objectively intended by the manufacturer for a nonhomologous use, or combined with certain drugs or devices.

(Comment 22) In the proposed rule, we stated in proposed § 1271.3(f) that ''*manufacture* means, but is not limited to, any or all steps in the recovery, screening, testing, processing, storage, labeling, packaging, or distribution of any human cellular or tissue-based product'' (63 FR 26744 at 26754). Approximately 10 comments objected that the term ''manufacture'' is inappropriate. Some comments asserted that fertility clinics are not ''manufacturers'' of human tissue. Comments from the eye banks asserted that it is inaccurate to use the word ''manufacture'' with respect to corneal tissue; along with ''product,'' the term could raise legal issues (e.g., subjecting eye banks to inappropriate product liability litigation). Another comment asserted that tissue banks do not manufacture tissue, but rather process it.

We have considered substituting a different term for ''manufacture,'' but have been unable to find a satisfactory replacement. Most of the terms that we considered (e.g., produce, handle) were too limited in scope. Moreover, comments that objected to the term did not suggest alternatives. For these reasons, we continue to use the word ''manufacture'' as an umbrella term to capture the many different actions that HCT/P establishments might take in preparing HCT/P's for use. These steps may include, but are not limited to, recovery, screening, testing, processing, storage, labeling, packaging, and distribution. No comments disagreed with or objected to any of the actions listed in the definition of manufacture.

Rather than list each of these activities repeatedly throughout this preamble and the regulation, we have decided to maintain the term ''manufacture,'' as defined in this rule (proposed § 1271.3(f) is codified at § 1271.3(e)).

(Comment 23) One comment on *manufacture* questioned the rationale for requiring testing establishments to register. Three comments asserted that testing laboratories should not be required to register because CLIA certification is sufficient. One comment asked if labs that test for other diseases or that perform bacterial cultures need to register.

The definition of ''manufacture'' is intended to cover all steps in the process of handling HCT/P's. Testing donors for communicable diseases is a critical step in this process and for that reason is included the definition of manufacture. The registration requirement for testing laboratories enables us to have a list of all parties involved in manufacturing activities.

Having a list of testing laboratories enables us to inspect laboratories to ensure that testing is performed in a correct manner according to test kit instructions. The CLIA certification referred to in the comments is important, and in fact we are requiring CLIA certification. However, because there are differences between inspections under CLIA and inspections carried out by FDA, CLIA certification alone is not adequate for our purposes. CLIA requirements address only a limited spectrum of laboratory testing and personnel requirements and do not focus on donor testing. Moreover, our experience with inspecting testing laboratories indicates that significant violations have been found. To exclude testing laboratories from the scope of this regulation would not be consistent with our goal of preventing the transmission of communicable diseases.

The registration requirement for testing laboratories extends to those laboratories that test donor specimens for communicable disease. Only laboratories that test for relevant communicable diseases as defined in the proposed donor-suitability rule are required to register. We have clarified the definition of ''manufacture'' to refer to ''screening or testing of the cell or tissue donor'' rather than to screening or testing of the cell or tissue. In the situation where communicable disease testing to determine donor suitability might be appropriately performed on the cells or tissues, rather than on the donor (as might be the situation with cord blood), such testing would be included within the meaning of donor testing.

(Comment 24) One comment noted that entities engaged only in labeling and packaging are not explicitly within the scope of part 1270, but are covered by this new rule.

Part 1271 covers more activities than part 1270.

(Comment 25) In the preamble to the proposed rule, we noted that *distribution* ''includes any conveyance or shipment of human cellular or tissue-based product (including importation and exportation), whether or not such conveyance or shipment is entirely intrastate and whether or not possession of the human cellular or tissue-based product is taken'' (63 FR 26750). We have proposed a codified definition of ''distribution'' in the GTP proposed rule.

For purposes of the regulations in part 1271 only, we have proposed in the GTP rule to define ''distribute'' to mean the conveyance or shipment of an HCT/P. In other contexts, FDA has defined ''distribution'' more broadly. Under the act, FDA has interpreted the term ''distribute'' to include the delivery, transfer, and dispensing of products. Moreover, the ordinary, dictionary meaning of the term ''distribute'' includes acts such as delivering, dispensing, supplying, and giving out. In this rule, we do not intend the term to include the dispensing or the transfer of an HCT/P to or in a patient.

Two comments on the registration proposed rule disagreed with the phrase ''whether or not possession is taken.'' They asserted that merely taking orders for a product should not be included within the meaning of ''distribution,'' and thus should be excluded from ''manufacture.'' One of these comments described its ''service and distribution'' agreement with a tissue processor, noting that although it does not ship or take possession of the product, its name appears on the product label along with that of the processor. A third comment recommended that the term ''distributes'' be clarified to exclude ''distributors''; i.e., organizations that receive processed/manufactured allografts and ship them to hospitals. Another comment noted that hospitals and other establishments sometimes provide tissue to other institutions in emergencies or in cases of special need. The comment requested that these limited activities not be considered distribution.

We agree that an entity that does not take possession of HCT/P's is not distributing them for the purposes of this rule. However, we disagree that distributors should be excluded from the terms of the definition of ''distribution.'' We agree that the occasional provision of HCT/P's to other institutions on an emergency basis does not fall within the meaning of ''distribution.''

We will consider any additional comments on the definition of ''distribution'' when finalizing the other proposed rules that will make up part 1271.

C. Comments on Subpart A: Proposed §§ 1271.10 and 1271.15 (Final §§ 1271.10 and 1271.20)

In proposed § 1271.10, we set out the criteria for regulating certain HCT/P's solely under section 361 of the PHS Act and the regulations to be contained in part 1271. An HCT/P would be subject to this level of regulation if it: (1) Was minimally manipulated; (2) was not promoted or labeled for any use other than a homologous use; (3) was not combined with or modified by the addition of any component that is a drug or a device; and (4) either does not have a systemic effect, or has a systemic effect and is for autologous, family-related allogeneic, or reproductive use (64 FR 52720).

Proposed § 1271.15 was intended to describe the HCT/P's that did not meet the criteria set out in § 1271.10 and for which we therefore did not consider regulation solely under section 361 of the PHS Act to be justified (64 FR 52699). The section set out the ''mirror images'' of the criteria in § 1271.10 to assist readers in understanding which HCT/P's would not be regulated solely under part 1271. However, rather than providing clarification, the proposed section could have been interpreted to create an additional hurdle for regulation of certain HCT/P's as drugs, devices, and/or biological products.

Our ability to regulate an HCT/P as a drug, device, and/or biological product derives from the act and section 351 of the PHS Act, authorities that are distinct from our authority to issue regulations to prevent the transmission of communicable disease under section 361 of the PHS Act. If an HCT/P does not meet the criteria in § 1271.10 for regulation solely under section 361 of the PHS Act, and the establishment does not qualify for any of the exceptions in final § 1271.15, the HCT/P will be regulated under the act and/or the PHS Act and applicable regulations. As part of this rulemaking process, we are amending certain drug and device regulations (e.g., §§ 207.20, 807.20) to require compliance with certain subparts of part 1271.

Therefore, we have modified proposed § 1271.15 and renumbered it § 1271.20. That section now refers to ''an HCT/P that does not meet the

criteria set out in § 1271.10(a),'' rather than setting out the mirror images of those criteria. As before, the section contains cross-references to those drug and device regulations (e.g., §§ 207.20 and 807.20) that will direct establishments to follow the procedures set out in subparts B, C, and D of part 1271. The section now also clarifies that the referenced drug and device regulations apply if the establishment does not qualify for any of the exceptions in § 1271.15.

We address below the comments received on proposed § 1271.10 and on the proposed definitions of ''homologous use'' and ''minimal manipulation.''

(Comment 26) One comment requested that we schedule a public meeting to discuss the appropriateness, legality, and practicality of using the criteria in § 1271.10 to reach jurisdictional determinations.

We value public input on the criteria in § 1271.10. In February 1997 we made available the proposed approach, which among other things described the factors that we would consider in choosing to regulate certain HCT/P's solely under the authority of section 361 of the PHS Act rather than as drugs, devices, and/or biological products. On March 17, 1997, we held a public meeting to solicit information and views on the proposed approach from the interested public, and we opened a docket for the submission of comments (Docket No. 97N–0068).

We have published three proposed rules in the **Federal Register**. Two of those rules specifically solicited comments on the criteria for regulating certain HCT/P's solely under section 361 of the PHS Act. On August 2, 2000, we held an open public meeting to solicit information on current practices related to the manipulation and homologous use of human bone allograft in the spine and other orthopedic reconstruction and repair. Many of the comments presented at the meeting indicated that there were misunderstandings about how the criteria set out in § 1271.10 would be applied, and about the meaning of the terms ''minimal manipulation'' and ''homologous use.'' This final rule contains clarifications and additional examples that we believe will clear up much of the confusion expressed at the meeting. We will consider issuing a guidance document if establishments need additional help in understanding the terms.

We intend to schedule additional public meetings as necessary. For example, FDA believes that additional public discussion of how the criteria in § 1271.10 would apply to reproductive tissues would be helpful, and further development of policy in this area may be warranted.

(Comment 27) We received numerous comments on the definition of *minimal manipulation*. The proposed definition reads as follows:

Minimal manipulation means:

(1) For structural tissue, processing that does not alter the original relevant characteristics of the tissue relating to the tissue's utility for reconstruction, repair, or replacement; and

(2) For cells and nonstructural tissues, processing that does not alter the relevant biological characteristics of cells or tissues.

One comment urged us to state in the preamble of the final rule those activities that FDA presently considers to be minimal manipulation. Two comments recommended that the following procedures be considered minimal manipulation: Selective removal of B-cells, T-cells, or malignant cells; blood or platelet depletion; centrifugation; density gradient separation; and cryopreservation. Two comments supported the use of clinical and scientific data to determine whether a tissue-processing method is appropriately considered to be minimal manipulation or more than minimal manipulation.

Eight comments asserted that ''minimal manipulation'' is vague and open to subjective interpretation, and should be eliminated. Two comments asserted that it is difficult to draw a meaningful distinction between tissues that are minimally manipulated and those that are more than minimally manipulated. One of these comments suggested that instead of the minimal manipulation criterion, FDA should propose that tissue products labeled or promoted for tissue replacement, reconstruction, or restoration of function be regulated as tissue. Another comment requested the development of guidance and noted that, in light of future technological advances, a broader definition of minimal manipulation may be more appropriate. One comment recommended that the TRG serve as the liaison for communicating with manufacturers concerning FDA's intended application of the definition of minimal manipulation to particular tissues.

We received many comments on the regulation of bone allografts, INCLUDING bone dowels, submitted in response to the donor-suitability proposed rule. (The agency had previously considered regulating certain bone dowels as medical devices.) Many of these comments addressed the concept of minimal manipulation. Several comments supported regulating machined bone allografts as medical devices in order to evaluate their safety and efficacy and protect the public health. However, most comments opposed such regulation, pointing to the long history of safe use of bone allografts and citing concerns about decreased supply, among other issues.

Comments did not suggest changes to the definition of minimal manipulation, and we have not changed the regulation's wording. We disagree that the term should be eliminated, however, as it serves as a valid indicator of those HCT/P's that present fewer risks and that are most appropriately regulated solely under section 361 of the PHS Act and part 1271 (so long as other criteria are also met).

We agree that the TRG will continue to play a role in providing recommendations for certain decisions made by the Center director interpreting the term ''minimal manipulation.'' At this time, examples of HCT/P's that we consider to be minimally manipulated include those that have been subjected to the following procedures: Density gradient separation; selective removal of B-cells, T-cells, malignant cells, red blood cells, or platelets; centrifugation; cutting, grinding, or shaping; soaking in antibiotic solution; sterilization by ethylene oxide treatment or irradiation; cell separation; lyophilization; cryopreservation; or freezing. We do not agree that the expansion of mesenchymal cells in culture or the use of growth factors to expand umbilical cord blood stem cells are minimal manipulation.

Most of the comments we received on the regulation of bone allografts and bone dowels assumed that we planned to regulate all bone allografts as medical devices. This is a misunderstanding. We are not considering regulating all bone allografts as medical devices. Like all other HCT/P's, the regulation of bone allografts depends on the four factors set out in § 1271.10. If the allograft is minimally manipulated, is not advertised, labeled, or otherwise objectively intended by the manufacturer for a nonhomologous use, and is not combined with a drug or device (except as described in § 1271.10(a)(3)), then it will be regulated as a 361 HCT/P and subject only to the regulations in part 1271. (Bone allografts do not have a systemic effect, so the fourth factor is not at issue.) We consider cutting, shaping and grinding of bone minimal manipulation. Threading and other machining procedures that are performed to create bone dowels, screws, and pins are also considered minimal manipulation.

(Comment 28) We received many comments on the term *homologous use*, which we defined in proposed § 1271.3(d) as follows:

Homologous use means the use of a cellular or tissue-based product for replacement or supplementation and:

(1) For structural tissue-based products, occurs when the tissue is used for the same basic function that it fulfills in its native state, in a location where such structural function normally occurs; or

(2) For cellular and nonstructural tissue-based products, occurs when the cells or tissue is used to perform the function(s) that they perform in the donor.

One comment praised the definition as reasonable, but urged us to develop a process for resolving differences of opinion between FDA and tissue manufacturers. Another comment supported our preamble statement that the ''[b]asic function of a structural tissue is what the tissue does from a biological/physiological point of view, or is capable of doing when in its native state'' (63 FR 26744 at 26749). As an example, this comment pointed to surgical use of fascia lata or pericardium allografts to replace or repair damaged dura mater or to construct a bladder support sling from a fascia lata allograft to prevent incontinence. Another comment questioned whether the homologous/nonhomologous criterion is a meaningful indicator of the need for premarket review; this comment cited fascia lata as an example of a tissue that has been used safely and effectively for years in ways that may be considered nonhomologous. One comment in response to our statement (63 FR 26744 at 26749) that the use of hematopoietic stem cells for treatment of adrenal leukodystrophy is an example of nonhomologous use stated that logical application of hematopoietic stem cells for their known hematologic, immunologic or metabolic effects as treatment of human disease should be considered within the practice of medicine and not subject to regulation by FDA.

Approximately 10 comments argued that the term ''homologous use'' should be eliminated. Many of these comments asserted that the term is vague and open to subjective interpretation. One comment stated that the phrase ''fulfills in its native state'' implies that tissue must be used in the identical place and for identical purposes, which ignores the realistic use of most tissue products. Many comments questioned the application of the term ''homologous use'' to bone allografts. One asserted that it is unusual for allograft tissues to be used in a homologous location, especially with regard to the spine.

Below, in comment 29, we discuss our decision to look not at the actual use of an HCT/P, but at the manufactuer's objective intent for a nonhomologous use. Under this approach, a practitioner could use an HCT/P, such as hematopoietic stem cells or fascia lata, for a nonhomologous use in the treatment of the physician's patients. Thus, we would not look at the surgical use of HCT/P's such as fascia lata or pericardium allografts, but instead at whether they were advertised, labeled, or otherwise objectively intended by the manufacturer for a nonhomologous use. In the absence of advertising, labeling, or other indications of the manufacturer's intent for such use, we would not require premarket submissions. Should such review be required for a product that has been used safely and effectively for years in nonhomologous ways, and that is intended for a nonhomologous use, we would expect that data would already exist to facilitate the review process.

We disagree that the term ''homologous use'' should be eliminated as a criterion for regulation of human cells or tissues under section 361 of the PHS Act. Regulation solely under section 361 and part 1271 is not warranted unless it is clearly demonstrated that the use of an HCT/P in the recipient is homologous to the function the HCT/P would carry out in the donor. We continue to consider nonhomologous use to be a meaningful indicator that regulation solely under section 361 of the PHS Act is not sufficient. For example, promotion of an HCT/P for an unproven therapeutic use, such as curing cancer, would clearly make it inappropriate to regulate the HCT/P solely under section 361 of the PHS Act and the regulations that will be in part 1271.

We have, however, rewritten the definition of homologous use in response to the comments' concerns. The new definition (codified at § 1271.3(c)) reads: ''Homologous use means the replacement or supplementation of a recipient's cells or tissues with an HCT/P that performs the same basic function or functions in the recipient as in the donor.'' The rewording eliminates the distinction between, on the one hand, structural tissues and, on the other, nonstructural tissues and cells. The new wording does not include the statement that, for structural tissues, homologous use occurs ''in a location where such structural function normally occurs.'' This language was understood, contrary to our intention, to limit the use of structural tissue to the same location from which is was derived. However, a use of a structural tissue may be homologous even when it does not occur in the same location as it occurred in the donor. For example, the use of bone for repair, replacement, or reconstruction anywhere in the skeleton of the recipient (including the vertebral column) would be considered homologous use. However, it should be understood that, for the use of a structural tissue to be considered homologous, the HCT/P must perform the same basic function or functions in the recipient as it did in the donor; the use of structural tissue in a location where it does not perform the same basic function as it did in the donor would not be homologous.

We intend to interpret ''nonhomologous'' narrowly. Examples of uses that would be considered nonhomologous include: The use of dermis as a replacement for dura mater, the use of amniotic membrane in the eye, and the use of cartilage in the bladder. As noted above, an HCT/P that is intended by the manufacturer for one of these uses would not be regulated solely under section 361 of the PHS Act and these regulations, but as a drug, device, and/or biological product.

(Comment 29) We received approximately six comments agreeing with our focus in proposed § 1271.10(b) on the promotion or labeling of HCT/P's for nonhomologous uses, rather than on their actual use. One of these comments noted that the use of a product should be determined not by the practice of surgeons but by the promotion, labeling, and objective intent of the manufacturer. Another noted that the manner in which we intend to determine homologous use is consistent with the way we determine the intended use of other products under our jurisdiction. Two comments interpreted proposed § 1271.10(b) as relieving clinicians from restrictions on use of tissue, and one of these comments asserted that the exception should be extended to certain clinical transplant programs.

Another supportive comment questioned how we will regulate the labeling of 361 HCT/P's. Among other things, the comment asked whether we will require 361 HCT/P's to be labeled for their homologous use. The comment also queried whether cutting, shaping, or processing a product in a manner that makes it amenable to nonhomologous use would be considered promotion, in the absence of labeling or advertising.

We appreciate the comments on this issue, and we have decided to maintain the regulation's focus on the objective intent of the HCT/P's manufacturer for a nonhomologous use, rather than on

the intent of the practitioner who uses the HCT/P. We believe this approach will lead to more efficient use of our resources. The focus on labeling, advertising, and other indications of the manufacturer's objective intent does not relieve clinicians from all restrictions on the use of HCT/P's. However, it does mean that clinical use of an HCT/P in a nonhomologous manner, whether by an individual practitioner or a transplant program, can be consistent with regulation of the HCT/P solely under section 361 of the PHS Act and the regulations to be contained in part 1271. In order to clarify this provison, we are revising proposed § 1271.10(b) to read, in new § 1271.10(a)(2), as follows: ''The HCT/P is intended for homologous use only, as reflected by the labeling, advertising, or other indications of the manufacturer's objective intent.

By labeling, we refer to the HCT/P label and any written, printed, or graphic materials that supplement, explain, or are textually related to the product, and which are disseminated by or on behalf of its manufacturer. We will address specific labeling requirements after reviewing comments to the GTP proposed rule.

In order to be more consistent with terminology used by the rest of the agency, we have replaced the word ''promoted'' with ''advertised.'' The terms ''advertised,'' ''advertisement,'' and ''advertising'' include information, other than labeling, that originates from the same source as the product and that is intended to supplement, explain, or be textually related to the product (e.g., print advertising, broadcast advertising, electronic advertising (including the Internet), statements of company representatives).

(Comment 30) As originally proposed, § 1271.10(c) contained the following criterion for regulation of an HCT/P solely under section 361 of the PHS Act: ''Not combined with or modified by the addition of any nontissue or noncellular component that is a drug or a device.'' We modified that wording in the donor-suitability proposed rule by deleting the phrase ''nontissue or noncellular.''

Two comments questioned the meaning of § 1271.10(c) and requested additional explanation. For example, the comments asked whether we would regard a component as being a drug or device based on its actual function in the product, or based on how the component is already regulated. The comments also questioned whether all products containing a ''nontissue or noncellular component that is a drug or device'' would automatically be subject to regulation and premarket review as drugs or devices, and expressed concern that application of the criterion might result in unnecessary regulation of HCT/P's as drugs or devices. Another comment asserted that we should not regulate a product containing a drug or device component unless it could affect recipient safety, and that the manufacturer should make the initial determination of whether this threshold has been crossed. One comment stated that hematopoietic stem cell components are routinely processed using centrifuges and other laboratory equipment, combined with dimethylsulfoxide (DMSO) and other reagents for cryopreservation, and separated using devices approved for the processing of hematopoietic stem cells components, and that we have previously classified these steps as minimal manipulation. The comment expressed concern that these steps might be considered to combine the cells with a drug or device component.

In response to the concerns expressed by these comments, we have rewritten the proposed language. Proposed § 1271.10(c) has been renumbered as § 1271.10(a)(3), and now reads: ''The manufacture of the HCT/P does not involve the combination of the cell or tissue component with a drug or a device, except for a sterilizing, preserving, or storage agent, if the addition of the agent does not raise new clinical safety concerns with respect to the HCT/P.''

The addition of a drug or a device to the cell or tissue component of an HCT/P may ordinarily be expected to add a therapeutic effect and may also raise safety concerns. For these reasons, the addition of a drug or a device to a cell or tissue makes it no longer appropriate to regulate the HCT/P solely under section 361 of the PHS Act. (As used, the terms *drug* and *device* are defined in section 201(g) of the act (21 U.S.C. 321(g)).

However, we recognize that the use of certain sterilizing, preserving, and storage agents do not raise the same concerns. For this reason, we have excepted sterilizing, preserving, and storage agents, but only if the addition of the agent does not raise new clinical safety concerns with respect to the HCT/P. Examples of substances that would generally be acceptable include: (1) Cryoprotectants (e.g., DMSO); (2) chemicals used for sterilization (e.g., ethylene oxide); and (3) storage solutions. We encourage the development of industry standards that describe the safe use of sterilization, preserving, and storage agents.

Some drugs or devices that have as their principal purpose sterilizing, preserving, or storage may also have a therapeutic effect or may be claimed to have such an effect. The addition of such drugs or devices would not fall within the exception for sterilizing, preserving, and storage agents. We agree that the establishment that manufactures the HCT/P should make the initial determination of whether the addition of a drug or device that is a sterilizing, preserving, or storage agent to an HCT/P raises new clinical safety concerns.

(Comment 31) We received one comment in response to our request for comments on whether the term ''systemic effect'' adequately characterizes those HCT/P's that should be regulated under section 351 of the PHS Act, such as neural-derived tissues and cells used to replace or supplement neurons in the brain (donor suitability proposed rule, 64 FR 52699). This comment expressed concern that the intent of the proposed change is vague and that currently there is little or no evidence that supports such cells or tissues having any systemic effect when implanted in the brain.

After further consideration, we agree that the term ''systemic effect'' may not cover all of the HCT/P's that we intended to cover. Because the effect of implanted neurons or neural tissue into the brain would likely be restricted to the site where the tissue/cells were placed, this effect might not be included within the meaning of systemic. However, as discussed in the proposed approach, HCT/P's that rely on living cells for their primary function, such as neuronal tissue, raise clinical safety and effectiveness concerns that are not appropriately addressed solely under section 361 of the PHS Act. Such concerns include viability, efficacy, malignant transformation, or rejection after transplantation. Thus, although neuronal cells may not be considered to have a systemic effect, they nonetheless require regulation under the act and/or section 351 of the PHS Act.

Therefore, we have clarified § 1271.10(a)(4) to indicate that an HCT/P that either has systemic effect or depends upon the metabolic activity of living cells for its primary function would not be appropriately regulated solely under section 361 of the PHS Act, and therefore will be regulated as a drug, device, and/or biological product. Cells or tissues such as pancreatic islet cells, which have effects on many different organs throughout the body through the secretion of insulin, are appropriately characterized by the term ''systemic effect.'' Neurons for implantation in the brain would fall into the category of HCT/P's that depend upon the metabolic activity of living

cells for their primary function. In contrast, some HCT/P's (such as corneas, skin, or osteochondral allografts) may contain living cells, but do not depend on them for their primary function, which is structural.

(Comment 32) Two comments on proposed § 1271.10 suggested that isolated human hepatocytes intended for transplantation be considered to meet the criteria in § 1271.10 and therefore be regulated as 361 HCT/P's.

We do not consider human hepatocytes, isolated in tissue culture medium, infused into the spleen, and intended for temporary treatment of liver failure to be suitable for regulation solely under section 361 of the PHS Act. Human hepatocytes have a systemic effect. Therefore, regardless of the level of manipulation of the hepatocytes, these cells would be regulated under the act and section 351 of the PHS Act.

D. Comments on Subpart A: Proposed § 1271.20 (Final § 1271.15)

Proposed § 1271.20, as modified in the donor-suitability proposed rule, set out four specific exceptions from the requirements of part 1271. We address comments on these proposed exceptions below. In this final rule, we have renumbered proposed § 1271.20 as § 1271.15.

(Comment 33) We received one comment on the proposed exception in § 1271.20(b) for establishments that remove human cells or tissues from an individual and implant such cells or tissues into the same individual during the same surgical procedure. The comment assumed that hospitals retaining autologous tissue, not used in a scheduled surgical procedure, to be used in a subsequent application on the same patient, are exempt from registration and listing because the two applications are essentially a single continuous procedure.

We agree that, so long as the hospital does not engage in any other activity encompassed with in the definition of ''manufacture,'' the hospital would not be required to register or comply with the other provisions to be codified in part 1271. For example, if the hospital expanded the cells or tissues, it would not meet the terms of the exception. In reaching this conclusion, we note that hospitals that store autologous cells or tissues for subsequent application in the same patient must follow the guidelines of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) for tissue storage, monitoring of storage devices, and tracking in order to obtain or maintain accreditation.

(Comment 34) We received comments questioning the proposed exception in § 1271.20(d) for establishments that ''receive or store human cellular or tissue-based products solely for pending scheduled implantation, transplantation, infusion, or transfer within the same facility.'' Approximately eight comments asserted that hospitals and other surgical facilities keep tissue allografts on hand for future use and suggested that the phrase ''pending scheduled'' be deleted from the exception. One comment projected that institutions would discontinue stocking tissue in order to avoid the registration requirement, leading to the denial to patients of appropriate implants. Another comment noted that thousands of hospitals and physician's offices store cells and tissue, and argued that registration could cause an unnecessary burden for facilities and FDA. One comment asserted that hospitals must follow the JCAHO guidelines for storage of tissues, monitoring of storage devices, and tracking of tissue use to provide for the safe storage of tissue. Another comment questioned whether physicians who receive sperm from a sperm bank and examine it for viability would be covered by the exception.

In response to many of these comments, we have deleted the phrase ''pending scheduled.'' The exception, codified at § 1271.15(d), now reads:

> You are not required to comply with the requirements of this part if you are an establishment that does not recover, screen, test, process, label, package, or distribute, but only receives or stores human cells or tissue solely for implantation, transplantation, infusion, or transfer within your facility.

As we noted in the preamble to the registration proposed rule (63 FR 26744 at 26748), this exception is intended only for end-user establishments; that is, establishments that do not recover, distribute, or otherwise manufacture human cells or tissue. Examples of such establishments might include some hospitals, dental offices, and physicians' offices. Physicians who do not recover sperm from donors but only receive sperm from a sperm bank would fall within the exception; examining the received sperm sample for viability would not be considered screening.

We believe that expanding this exception will ease the regulatory burden without posing public health concerns. To date, we have not become aware of problems with the types of facilities that will fall under the exception. However, should that situation change—e.g., should we encounter problems with tracking systems or learn of storage problems—we will consider narrowing the exception through rulemaking to bring these establishments within the scope of the regulation.

(Comment 35) One comment argued that registration should not be required for facilities collecting or using reproductive tissues from sexually intimate partners or close relatives. The comment strongly urged us to expand proposed § 1271.20(d) to include establishments that collect reproductive materials for use between sexually intimate partners or close relatives.

We agree with this comment, in part, and have added new paragraph (e) to the exceptions in § 1271.15. This exception is limited to establishments that recover reproductive materials for immediate use between sexually intimate partners. (By ''immediate use,'' we mean that the reproductive materials are used promptly enough that cryopreservation is not necessary and is not performed.) The exception is intended to cover an establishment that recovers semen for use in the artificial insemination of the donor's sexually intimate partner. We believe that this situation raises few new infectious disease concerns. For this reason, we are excepting these establishments from registering and from the other requirements that will be contained in part 1271. The exception does not extend to the recovery of cells or tissues from close relatives who are not sexually intimate partners, since an increased risk of communicable disease transmission exists in this situation.

E. Comments on Subpart B of Part 1271: Procedures for Registration and Listing

Many comments expressed general agreement with the proposed registration and listing procedures. One comment stated that the rule set forth a reasonable structure of requirements to be applied uniformly.

(Comment 36) One comment expressed concern that we might impose a registration fee.

We stated in the preamble to the registration proposed rule that we were evaluating our authority to assess a fee and the impacts of such a fee (63 FR 26744 at 26751). At this time, we have no plans to impose a registration fee.

(Comment 37) Comments opposed the proposed requirement in § 1271.21 for twice yearly reporting as excessive and supported annual listing updates instead. One comment noted that it is unlikely that the components processed by individual laboratories will change greatly over a 12-month period.

We disagree that the requirement for updating HCT/P lists is excessive. Establishments are required to update

their listings with information on changes that have occurred since the previously submitted list. These changes include the introduction of new HCT/P's, the discontinuation of HCT/P's, the reintroduction of previously discontinued HCT/P's, and material changes in information previously submitted. However, if no such change has occurred since the previously submitted list, the establishment is not required to submit an update.

Those establishments that must update their lists will likely find the task relatively simple. As discussed in section III.G of this document, Form FDA 3356 was designed with ease of completion in mind. Yet the information to be submitted on those updates is crucial if we are to keep abreast of developments in the cell and tissue industry. Without current information, we will be restricted in our ability to understand the industry and achieve our public health goals.

In setting up a unified registration system for all HCT/P's, we incorporated certain components from current registration and listing regulations for drugs and devices, such as the update requirements. By doing so, we made it possible for establishments that manufacture HCT/P's regulated as devices, drugs, and/or biological drugs to register and list their products with the agency using the same form as manufacturers of 361 HCT/P's. Thus, the requirement for updating is similar to the requirements in §§ 207.30 and 807.30 and is consistent with the requirements of section 510(j)(2) of the act.

We have rewritten the requirement for updates for greater clarity. Section 1271.21(c) now contains timeframes for updating. Section 1271.25(c) lists the changes that must be reported. The listed events to be reported have been corrected to reflect the type of information required to be included in the initial listing. Thus, for example, just as a listing includes the names of HCT/P's that an establishment recovers, processes, stores, labels, packages, distributes, or for which it performs donor screening or testing, so the updated listing would reflect any changes in the HCT/P's for which any of these activities are performed.

We have made an additional change to proposed § 1271.25(c), which would have required that copies of all contract service agreements be available at the time of inspection of the establishment. In order to avoid duplicating a similar requirement proposed in the GTP regulations, we have deleted the requirement from § 1271.25(c).

(Comment 38) We earlier stated that we were developing an electronic version of Form FDA 3356 (registration proposed rule, 63 FR 26750). One comment strongly supported these efforts and asserted that manufacturers should also be able to submit registration and listing information electronically.

We understand that it would be convenient to submit registration and listing information electronically over the Internet. We intend to rely on our experience in developing electronic submission capability in other areas (e.g., biological product deviations in manufacturing reports) to develop an electronic submission process for HCT/P registration and listing. When electronic submissions of Form FDA 3356 are possible, we will make an announcement to that effect.

(Comment 39) Two comments disagreed with the requirement proposed in § 1271.25(a)(4) for a statement affirming the truth and accuracy of all information in the registration and listing form. The comments argued that no similar requirement exists in the registration and listing regulations for drugs and devices, parts 207 and 807. The comments proposed that, if the requirement is maintained, the statement be qualified with a phrase such as ''to the best of my knowledge.''

To be of use, information submitted on the registration and listing form must be truthful and accurate. Moreover, the reporting official who completes and signs the form should be aware of the obligation to report truthfully and accurately. Although, as the comment points out, the registration and listing regulations for drugs and devices do not contain a similar statement, the act specifically prohibits the submission of false or misleading reports with respect to any device (section 301(q)(2) of the act (21 U.S.C. 331(q)(2)). Furthermore, a willfully false statement to a Federal agency is a criminal offense, and it is not uncommon for forms submitted to the agency to so note (18 U.S.C. 1001).

For these reasons, we are maintaining the requirement for a statement affirming the truth and accuracy of the information submitted on the registration and listing form. However, the reporting official may reasonably obtain the reported information from reliable sources rather than firsthand. For this reason, we believe it is reasonable to modify the required statement with the language ''to the best of my knowledge.'' We have made this change to the regulation and to the form.

(Comment 40) Two comments questioned the requirement proposed in § 1271.25(b) for a statement of whether each listed product meets the criteria set out in § 1271.10. One comment queried whether we plan to regard this statement as an admission that a product is or is not a 361 HCT/P. This comment suggested the addition of language consistent with that of other product registration and listing regulations clarifying that registration and listing under part 1271 does not constitute such an admission of product regulatory status. Both comments noted that only the statement is required, not an explanation or summary of why a product does or does not meet the criteria or which criteria are not met.

The categorization of HCT/P's as 361 HCT/P's or as drugs, devices, and/or biological products is a fundamental component of the new tiered, risk-based system. We are requiring this information for each HCT/P type to help us understand the HCT/P industry. Establishments need to know how their products are regulated in order to comply with appropriate requirements; therefore, the information required should be readily available. We understand that there may be instances where an establishment is unsure into which category its HCT/P falls; the establishment should contact the executive secretariat of the TRG in these situations. (For more information on the TRG, see CBER's website at http://www.fda.gov/cber/tissue/trg.htm.)

The requirement in § 1271.25(b) is for a statement only, not an explanation. The statement will inform the agency of the manufacturer's opinion, but will not be an ''admission'' with respect to how an HCT/P will be regulated. To be regulated solely under section 361 of the PHS Act and part 1271, an HCT/P must meet the criteria set forth under § 1271.10.

(Comment 41) Two comments requested that we clarify whether individual sizes or configurations of tissues should be listed separately, or instead under more general headings. One of these comments questioned whether a ''new'' product would include a new size of a product.

The information currently required on the registration and listing form is of a more general nature. Because the form does not ask for sizes, a new product would not include a new product size.

(Comment 42) One comment encouraged the use of standard product names for hematopoietic progenitor cell therapies in order to make product listing consistent.

We encourage the development of standard names. However, at this point we are requesting more general information on Form FDA 3356. In the

future, we may ask for more detailed information.

(Comment 43) One comment recommended that required listing information include, with respect to each listed type of tissue, the specific manufacturing activities conducted at each registered establishment.

To simplify the registration and listing form, we are not asking for specific manufacturing information for each product but for the establishment in general. If there is a need, we may possibly ask for more specific information in the future.

(Comment 44) One comment questioned whether the addition of an adjacent building with a different address would be considered a new location, requiring an amendment to registration under § 1271.26.

No. Adding an adjacent building would not require an amendment to registration.

(Comment 45) No comments were received on proposed § 1271.27, which deals with the assignment of a registration number. We wish, however, to note that establishments that are currently registered under the drug or device registration and listing requirements, and who would in the future register and list using the procedures in part 1271, when that part is fully effective, would keep the same registration number that was issued previously. Those establishments should provide that number to us when registering for the first time using the new procedures.

(Comment 46) One comment supported the release of registration and listing information under § 1271.37, but questioned how we would determine which information to disclose to the public.

The information submitted on Form FDA 3356 is not proprietary or confidential in nature and may be released to the public. Section 1271.37(a)(4) notes that the agency may also release all data or information that has already become a matter of public record. The agency will follow the procedures and requirements set out in 21 CFR part 20 to determine which information has become a matter of public record and may be released.

F. Comments on the Proposed Amendments to §§ 207.20 and 807.20

(Comment 47) No comments were submitted on the proposed amendments to §§ 207.20 and 807.20.

We have modified the language proposed for §§ 207.20(f) and 807.20(e) to clarify that establishments that manufacture HCT/P's regulated as devices, drugs, and/or biological products will register and list their products following the procedures in part 1271 instead of the procedures in parts 207 and 807. Thus, when this rule is effective for HCT/P's regulated as devices, drugs, and or biological products, these establishments will submit Form FDA 3356 according to the procedures set out in subpart B of part 1271, at the same time as other cell and tissue establishments, and will no longer have to submit other registration and listing forms. We have also renumbered proposed § 807.20(e) as § 807.20(d).

The effective date of §§ 207.20(f) and 807.20(d) is 2 years after the publication of this rule.

G. Comments on the Registration and Listing Form (Form FDA 3356)

We asked nine manufacturers to participate in a pilot study to evaluate FDA Form 3356 in draft form, as allowed by the Office of Management and Budget (OMB) before we finalized the paperwork burden analysis. The pilot study had two purposes: To evaluate the ease of use of Form FDA 3356, and to validate the data base software developed for FDA under contract. The pilot study took place in May 1998, and in August 1998 we submitted to the docket a summary of the results of the study.

Six of the participating establishments noted that the draft form was easy to use and required less than 1 hour to complete. Other comments on the form noted several areas of potential confusion. We have addressed many of these issues elsewhere in this document, in response to comments submitted to the docket. We have addressed other issues by modifying the instructions for completing the form.

We have made minimal changes to Form FDA 3356 and its instructions to conform to the revised requirements in part 1271, subpart B. We have not added any additional information requirements.

IV. Analysis of Economic Impacts

FDA has examined the impacts of the rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104–121) and under the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes the final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. OMB has determined that the final rule is a significant action as defined in Executive Order 12866.

The Regulatory Flexibility Act requires agencies to analyze whether a rule may have a significant impact on a substantial number of small entities and, if it does, to analyze regulatory options that would minimize the impact. The Unfunded Mandates Reform Act requires that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 (adjusted annually for inflation) in any one year. We have also determined that this rule will not result in aggregate expenditures for State, local, and tribal governments, or the private sector of $100 million in any one year (adjusted for inflation).

An analysis of available information suggests that costs to the entities most affected by this rule, including small entities, are not expected to be significant, as described in the analysis below. Therefore, the agency certifies that this rule will not have a significant impact on a substantial number of small entities.

A. Objective and Basis of the Action

This action is a first step in the regulation of the rapidly evolving industry of human cells and tissue. The entire industry has not been previously regulated under a single comprehensive regulatory program by FDA or other public health authorities. Lack of a single regulatory approach or registration system has prevented the agency from acquiring information regarding the full size of the cell and tissue industry and the scope of human cells, tissues, and cellular and tissue-based products (HCT/P's) that are used by the industry. The rule will require all manufacturers of HCT/P's to register with the agency and to submit to the agency a list of their HCT/P's. Through registration and listing, FDA will be able to identify industry participants and the scope of the HCT/P's produced. This will enable the agency to more efficiently monitor the industry, distribute new information such as guidances, policies, or requirements, and identify entities that may be subject to FDA oversight. This action is taken solely under the authority of section 361 of the PHS Act. Section 361 of the PHS

Act is also used as authority to amend parts 207 and 807 so that the registration and data bases for all human cells, tissues, and cellular and tissue-based products may be consolidated. FDA has reviewed related Federal rules and has not identified any rules that duplicate, overlap, or conflict with the rule.

B. Small Entities Affected

This rule affects both establishments that currently register with FDA and submit product lists to the agency under applicable sections of the act (parts 207 and 807), and those establishments that are not presently required to register or list with the agency. FDA has structured registration and listing for HCT/P's to have a minimal impact on affected establishments. However, the agency anticipates that the impact will be greater for those establishments that do not currently register or list. Because the final rule is effective 75 days after publication of this document for those establishments currently regulated under part 1270, and is effective in 2 years for all other HCT/P establishments, the economic impact on the industry will be staggered.

The total number of establishments that are required to register and list under part 1271 in 2 years after the publication of this rule is estimated to be 1,225. The registration and listing initiative will, in part, help the agency obtain more accurate numbers of HCT/P's establishments. In calculating the burden, the agency has relied on information obtained from trade organizations related to the human cells, tissue, and cellular and tissue-based products industry, several of which also provided estimates of what portion of the industry their membership represented. Along with this information and from our own research, we determined that 65 manufacturers of human cells, tissue, and cellular and tissue-based products are registered with the agency as required by part 807. The agency also determined that one manufacturer of an HCT/P drug is registered as required by part 207

According to the U.S. Small Business Administration, a tissue bank is a small entity if it has annual revenues less than $5 million. FDA estimates that 110 tissue banks are involved in the manufacture of conventional tissue and that approximately 77.5 percent (or 85) of these banks are small entities. FDA estimates that there are 425 stem cell facilities (400 peripheral blood stem cell facilities and 25 cord blood facilities), and that all are small entities. FDA estimates that approximately 114 eye banks are currently operating in the United States, and industry experts estimate that virtually all facilities would be classified as small. FDA estimates that there are approximately 400 assisted reproductive technology (ART) facilities. This estimate is consistent with industry comments. Consultants estimate that two-thirds of all ART facilities (or 267 establishments) would be classified as small entities. In addition, the American Society of Reproductive Medicine (ASRM) has a 1996 list of approximately 110 sperm banks operating in the U.S. Information about sperm banks from a report by Eastern Research Group (ERG) indicates that 95 percent (or 105) of these sperm banks are small. Thus, approximately 996 (85 + 425 + 114 + 267 + 105) of all 1,225 establishments would be considered small entities. In addition, 66 establishments are currently regulated as drugs, devices, or biological products under parts 207 and 807. Approximately 90 percent of these (or 60 establishments) are small entities. Therefore, we estimate that a total 1,056 establishments (996 + 60) are small entities.

C. Nature of the Impact

The main cost in implementing this final rule is staff time, which we estimate to cost $38.00 per hour, based on 1997 Bureau of Labor Statistics estimates.

Out of a total 1,225 establishments affected by this rule, 66 HCT/P drug and device establishments currently submit registration and product listing information under parts 207 and 807. In the proposed rule, we incorrectly estimated both the time and the scope of annual information collection for these establishments. Our estimate inaccurately lumped the submission of all required information into one year and concluded that 2 hours would be needed annually to register and list initially, submit a subsequent annual registration, update HCT/P listings, and amend ownership or location information.

As proposed, however, this final rule requires that HCT/P drug and device manufacturers use a new, single form to register and list their HCT/P products. This rule does not impose any new registration or listing requirements for establishments regulated under parts 207 and 807. To avoid duplication, the rule provides HCT/P drug and device manufacturers a single, new form to replace the multiple forms currently required under parts 207 and 807. Therefore, we now estimate only the time needed to transition from the use of multiple forms to the use of the one form. Based on results from the pilot study described above in section III.G of this document, we estimate that establishments will need approximately 0.5 hour to transition to Form FDA 3356 at a one-time transition cost of approximately $19 [$38 x 0.5]. We estimate that the total impact for all 66 establishments will be approximately $1,254 [66 x $38 x 0.5].

For the 1,159 HCT/P manufacturers not regulated under parts 207 and 807, the costs are based upon the staff time needed to obtain the form, read the instructions, and complete and submit the form for the initial registration and HCP/T listing, subsequent annual registration, and, as needed, listing updates and location/ownership amendments. Based on the pilot study described above, FDA estimates that it will take an average of 0.75 hour of staff time per establishment for the initial submission. At $38.00 per hour of staff time, each establishment is expected to incur an initial one-time cost of approximately $28 [$38 x 0.75]. We estimate the total impact for all 1,159 establishments for the submission of initial registration and HCT/P listing to be approximately $33,032 [1,159 x $38 x 0.75].

After the initial registration, the final rule requires annual registration, which we estimate will take 0.5 hour to complete and submit to FDA. We estimate that the annual cost of these submissions will be approximately $22,021 [1,159 x $38 x 0.5] or $19 per establishment.

The final rule also requires HCT/P listing updates twice a year, a submission that is required only when a change has been made since the previous listing submission. FDA assumes that in any given year, 5 percent or 58 of the 1,159 establishments [1,159 x 0.05] will submit one listing. The listing update is estimated to take about 0.5 hours to complete and submit to FDA. We estimate that each establishment will incur an annual cost of approximately $19 [$38 x 0.5], for a total of $1,102 for all 58 establishments.

The rule also requires changes in ownership or location to be reported as an amendment within 5 days of such changes. FDA expects that this will be a rare event and that in any given year, no more than 5 percent or 58 of the 1,159 establishments [1,159 x 0.05] will change location or ownership and submit an amendment. This amendment is estimated to take 0.25 hours of staff time. We estimate that each establishment will incur a cost of approximately $10 [$38 x 0.25], totaling $580 for all 58 establishments.

In sum, we estimate the total annual for all submissions subsequent to the initial registration and listing (annual registration and, as needed, listing updates and location/ownership amendments) to be $23,702 [$22,021 + $1,101 + $580].

There are no specific educational or technical skills required to complete and submit the registration and listing form. Trained and qualified employees of an establishment who are involved with its operations generally complete similar activities.

This final rule is the first step in creating a tiered, risk-based regulatory scheme that will tailor the degree of scrutiny afforded to different HCT/P's to the risks associated with each of them. Through registration and listing, FDA will acquire the information needed to characterize the nature and extent of HCT/P's. This information will enable FDA to efficiently and effectively respond to emerging public health concerns related to human cells or tissue. Lists of industry members and their HCT/P's will also help FDA disseminate educational materials and other important information regarding FDA policies, guidances, and requirements.

D. Minimizing the Impact on Small Entities

FDA recognizes that a large number of the establishments that would be required to register and list under the rule will be small entities with limited resources. In recognition of this, the agency is proposing that the information to be provided during registration and listing be only that which is necessary to achieve the agency's goals of industry characterization and identification of its participants. To alleviate the impact on entities, especially small entities, FDA will consider the use of electronic submissions (e-mail or Internet) and electronic signatures.

V. Environmental Impact

The agency has determined under 21 CFR 25.30(h) that this action is of a type that is categorically excluded from the preparation of an environmental assessment because these actions, as a class, will not result in the production or distribution of any substance and therefore will not result in the production of any substance into the environment.

VI. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

VII. The Paperwork Reduction Act of 1995

This final rule contains information collection requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection requirements are shown below with an estimate of the initial one-time reporting burden and the annual reporting burden. Included in the estimate is the time for reviewing the instructions, searching existing data sources, gathering and maintaining the data needed, completing and reviewing each collection of information.

Title: Establishment Registration and Listing Requirements for Human Cells, Tissues, and Cellular and Tissue-Based Products.

Description: The final rule requires establishments that recover, process, store, label, package, or distribute any human cell, tissue, and cellular and tissue-based product (HCT/P), or that perform donor screening or testing, to submit an initial establishment registration and HCT/P list to FDA. Subsequently, establishments must submit an annual update to their establishment registration. In addition, establishments are required to submit HCT/P list updates, if any, and amendments whenever an establishment changes ownership or locations. FDA provides a registration and listing form (Form FDA 3356) to facilitate the ease and speed of submissions. Form FDA 3356 is an approved information collection format under OMB control number 0910–0372. The approval expires July 31, 2001.

Description of Respondents: Establishments that recover, process, store, label, package, or distribute any human cells, tissue, and cellular and tissue-based product.

As required by section 3506(c)(2)(B) of the PRA, FDA provided an opportunity for public comment on May 14, 1998 (63 FR 26744), on the information collection requirements of the proposed rule.

Table 1 of this document lists the estimated one-time reporting burden for the initial establishment registration and HCT/P listing, which is required under § 1271.10(b). Section 1271.25(a) and (b) identify the initial establishment and HCT/P listing information required. Sections 207.20(f) and 807.20(d) require HCT/P establishments to use Form FDA 3356 for providing registration and listing information required under parts 207 and 807.

Table 2 of this document provides the estimate of the ongoing annual reporting burden for establishment registration. In addition, table 2 of this document sets out estimated reporting burdens for HCT/P listing updates and establishment location or ownership amendments that would occur during any given year. If there is no change to an HCT/P listing, establishment location or ownership, a submission is not required.

Sections 1271.21(b) and 1271.10(b) require the annual establishment registration by domestic and foreign HCT/P establishments that are solely regulated under section 361 of the PHS Act and this part.

Sections 1271.21(c)(ii), 1271.25(c), and 1271.10(b) require domestic and foreign HCT/P establishments to submit HCT/P listing updates only when an HCT/P is changed, added, or discontinued, and when there has been a material change to information submitted previously to the agency. If no change has occurred since the previous submission, an update is not required.

Sections 1271.26 and 1271.10(b) require domestic and foreign HCT/P establishments to submit an amendment, but only when the establishment makes a change in location or ownership.

Sections 207.20, 207.26, 207.30, 807.20, 807.26, and 807.30 already require establishments that manufacture drug or device products to submit initial establishment registration and product listing, as well as annual establishment registration, product listing updates, and location and ownership amendments. This final rule adds §§ 207.20(f) and 807.20(d), which require that manufacturers of HCT/P drugs and devices submit this registration and listing information using Form FDA 3356 instead of the multiple forms identified under parts 207 and 807. Therefore, these establishments will incur only a one-time burden to transition from the use of several forms to the use of one form (see table 1 above). This rule adds no new registration and listing requirements.

This final rule is implemented according to the staggered effective dates. Human tissues intended for transplantation that are currently regulated under section 361 of the PHS Act and part 1270 are required to register with the agency and list their HCT/P's within 5 days of the first effective date. The effective date for all other HCT/P's is 2 years after publication of this rule in the **Federal Register**, about which time we expect that the remaining subparts of part 1271 will become effective.

In the proposed rule, FDA underestimated the number of respondents. Based on additional information provided to FDA by industry representatives, trade organizations, and professional societies, we have revised our estimate of establishments to approximately 1,225 (i.e., approximately 110 conventional tissue, 114 eye tissue banks, 400 peripheral blood stem cells, 25 stem cell products from cord blood, 400 reproductive tissue, 110 sperm banks, and 66 licensed biological products and approved devices).

Our burden estimates for the annual frequency per response and average hours per response are based on institutional experience with comparable reporting provisions for drugs, including biological products, and devices, information from industry representatives and trade organizations, and data provided by the Eastern Research Group (ERG), a consulting firm hired by FDA to prepare an economic analysis of the potential economic impact on sperm banks and other reproductive tissue facilities.

In the final rule, we have separated the initial, one-time reporting requirements (table 1 of this document) from the subsequent ongoing annual establishment registration, HCT/P updates and amendment requirements (table 2 of this document).

Table 1 of this document provides the initial, one-time estimated burden for HCT/P establishment registration and HCT/P listing. This information may be submitted simultaneously on the same form, Form FDA 3356. We estimate that 0.75 hour of staff time will be needed for each initial submission. This estimate is based on a pilot program described above in section III.G of this document conducted to evaluate Form FDA 3356.

In table 1 of this document we also include the one-time burden for HCT/P drug and device manufacturers regulated under parts 207 and 807. Parts 207 and 807 require that drug and device manufacturers submit initial establishment registration and product listing, annual establishment registration, product listing updates, and location/ownership amendments. New §§ 207.20(f) and 807.20(d) change only the reporting format and require use of only one form, new Form FDA 3356, in place of the multiple forms currently required, i.e., Forms FDA–2656 and FDA–2657 for drug manufacturers, and Forms FDA–2891, FDA–2891(a), and FDA–2892 for device manufacturers. Therefore, the one-time reporting burden estimate for §§ 207.20(f) and 807.20(d) in table 1 of this document reflects only the time necessary to transition from the use of current multiple forms to the use of Form FDA 3356. In the proposed rule, we incorrectly included the time needed to submit the registration and listing information already required under parts 207 and 807. As revised here, the reporting burden under new §§ 207.20(f) and 807.20(d) reflects only the time necessary to transition from the use of current multiple forms to the use of Form FDA 3356.

Table 2 of this document shows more accurately than in the proposed rule that on-going annual registration, updates and amendments require 0.50 hour, while the initial submission requires on average 0.75 hour. In addition, table 2 of this document shows that the average hours per response is less for the HCT/P listing updates and location/ownership amendments, which are required only when a change is made, than for the annual registration, which must be submitted every year. In table 2 of this document, we also estimate that approximately 5 percent of the 1,159 establishments, or 58 establishments, will make changes to HCT/P's, location, or ownership in any one year after the initial registration and listing. Based on additional information from industry representatives and from our own experiences, we estimate that annual registration, HCT/P listing updates, and location/ownership amendments will require 0.5, 0.5, and 0.25 hours, respectively, as opposed to the full hour estimated for every establishment submission in the proposed rule. The greater precision afforded by this breakout shows that, despite the increased number of total estimated respondents, the estimated total burden hours is lower than in the proposed rule. In table 2 of this document, the total annual burden of 623 hours for ongoing reporting is slightly less than the initial, one-time reporting burden total of 902.25 hours in table 1 of this document.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED INITIAL (ONE–TIME) REPORTING BURDEN [1]

21 CFR	No. of respondents	Annual frequency per response	Total annual responses	Hours per response (average)	Total hours
207.20(f)	1	1	1	0.5	0.5
807.20(d)	65	1	65	0.5	32.50
Initial Registration and HCT/P Listing 1271.25(a), with 1271.25(b) and 1271.10(b)	1,159	1	1,159	0.75	869.25
TOTAL					902.25

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN [2]

21 CFR	No. of respondents	Annual frequency per response	Total annual responses	Hours per response (average)	Total hours
Annual Registration 1271.21(b) and 1271.10(b)	1,159	1	1,159	0.5	579.50
HCT/P Listing Update 1271.21(c), 1271.25(c), and 1271.10(b)	58	1	58	0.5	29.00

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN [2]—Continued

21 CFR	No. of respondents	Annual frequency per response	Total annual responses	Hours per response (average)	Total hours
Location/Ownership Amendment 1271.26 and 1271.10(b)	58	1	58	0.25	14.50
TOTAL					623

[2] There are no capital costs or operating and maintenance costs associated with this collection of information.

Individuals and organizations may submit comments on these burden estimates or on any other aspect of these information collection requirements, including suggestions for reducing the burden. Comments should be directed to the Food and Drug Administration, Center for Biologics Evaluation and Research, Tissue Establishment Registration Coordinator (HFM–305), 1401 Rockville Pike, suite 200N, Rockville, MD 20852.

The information collection requirements of the final rule have been submitted to OMB for review. Prior to the effective date of the final rule, FDA will publish a document in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection requirements in the final rule. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

VIII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Vice President's National Performance Review report, ''Reinventing the Regulation of Human Tissue,'' February 1997.

2. Schipper, R. F., D'Amaro, J., and Oudshoorn, M., ''The Probability of Finding a Suitable Related Donor for Bone Marrow Transplantation in Extended Families,'' *Blood*, 87:800–804, 1996.

3. Kaufman, R., ''A Generalized HLA Prediction Model for Related Donor Matches,'' *Bone Marrow Transplantation*, 17:1013–1020, 1996.

List of Subjects

21 CFR Part 207

Drugs, Reporting and recordkeeping requirements.

21 CFR Part 807

Confidential business information, Imports, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 1271

Human cells, Reporting and recordkeeping requirements, tissue-based products.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, chapter I of title 21 of the Code of Federal Regulations is amended as follows:

PART 207—REGISTRATION OF PRODUCERS OF DRUGS AND LISTING OF DRUGS IN COMMERCIAL DISTRIBUTION

1. The authority citation for 21 CFR part 207 is revised to read as follows:

Authority: 21 U.S.C. 331, 351, 352, 355, 356, 360, 360b, 371, 374; 42 U.S.C. 262, 264, 271.

2. Section 207.20 is amended by revising the heading and adding paragraph (f) to read as follows:

§ 207.20 Who must register and submit a drug list?

* * * * *

(f) Owners and operators of establishments or persons engaged in the recovery, screening, testing, processing, storage, or distribution of human cells, tissues, and cellular and tissue-based products, as defined in § 1271.3(d) of this chapter, that are regulated under section 351 of the Public Health Service Act and/or the Federal Food, Drug, and Cosmetic Act must register and list those human cells, tissues, and cellular and tissue-based products with the Center for Biologics Evaluation and Research on Form FDA 3356 following the procedures set out in subpart B of part 1271 of this chapter, instead of the procedures for registration and listing contained in this part, except that the additional listing information requirements in § 207.31 remain applicable.

PART 807—ESTABLISHMENT REGISTRATION AND DEVICE LISTING FOR MANUFACTURERS AND DISTRIBUTORS OF DEVICES

3. The authority citation for 21 CFR part 807 is revised to read as follows:

Authority: 21 U.S.C. 331, 351, 352, 360, 360c, 360e, 360i, 360j, 371, 374; 42 U.S.C. 264, 271.

4. Section 807.20 is amended by revising the heading and adding paragraph (d) to read as follows:

§ 807.20 Who must register and submit a device list?

* * * * *

(d) Owners and operators of establishments or persons engaged in the recovery, screening, testing, processing, storage, or distribution of human cells, tissues, and cellular and tissue-based products, as defined in § 1271.3(d) of this chapter, that are regulated under the Federal Food, Drug, and Cosmetic Act must register and list those human cells, tissues, and cellular and tissue-based products with the Center for Biologics Evaluation and Research on Form FDA 3356 following the procedures set out in subpart B of part 1271 of this chapter, instead of the procedures for registration and listing contained in this part, except that the additional listing information requirements of § 807.31 remain applicable.

5. Part 1271 is added to read as follows:

PART 1271—HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE–BASED PRODUCTS

Subpart A—General Provisions

Sec.

1271.1 What are the purpose and scope of this part?
1271.3 How does FDA define important terms in this part?
1271.10 Are my HCT/P's regulated solely under section 361 of the PHS Act and the regulations in this part, and if so what must I do?
1271.15 Are there any exceptions from the requirements of this part?
1271.20 If my HCT/P's do not meet the criteria in § 1271.10, and I do not qualify

for any of the exceptions in § 1271.15, what regulations apply?

Subpart B—Procedures for Registration and Listing

1271.21 When do I register, submit an HCT/P list, and submit updates?
1271.22 How and where do I register and submit an HCT/P list?
1271.25 What information is required for establishment registration and HCT/P listing?
1271.26 When must I amend my establishment registration?
1271.27 Will FDA assign me a registration number?
1271.37 Will establishment registrations and HCT/P listings be available for inspection, and how do I request information on registrations and listings?

Authority: 42 U.S.C. 216, 243, 264, 271.

Subpart A—General Provisions

§ 1271.1 What are the purpose and scope of this part?

(a) *Purpose*. The purpose of this part, in conjunction with §§ 207.20(f), 210.1(c), 210.2, 807.20(d), and 820.1(a) of this chapter, is to create a unified registration and listing system for establishments that manufacture human cells, tissues, and cellular and tissue-based products (HCT/P's) and to establish donor-suitability, current good tissue practice, and other procedures to prevent the introduction, transmission, and spread of communicable diseases by HCT/P's.

(b) *Scope.* (1) If you are an establishment that manufactures HCT/P's that are regulated solely under the authority of section 361 of the Public Health Service Act (the PHS Act), this part requires you to register and list your HCT/P's with the Food and Drug Administration's (FDA's) Center for Biologics Evaluation and Research and to comply with the other requirements contained in this part, whether or not the HCT/P enters into interstate commerce. Those HCT/P's that are regulated solely under the authority of section 361 of the PHS Act are described in § 1271.10.

(2) If you are an establishment that manufactures HCT/P's that are regulated as drugs, devices and/or biological products under section 351 of the PHS Act and/or the Federal Food, Drug, and Cosmetic Act, §§ 207.20(f) and 807.20(d) of this chapter require you to register and list your HCT/P's following the procedures in subpart B of this part. Sections 210.1(c), 210.2, 211.1(b), and 820.1(a) of this chapter require you to comply with the donor-suitability procedures in subpart C of this part and the current good tissue practice procedures in subpart D of this part, in addition to all other applicable regulations.

§ 1271.3 How does FDA define important terms in this part?

The following definitions apply only to this part:

(a) *Autologous use* means the implantation, transplantation, infusion, or transfer of human cells or tissue back into the individual from whom the cells or tissue were recovered.

(b) *Establishment* means a place of business under one management, at one general physical location, that engages in the manufacture of human cells, tissues, and cellular and tissue-based products. ''Establishment'' includes:

(1) Any individual, partnership, corporation, association, or other legal entity engaged in the manufacture of human cells, tissues, and cellular and tissue-based products; and

(2) Facilities that engage in contract manufacturing services for a manufacturer of human cells, tissues, and cellular and tissue-based products.

(c) *Homologous use* means the replacement or supplementation of a recipient's cells or tissues with an HCT/P that performs the same basic function or functions in the recipient as in the donor.

(d)(1) *Human cells, tissues, or cellular or tissue-based products (HCT/P's)* means any human tissue derived from a human body and intended for transplantation into another human, as defined under § 1270.3(j). Examples of HCT/P's include, but are not limited to, bone, ligament, skin, and cornea.

(2) *Human cells, tissues, or cellular or tissue-based products (HCT/P's)* means articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient. Examples of HCT/P's include, but are not limited to, bone, ligament, skin, dura mater, heart valve, cornea, hematopoietic stem cells derived from peripheral and cord blood, manipulated autologous chondrocytes, epithelial cells on a synthetic matrix, and semen or other reproductive tissue. The following articles are not considered HCT/P's:

(i) Vascularized human organs for transplantation;

(ii) Whole blood or blood components or blood derivative products subject to listing under parts 607 and 207 of this chapter, respectively;

(iii) Secreted or extracted human products, such as milk, collagen, and cell factors; except that semen is considered an HCT/P;

(iv) Minimally manipulated bone marrow for homologous use and not combined with a drug or a device (except for a sterilizing, preserving, or storage agent, if the addition of the agent does not raise new clinical safety concerns with respect to the bone marrow);

(v) Ancillary products used in the manufacture of HCT/P;

(vi) Cells, tissues, and organs derived from animals other than humans; and

(vii) In vitro diagnostic products as defined in § 809.3(a) of this chapter.

(e) *Manufacture means*, but is not limited to, any or all steps in the recovery, processing, storage, labeling, packaging, or distribution of any human cell or tissue, and the screening or testing of the cell or tissue donor.

(f) *Minimal manipulation* means:

(1) For structural tissue, processing that does not alter the original relevant characteristics of the tissue relating to the tissue's utility for reconstruction, repair, or replacement; and

(2) For cells or nonstructural tissues, processing that does not alter the relevant biological characteristics of cells or tissues.

(g) *Transfer* means the placement of human reproductive cells or tissues into a human recipient.

§ 1271.10 Are my HCT/P's regulated solely under section 361 of the PHS Act and the regulations in this part, and if so what must I do?

(a) An HCT/P is regulated solely under section 361 of the PHS Act and the regulations in this part if it meets all of the following criteria:

(1) The HCT/P is minimally manipulated;

(2) The HCT/P is intended for homologous use only, as reflected by the labeling, advertising, or other indications of the manufacturer's objective intent;

(3) The manufacture of the HCT/P does not involve the combination of the cell or tissue component with a drug or a device, except for a sterilizing, preserving, or storage agent, if the addition of the agent does not raise new clinical safety concerns with respect to the HCT/P; and

(4) Either:

(i) The HCT/P does not have a systemic effect and is not dependent upon the metabolic activity of living cells for its primary function; or

(ii) The HCT/P has a systemic effect or is dependent upon the metabolic activity of living cells for its primary function, and:

(*a*) Is for autologous use;

(*b*) Is for allogeneic use in a first-degree or second-degree blood relative; or

(*c*) Is for reproductive use.

(b) If you are a domestic or foreign establishment that manufactures an HCT/P described in paragraph (a) of this section:

(1) You must register with FDA;

(2) You must submit to FDA a list of each HCT/P manufactured; and

(3) You must comply with the other requirements contained in this part.

§ 1271.15 Are there any exceptions from the requirements of this part?

(a) You are not required to comply with the requirements of this part if you are an establishment that uses HCT/P's solely for nonclinical scientific or educational purposes.

(b) You are not required to comply with the requirements of this part if you are an establishment that removes HCT/P's from an individual and implants such HCT/P's into the same individual during the same surgical procedure.

(c) You are not required to comply with the requirements of this part if you are a carrier who accepts, receives, carries, or delivers HCT/P's in the usual course of business as a carrier.

(d) You are not required to comply with the requirements of this part if you are an establishment that does not recover, screen, test, process, label, package, or distribute, but only receives or stores HCT/P's solely for implantation, transplantation, infusion, or transfer within your facility.

(e) You are not required to comply with the requirements of this part if you are an establishment that only recovers reproductive cells or tissue and immediately transfers them into a sexually intimate partner of the cell or tissue donor.

(f) You are not required to register or list your HCT/P's independently, but you must comply with all other applicable requirements in this part, if you are an individual under contract, agreement, or other arrangement with a registered establishment and engaged solely in recovering cells or tissues and sending the recovered cells or tissues to the registered establishment.

§ 1271.20 If my HCT/P's do not meet the criteria in § 1271.10, and I do not qualify for any of the exceptions in § 1271.15, what regulations apply?

If you are an establishment that manufactures an HCT/P that does not meet the criteria set out in § 1271.10(a), and you do not qualify for any of the exceptions in § 1271.15, your HCT/P will be regulated as a drug, device, and/or biological product under the act and/or section 351 of the PHS Act, and applicable regulations in title 21, chapter I. Applicable regulations include, but are not limited to, §§ 207.20(f), 210.1(c), 210.2, 211.1(b), 807.20(d), and 820.1(a) of this chapter, which require you to follow the procedures in subparts B, C, and D of this part.

Subpart B—Procedures for Registration and Listing

§ 1271.21 When do I register, submit an HCT/P list, and submit updates?

(a) You must register and submit a list of every HCT/P that your establishment manufactures within 5 days after beginning operations or within 30 days of the effective date of this regulation, whichever is later.

(b) You must update your establishment registration annually in December, except as required by § 1271.26. You may accomplish your annual registration in conjunction with updating your HCT/P list under paragraph (c) of this section.

(c)(i) If no change described in § 1271.25(c) has occurred since youpreviously submitted an HCT/P list, you are not required to update your listing.

(ii) If a change described in § 1271.25(c) has occurred, you must update your HCT/P listing with the new information:

(*a*) At the time of the change, or

(*b*) Each June or December, whichever month occurs first after the change.

§ 1271.22 How and where do I register and submit an HCT/P list?

(a) You must use Form FDA 3356 for:

(i) Establishment registration,

(ii) HCT/P listings, and

(iii) Updates of registration and HCT/P listing.

(b) You may obtain Form FDA 3356:

(i) By writing to the Center for Biologics Evaluation and Research (HFM–305), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, Attention: Tissue Establishment Registration Coordinator;

(ii) By contacting any Food and Drug Administration district office;

(iii) By calling the CBER Voice Information System at 1–800–835–4709 or 301–827–-1800;

(iv) By calling the Fax Information System at 1–888–CBER–FAX or 301–827–3844; or

(v) By connecting to http://forms.psc.gov/forms/FDA/fda.html on the Internet.

(c)(i) You may submit Form FDA 3356 to the Center for BiologicsEvaluation and Research (HFM–305), Food and Drug Administration, 1401 Rockville, Pike, Rockville, MD 20852–1448, Attention: Tissue Establishment Registration Coordinator; or

(ii) You may submit Form FDA 3356 electronically in accordance with the instructions provided with the form.

§ 1271.25 What information is required for establishment registration and HCT/P listing?

(a) Your establishment registration Form FDA 3356 must include:

(1) The legal name(s) of the establishment;

(2) Each location, including the street address of the establishment and the postal service zip code;

(3) The name, address, and title of the reporting official; and

(4) A dated signature by the reporting official affirming that all information contained in the establishment registration and HCT/P listing form is true and accurate, to the best of his or her knowledge.

(b) Your HCT/P listing must include all HCT/P's (including the established name and the proprietary name) that you recover, process, store, label, package, distribute, or for which you perform donor screening or testing. You must also state whether each HCT/P meets the criteria set out in § 1271.10.

(c) Your HCT/P listing update must include:

(1) A list of each HCT/P that you have begun recovering, processing, storing, labeling, packaging, distributing, or for which you have begun donor screening or testing, that has not been included in any list previously submitted. You must provide all of the information required by § 1271.25(b) for each new HCT/P.

(2) A list of each HCT/P formerly listed in accordance with § 1271.21(a) for which you have discontinued recovery, processing, storage, labeling, packaging, distribution, or donor screening or testing, including for each HCT/P so listed, the identity by established name and proprietary name, and the date of discontinuance. We request but do not require that you include the reason for discontinuance with this information.

(3) A list of each HCT/P for which a notice of discontinuance was submitted under paragraph (c)(2) of this section and for which you have resumed recovery, processing, storage, labeling, packaging, distribution, or donor screening or testing, including the identity by established name and proprietary name, the date of resumption, and any other information required by § 1271.25(b) not previously submitted.

(4) Any material change in any information previously submitted. Material changes include any change in information submitted on Form FDA 3356, such as whether the HCT/P meets the criteria set out in § 1271.10.

§ 1271.26 When must I amend my establishment registration?

If the ownership or location of your establishment changes, you must submit an amendment to registration within 5 days of the change.

§ 1271.27 Will FDA assign me a registration number?

(a) FDA will assign each location a permanent registration number.

(b) FDA acceptance of an establishment registration and HCT/P listing form does not constitute a determination that an establishment is in compliance with applicable rules and regulations or that the HCT/P is licensed or approved by FDA.

§ 1271.37 Will establishment registrations and HCT/P listings be available for inspection, and how do I request information on registrations and listings?

(a) A copy of the Form FDA 3356 filed by each establishment will be available for public inspection at the Office of Communication, Training, and Manufacturers Assistance (HFM–48), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. In addition, there will be available for inspection at each of the Food and Drug Administration district offices the same information for firms within the geographical area of such district office. Upon request and receipt of a self-addressed stamped envelope, verification of a registration number or the location of a registered establishment will be provided. The following information submitted under the HCT/P requirements is illustrative of the type of information that will be available for public disclosure when it is compiled:

(1) A list of all HCT/P's;

(2) A list of all HCT/P's manufactured by each establishment;

(3) A list of all HCT/P's discontinued; and

(4) All data or information that has already become a matter of public record.

(b) You should direct your requests for information regarding HCT/P establishment registrations and HCT/P listings to the Office of Communication, Training and Manufacturers Assistance (HFM–48), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448.

Dated: January 2, 2001.

Jane E. Henney,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

[FR Doc. 01–1126 Filed 1–18–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

27 CFR Parts 17 and 18

[T.D. ATF–436]

RIN 1512–AB99

Delegation of Authority for Parts 17 and 18

AGENCY: Bureau of Alcohol, Tobacco and Firearms (ATF), Treasury.

ACTION: Treasury decision, final rule.

SUMMARY: Authority delegation. This final rule places most ATF authorities contained in parts 17 and 18, title 27 Code of Federal Regulations (CFR), with the ''appropriate ATF officer'' and requires that persons file documents required by parts 17 and 18, title 27 Code of Federal Regulations (CFR), with the ''appropriate ATF officer'' or in accordance with the instructions on the ATF form. Also, this final rule removes the definitions of, and references to, specific officers subordinate to the Director. Concurrently with this Treasury Decision, ATF Order 1130.13 is being published. Through this order, the Director has delegated most of the authorities in 27 CFR parts 17 and 18 to the appropriate ATF officers and specified the ATF officers with whom applications, notices and other reports, which are not ATF forms, are filed.

EFFECTIVE DATE: January 19, 2001.

FOR FURTHER INFORMATION CONTACT: Robert Ruhf, Regulations Division, Bureau of Alcohol, Tobacco and Firearms, 650 Massachusetts Avenue NW, Washington, DC 20226 (202–927–8210).

SUPPLEMENTARY INFORMATION:

Background

Pursuant to Treasury Decision 120–01 (formerly 221), dated June 6, 1972, the Secretary of the Treasury delegated to the Director of the Bureau of Alcohol, Tobacco and Firearms (ATF), the authority to enforce, among other laws, the provisions of chapter 51 of the Internal Revenue Code of 1986 (IRC). The Director has subsequently redelegated certain of these authorities to appropriate subordinate officers by way of various means, including by regulation, ATF delegation orders, regional directives, or similar delegation documents. As a result, to ascertain what particular officer is authorized to perform a particular function under chapter 51, each of these various delegation instruments must be consulted. Similarly, each time a delegation of authority is revoked or redelegated, each of the delegation documents must be reviewed and amended as necessary.

ATF has determined that this multiplicity of delegation instruments complicates and hinders the task of determining which ATF officer is authorized to perform a particular function. ATF also believes these multiple delegation instruments exacerbate the administrative burden associated with maintaining up-to-date delegations, resulting in an undue delay in reflecting current authorities.

Accordingly, in this final rule, the Director of ATF is rescinding all authorities of the Director in parts 17 and 18 which were previously delegated to a specified ATF officer and placing all authorities of the Director with the ''appropriate ATF officer.'' Along with this final rule, ATF is publishing ATF Order 1130.13, Delegation Order—Delegation of the Director's Authorities in parts 17 and 18, in which certain of these authorities are then delegated down to the appropriate organizational level. The effect of these changes is to consolidate all delegations of authority in parts 17 and 18 into one delegation instrument. This action both simplifies the process for determining what ATF officer is authorized to perform a particular function and facilitates the updating of delegations in the event of a change in delegation or in the event of a restructuring. As a result, delegations of authority will be reflected in a more timely and user-friendly manner.

In addition to the above, this final rule also eliminates all references in the regulations which identify the ATF officer with whom an ATF form is filed. Thus, in lieu of identifying the authorized officer in the regulations, the form itself will indicate the officer with whom it shall be filed. Similarly, this final rule also amends parts 17 and 18 to provide that documents other than ATF forms (such as letterhead applications, notices and reports) will be filed with the ''appropriate ATF officer.'' The ''appropriate ATF officer'' is the Director's delegate and will be identified in the accompanying ATF Order (ATF Order 1130.13, Delegation Order—Delegation of the Director's

Authorities in part 17 and 18). These changes will facilitate the identification of the officer with whom forms and other required submissions are filed in the event that authority to receive such submissions, or the title of the officer, changes.

Consistent with the above, this final rule makes various technical amendments to subpart C—Administrative and Miscellaneous Provisions of 27 CFR parts 17 and 18. Specifically, new §§ 17.7 and 18.12 will be added to recognize the authority of the Director to delegate regulatory authorities in parts 17 and 18, respectively, and to identify ATF Order 1130.13 as the instrument reflecting such delegations. Also, §§ 17.2 and 18.16 are amended to provide that the instructions on an ATF form identify the ATF officer with whom it is filed.

ATF has made or will make similar changes in delegations to all other parts of Title 27 of the Code of Federal Regulations through separate rulemakings. By amending the regulations part by part, rather than in one large rulemaking document and ATF Order, ATF minimizes the time expended in notifying interested parties of current delegations of authority.

Paperwork Reduction Act

The provisions of the Paperwork Reduction Act of 1995, Public Law 104–13, 44 U.S.C. chapter 35, and its implementing regulations, 5 CFR part 1320, do not apply to this final rule because there are no new or revised recordkeeping or reporting requirements.

Regulatory Flexibility Act

Because no notice of proposed rulemaking is required for this rule, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply. A copy of this final rule was submitted to the Chief Counsel for Advocacy of the Small Business Administration in accordance with 26 U.S.C. 7805(f). No comments were received.

Executive Order 12866

It has been determined that this rule is not a significant regulatory action because it will not: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866.

Administrative Procedure Act

Because this final rule merely makes technical amendments and conforming changes to improve the clarity of the regulations, it is unnecessary to issue this final rule with notice and public procedure under 5 U.S.C. 553(b). Similarly it is unnecessary to subject this final rule to the effective date limitation of 5 U.S.C. 553(d).

Drafting Information

The principal author of this document is Robert Ruhf, Regulations Division, Bureau of Alcohol, Tobacco and Firearms.

List of Subjects

27 CFR Part 17

Alcohol and alcoholic beverages, Authority delegations, Claims, Drugs, Excise taxes, Foods, Reporting and recordkeeping requirements, Spices and flavorings, Surety bonds.

27 CFR Part 18

Administrative practice and procedure, Authority delegations, Excise taxes, Exports, Labeling, Reporting and recordkeeping requirements, Security measures, Spices and flavorings, Surety bonds.

Authority and Issuance

Title 27, Code of Federal Regulations is amended as follows:

PART 17—DRAWBACK ON TAXPAID DISTILLED SPIRITS USED IN MANUFACTURING NONBEVERAGE PRODUCTS

Paragraph 1. The authority citation for part 17 continues to read as follows:

Authority: 26 U.S.C. 5010, 5131–5134, 5143, 5146, 5206, 5273, 6011, 6065, 6091, 6109, 6151, 6402, 6511, 7011, 7213, 7652, 7805, 5062, 5081, 5111–5113, 5121, 5122, 5142, 5143, 5173, 5206; 31 U.S.C. 9301, 9303, 9304, 9306.

§§ 17.2, 17.3, 17.122 and 17.134 [Amended]

Par. 2. In part 17 remove the word ''Director'' each place it appears and add, in substitution, the words ''appropriate ATF officer'' in the following places:

(a) Section 17.2(a);

(b) Section 17.3(a), introductory text, and (c);

(c) Section 17.122; and

(d) Section 17.134.

Par. 3. In addition to the amendment made above, § 17.2 is amended by adding a sentence at the end of paragraph (a) and revising paragraph (b) to read as follows:

§ 17.2 Forms prescribed.

(a) * * * The form will be filed in accordance with the instructions for the form.

(b) Forms may be requested from the ATF Distribution Center, P.O. Box 5950, Springfield, Virginia 22150–5190, or at the ATF web site (http://www.atf.treas.gov/).

Par. 4. The first sentence of paragraph (b) of § 17.3 is revised to read as follows:

§ 17.3 Alternate methods or procedures.

* * * * *

(b) Application. A letter of application to employ an alternate method or procedure must be submitted to the appropriate ATF officer. * * *

* * * * *

§§ 17.6, 17.55, 17.121, 17.161, 17.171, 17.182 and 17.183 [Amended]

Par. 5. Part 17 is further amended by adding the word ''appropriate'' before the words ''ATF officer'' each place it appears in the following places:

(a) Section 17.6;

(b) Section 17.55;

(c) Section 17.121(d);

(d) Section 17.161;

(e) Section 17.171;

(f) Section 17.182; and

(g) Section 17.183(a).

Par. 6. A new § 17.7 is added in Subpart A—General Provisions to read as follows:

§ 17.7 Delegations of the Director.

The regulatory authorities of the Director contained in this part 17 are delegated to appropriate ATF officers. These ATF officers are specified in ATF Order 1130.13, Delegation Order—Delegation of the Director's Authorities in 27 CFR parts 17 and 18. ATF delegation orders, such as ATF Order 1130.13, are available to any interested person by mailing a request to the ATF Distribution Center, P.O. Box 5950, Springfield, VA 22150–5190, or by accessing the ATF web site (http://www.atf.treas.gov/).

Par. 7. Section 17.11 is amended by removing the definitions of ''Alcohol and Tobacco Laboratory'', ''ATF Officer'', and ''Regional director (compliance)'', and by adding a new definition of ''Appropriate ATF officer'' and revising the definition of ''Director'' to read as follows:

§ 17.11 Meaning of Terms.

* * * * *

Appropriate ATF Officer. An officer or employee of the Bureau of Alcohol, Tobacco and Firearms (ATF) authorized to perform any functions relating to the administration or enforcement of this part by ATF Order 1130.13, Delegation Order—Delegation of the Director's Authorities in 27 CFR Parts 17 and 18.

* * * * *

Director. The Director, Bureau of Alcohol, Tobacco and Firearms, the Department of Treasury, Washington, DC 20226.

* * * * *

§§ 17.54, 17.101, 17.107, 17.108, 17.111, 17.112, 17.113, 17.114, 17.125, 17.141, 17.143, 17.147, 17.166, 17.167, 17.168, 17.170 and 17.183 [Amended]

Par. 8. Part 17 is further amended by removing the words ''regional director (compliance)'' or ''regional directors (compliance)'' each place it appears and adding, in substitution, the words ''appropriate ATF officer'' or ''appropriate ATF officers'', respectively, in the following places:

(a) Section 17.54;
(b) Section 17.101;
(c) Section 17.107;
(d) Section 17.108(c);
(e) Section 17.111 (a) introductory text and (b);
(f) Section 17.112;
(g) Section 17.113;
(h) Section 17.114;
(i) Section 17.125(a);
(j) Section 17.141;
(k) Section 17.143;
(l) Section 17.147(a);
(m) Section 17.166(c);
(n) Section 17.167(b);
(o) Section 17.168(a);
(p) Section 17.170; and
(q) Section 17.183(b) and (c).

Par. 9. The first three sentences of § 17.92 are revised into two sentences to read as follows:

Sec. 17.92 Filing of refund claim.

Claim for refund of special tax must be filed on ATF Form 2635 (5620.8), Claim—Alcohol, Tobacco and Firearms Taxes. The claim must set forth in detail sufficient reasons and supporting facts of the exact basis of the claim.* * *

* * * * *

Par. 10. The last sentence of § 17.101 is amended to remove the words ''Regional directors (compliance)'' and add, in substitution, the words ''Appropriate ATF officers''.

§§ 17.105, 17.144 and 17.145 [Amended]

Par. 11. Part 17 is further amended by removing the phrase ''with the regional director (compliance)'' each place it appears in the following places.

(a) Section 17.105(b);
(b) Section 17.144; and
(c) Section 17.145.

Par. 12. Paragraph (b) of § 17.121 is amended to remove the phrase ''with the Alcohol and Tobacco Laboratory''.

Par. 13. Section 17.122 is amended by removing the phrase ''to the Alcohol and Tobacco Laboratory'' and adding, in substitution, the phrase ''appropriate ATF officer''.

Par. 14. The third sentence of paragraph (b) of § 17.125 is revised to read as follows:

§ 17.125 Adoption of formulas and processes.

* * * * *

(b) Adoption of manufacturer's own forumulas from a different location. * * * A letterhead notice must be filed with the appropriate ATF officer and be accompanied by two photocopies of each formula to be adopted. * * *

* * * * *

§§ 17.126 and 17.136 [Amended]

Par. 15. Part 17 is further amended by removing the phrase ''to the Alcohol and Tobacco Laboratory'' each place it appears in the following places:

(a) Section 17.126(a); and
(b) Section 17.136.

Par. 16. Section 17.131 is amended by removing the phrase ''by the Alcohol and Tobacco Laboratory'' each place it appears.

Par. 17. The fifth sentence of paragraph (a) of § 17.142 is removed, and the first sentence of paragraph (a) of § 17.142 is revised to read as follows :

§ 17.142 Claims.

(a) General. The manufacturer must file claim for drawback with the appropriate ATF officer who has the authority to approve or disapprove claims. * * *

* * * * *

PART 18—PRODUCTION OF VOLATILE FRUIT FLAVOR CONCENTRATE

Par. 18. The authority citation for part 18 continues to read as follows:

Authority: 26 U.S.C. 5001, 5172, 5178, 5179, 5203, 5511, 5552, 6065, 7805; 44 U.S.C. 3504(h).

Par. 19. Section 18.11 is amended by removing the definitions of ''ATF officer'' and ''Regional director (compliance) and by adding the definition of ''Appropriate ATF officer'' and revising the definition of ''Registry number'' to read as follows:

§ 18.11 Meaning of Terms.

* * * * *

Appropriate ATF officer. An officer or employee of the Bureau of Alcohol, Tobacco and Firearms (ATF) authorized to perform any functions relating to the administration or enforcement of this part by ATF Order 1130.13, Delegation Order—Delegation of the Director's Authorities in 27 CFR Parts 17 and 18.

* * * * *

Registry number. The number assigned to a concentrate plant or a bonded wine cellar for an approved application as required by Parts 18 and 24, respectively.

* * * * *

Par. 20. A new § 18.12 is added in subpart C—Administrative and Miscellaneous Provisions to read as follows:

§ 18.12 Delegations of the Director.

The regulatory authorities of the Director contained in this part 18 are delegated to appropriate ATF officers. These ATF officers are specified in ATF Order 1130.13, Delegation Order—Delegation of the Director's Authorities in 27 CFR Parts 17 and 18. ATF delegation orders, such as ATF Order 1130.13, are available to any interested person by mailing a request to the ATF Distribution Center, PO Box 5950, Springfield, VA 22150–5190, or by accessing the ATF web site (http://www.atf.treas.gov/).

§§ 18.13, 18.16 and 18.52 [Amended]

Par. 21. Part 18 is further amended by removing the word ''Director'' each place it appears and adding, in substitution, the words ''appropriate ATF officer'' in the following places:

(a) Section 18.13(a), introductory text;
(b) Section 18.16(a); and
(c) Section 18.52(b).

Par. 22. Paragraph (b) of § 18.13 is revised to read as follows:

§ 18.13 Alternate Methods or Procedures.

* * * * *

(b) *Application.* A proprietor who desires to employ an alternate method or procedure shall submit a written application to the appropriate ATF officer. The application will specifically describe the proposed alternate method or procedure and set forth the reasons therefor. Alternate methods or procedures may not be employed until the application has been approved by the appropriate ATF officer. Authorization for any alternate method or procedure may be withdrawn whenever in the judgment of the appropriate ATF officer the revenue is jeopardized or the effective

administration of this part is hindered by the continuation of the authorization.

* * * * *

§§ 18.14, 18.22, 18.24 and 18.27 [Amended]

Par. 23. Part 18 is further amended by removing the words ''regional director (compliance)'' each place it appears and adding, in substitution, the words ''appropriate ATF officer'' in the following places:

(a) Section 18.14(a), introductory text and (b);

(b) Section 18.22(b);

(c) Section 18.24; and

(d) Section 18.27(a).

§§ 18.15, 18.17, 18.19 and 18.61 [Amended]

Par. 24. Part 18 is further amended by adding the word ''appropriate'' before the phrase ''ATF officers'' or ''ATF officer'' each place it appears in the following places:

(a) Section 18.15;

(b) Section 18.17;

(c) Section 18.19; and

(d) Section 18.61(a) and (b).

Par. 25. Section 18.16 is further amended by adding a sentence at the end of paragraph (a) and revising paragraph (b) to read as follows:

§ 18.16 Forms prescribed.

(a) * * * The form will be filed in accordance with the instructions for the form.

(b) Forms may be requested from the ATF Distribution Center, P.O. Box 5950, Springfield, Virginia 22150–5190, or at the ATF web site (http://www.atf.treas.gov/).

Par. 26. Section 18.21 is amended by removing the words ''to the regional director (compliance)''.

Par. 27. Section 18.26 is amended by removing the words ''with the regional director (compliance)''.

Par. 28. Section 18.65 is revised to read as follows:

Sec. 18.65 Annual report.

An annual report, on Form 1695(5520.2), of concentrate plant operations shall be prepared by each proprietor and forwarded in accordance with the instructions for the form. When a proprietor permanently discontinues the business of manufacturing concentrate, the proprietor shall submit the annual report in accordance with the instructions for the form.

Signed: July 13, 2000.

Bradley A. Buckles,

Director.

Approved: August 1, 2000.

John P. Simpson,

Deputy Assistant Secretary (Regulatory, Tariff and Trade Enforcement).

[FR Doc. 01–1162 Filed 1–18–01; 8:45 am]

BILLING CODE 4810–31–P

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

27 CFR Parts 20, 21 and 22

[T.D. ATF–435]

RIN 1512–AC13

Delegation of Authority for Parts 20, 21 and 22

AGENCY: Bureau of Alcohol, Tobacco and Firearms (ATF), Treasury.

ACTION: Treasury decision, final rule.

SUMMARY: This final rule places all ATF authorities contained in parts 20, 21 and 22, title 27 Code of Federal Regulations (CFR), with the ''appropriate ATF officer'' and requires that persons file documents required by such parts, with the ''appropriate ATF officer'' or in accordance with the instructions for the ATF form. Also, this final rule removes the definitions of, and references to, specific officers subordinate to the Director and the word ''region.'' Concurrently with this Treasury Decision, ATF Order 1130.9 is being published. Through this order, the Director has delegated all of the authorities in 27 CFR parts 20, 21 and 22 to the appropriate ATF officers and specified the ATF officers with whom applications, notices and other reports, which are not ATF forms, are filed.

EFFECTIVE DATE: This rule is effective January 19, 2001.

FOR FURTHER INFORMATION CONTACT: Robert Ruhf, Regulations Division, Bureau of Alcohol, Tobacco and Firearms, 650 Massachusetts Avenue, NW., Washington, DC 20226 (telephone 202–927–8210 or e-mail to alctob@atfhq.atf.treas.gov).

SUPPLEMENTARY INFORMATION:

Background

Pursuant to Treasury Order 120–01 (formerly 221), dated June 6, 1972, the Secretary of the Treasury delegated to the Director of the Bureau of Alcohol, Tobacco and Firearms (ATF), the authority to enforce, among other laws, the provisions of *chapter 51* of the Internal Revenue Code of 1986 (IRC). The Director has subsequently redelegated certain of these authorities to appropriate subordinate officers by way of various means, including by regulation, ATF delegation orders, regional directives, or similar delegation documents. As a result, to ascertain what particular officer is authorized to perform a particular function under chapter 51, each of these various delegation instruments must be consulted. Similarly, each time a delegation of authority is revoked or redelegated, each of the delegation documents must be reviewed and amended as necessary.

ATF has determined that this multiplicity of delegation instruments complicates and hinders the task of determining which ATF officer is authorized to perform a particular function. ATF also believes these multiple delegation instruments exacerbate the administrative burden associated with maintaining up-to-date delegations, resulting in an undue delay in reflecting current authorities.

Accordingly, this final rule rescinds all authorities of the Director in parts 20, 21 and 22 that were previously delegated and places those authorities with the ''appropriate ATF officer.'' All of the authorities of the Director that were not previously delegated are also placed with the ''appropriate ATF officer.'' Along with this final rule, ATF is publishing ATF Order 1130.9, Delegation Order—Delegation of the Director's Authorities in 27 CFR Parts 20, 21 and 22, Distilled Spirits Plants, which delegates certain of these authorities to the appropriate organizational level. The effect of these changes is to consolidate all delegations of authority in parts 20, 21 and 22 into one delegation instrument. This action both simplifies the process for determining what ATF officer is authorized to perform a particular function and facilitates the updating of delegations in the future. As a result, delegations of authority will be reflected in a more timely and user-friendly manner.

In addition, this final rule also eliminates all references in the regulations that identify the ATF officer with whom an ATF form is filed. This is because ATF forms will indicate the officer with whom they must be filed. Similarly, this final rule also amends parts 20, 21 and 22 to provide that the submission of documents other than ATF forms (such as letterhead applications, notices and reports) must be filed with the ''appropriate ATF officer'' identified in ATF Order 1130.9. These changes will facilitate the

identification of the officer with whom forms and other required submissions are filed.

This final rule also makes various technical amendments to parts 20, 21 and 22 of Title 27 of the Code of Federal Regulations. First, new sections are added in each part to recognize the authority of the Director to delegate regulatory authorities and to identify ATF Order 1130.9 as the instrument reflecting such delegations. Second, § 20.21, 21.2, 22.21 of Title 27 of the Code of Federal Regulations are amended to provide that the instructions for an ATF form identify the ATF officer with whom it must be filed. Third, this rule removes from part 22 of Title 27 of the Code of Federal Regulations the definition of the term ''delegate.'' This term is used only in the definition of Secretary in part 22 of Title 27 of the Code of Federal Regulations. We have removed the definition of ''delegate'' to be consistent with most other parts of Title 27 of the Code of Federal Regulations and to minimize potential confusion and misunderstanding with the appropriate ATF officers to whom the Director has delegated authority.

ATF has begun to make similar changes in delegations to all other parts of Title 27 of the Code of Federal Regulations through separate rulemakings. By amending the regulations part by part, rather than in one large rulemaking document and ATF Order, ATF minimizes the time expended in notifying interested parties of current delegations of authority.

Paperwork Reduction Act

The provisions of the Paperwork Reduction Act of 1995, Pub. L. 104–13, 44 U.S.C. Chapter 35, and its implementing regulations, 5 CFR part 1320, do not apply to this final rule because there are no new or revised recordkeeping or reporting requirements.

Regulatory Flexibility Act

Because no notice of proposed rulemaking is required for this rule, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply. A copy of this final rule was submitted to the Chief Counsel for Advocacy of the Small Business Administration in accordance with 26 U.S.C. 7805(f). No comments were received.

Executive Order 12866

It has been determined that this rule is not a significant regulatory action because it will not: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866.

Administrative Procedure Act

Because this final rule merely makes technical amendments and conforming changes to improve the clarity of the regulations, we can issue this final rule without the notice and public procedure under 5 U.S.C. 553(b). For these same reasons, we are issuing this final rule effective on the same date of its publication in the **Federal Register**. This final rule is not subject to the effective date limitation of 5 U.S.C. 553(d).

Drafting Information: The principal author of this document is Robert Ruhf, Regulations Division, Bureau of Alcohol, Tobacco and Firearms.

List of Subjects

27 CFR Part 20

Administrative practice and procedure, Advertising, Alcohol and alcoholic beverages, Authority delegations (Government agencies), Chemicals, Claims, Cosmetics, Excise taxes, Packaging and containers, Reporting and recordkeeping requirements, Security measures, Surety bonds, Transportation.

27 CFR Part 21

Administrative practice and procedure, Alcohol and alcoholic beverages, Authority delegations (Government agencies), Chemicals, Packaging and containers, Transportation.

27 CFR Part 22

Administrative practice and procedure, Alcohol and alcoholic beverages, Authority delegations (Government agencies), Claims, Excise taxes, Packaging and containers, Reporting and recordkeeping requirements, Security measures, Science and technology, Surety bonds, Transportation.

Authority and Issuance

Title 27, Code of Federal Regulations is amended as follows:

PART 20—DISTRIBUTION AND USE OF DENATURED ALCOHOL AND RUM

Paragraph 1. The authority citation for part 20 continues to read as follows:

Authority: 20 U.S.C. 5001, 5206, 5214, 5271–5275, 5311, 5552, 5555, 5607, 6065, 7805.

Par. 2. Section 20.11 is amended by removing the definitions of ''Area supervisor'', ''ATF Officer'', ''Region'', and ''Regional director (compliance)'', by adding a new definition of ''Appropriate ATF officer'', and by revising the definition of ''Bulk conveyance'' to read as follows:

§ 20.11 Meaning of Terms.

* * * * *

Appropriate ATF Officer. An officer or employee of the Bureau of Alcohol, Tobacco and Firearms (ATF) authorized to perform any functions relating to the administration or enforcement of this part by ATF Order 1130.9, Delegation Order—Delegation of the Director's Authorities in 27 CFR Parts 20, 21 and 22.

* * * * *

Bulk conveyance. Any tank car, tank truck, tank ship, or tank barge, or a compartment of any such conveyance, or any other container approved by the appropriate ATF officer for the conveyance of comparable quantities of denatured spirits or articles.

* * * * *

Par. 3. In Subpart C—Administrative and Miscellaneous Provisions after the undesignated center heading ''Authorities'', a new § 20.20 is added as follows:

§ 20.20 Delegations of the Director.

All of the regulatory authorities of the Director contained in this Part 20 are delegated to appropriate ATF officers. These ATF officers are specified in ATF Order 1130.9, Delegation Order—Delegation of the Director's Authorities in 27 CFR Parts 20, 21 and 22. ATF delegation orders, such as ATF Order 1130.9, are available to any interested person by mailing a request to the ATF Distribution Center, P.O. Box 5950, Springfield, Virginia 22150–5950, or by accessing the ATF web site (http://www.atf.treas.gov/).

§§ 20.21, 20.22, 20.23, 20.48, 20.91, 20.92, 20.100, 20.103, 20.111, 20.144, 20.177, 20.211, 20.245 and 20.246 [Amended]

Par. 4. Part 20 is further amended by removing the word ''Director'' each place it appears and adding, in its place, the words ''appropriate ATF officer'' in the following places:

(a) Section 20.21(a);

(b) Section 20.22(a)(2), (3) and (4), and (c);
(c) Section 20.23;
(d) Section 20.48(b) and (c);
(e) Section 20.91(a) and (c);
(f) Section 20.92(a) and (b);
(g) Section 20.100(a) introductory text;
(h) Section 20.103;
(i) Section 20.111;
(j) Section 20.144;
(k) Section 20.178(c)(1);
(l) Section 20.211(b);
(m) Section 20.245; and
(n) Section 20.246.

Par. 5. Section 20.21 is further amended by adding a sentence at the end of paragraph (a) and revising paragraph (b) to read as follows:

§ 20.21 Forms prescribed.

(a) * * * The form will be filed in accordance with the instructions for the form.

(b) Forms may be requested from the ATF Distribution Center, P.O. Box 5950, Springfield, Virginia 22150–5950, or by accessing the ATF web site (http://www.atf.treas.gov/).

Par. 6. The first and second sentences of § 20.22(a)(1) are revised to read as follows:

§ 20.22 Alternate methods or procedures; and emergency variations from requirements.

(a) *Alternate methods or procedures*—(1) *Application.* A permittee, after receiving approval from the appropriate ATF officer, may use an alternate method or procedure (including alternate construction or equipment) in lieu of a method or procedure prescribed by this part. A permittee wishing to use an alternate method or procedure may apply to the appropriate ATF officer. * * *

* * * * *

§ 20.22; 20.24, 20.26, 20.28, 20.41, 20.42, 20.43, 20.44, 20.48, 20.50, 20.51, 20.56, 20.57, 20.60, 20.61, 20.62, 20.63, 20.64, 20.68, 20.72, 20.74, 20.79, 20.80, 20.82, 20.132, 20.133, 20.134, 20.161, 20.163, 20.164, 20.181, 20.202, 20.204, 20.205, 20.213, 20.234, 20.235, 20.252, 20.261, 20.262, 20.263 and 20.265 [Amended]

Par. 7. Part 20 is further amended by removing the words ''regional director (compliance)'' each place it appears and adding, in substitution, the words ''appropriate ATF officer'' in the following places:
(a) Section 20.22(b)(1), (2) and (3);
(b) Section 20.24;
(c) Section 20.26;
(d) Section 20.28(b);
(e) Section 20.41(c) introductory text;
(f) Section 20.42(a)(11) and (b);
(g) Section 20.43(a) introductory text;
(h) Section 20.44 introductory text;
(i) Section 20.48(b);
(j) Section 20.50;
(k) Section 20.51 introductory text;
(l) Section 20.56(a)(1), (b) and (c)(1) and (3);
(m) Section 20.57(b)(1) and (2);
(n) Section 20.60;
(o) Section 20.61;
(p) Section 20.62(a);
(q) Section 20.63(a);
(r) Section 20.64;
(s) Section 20.68(a) introductory text;
(t) Section 20.72(b);
(u) Section 20.74;
(v) Section 20.79;
(w) Section 20.80;
(x) Section 20.82;
(y) Section 20.132(c);
(z) Section 20.133(a) introductory text and (b);
(aa) Section 20.134(c);
(bb) Section 20.161(c)(3);
(cc) Section 20.163(c)(2);
(dd) Section 20.164(e);
(ee) Section 20.181(a);
(ff) Section 20.202(a);
(gg) Section 20.204(b);
(hh) Section 20.205(f);
(ii) Section 20.213(a) and (b);
(jj) Section 20.234(b)(3);
(kk) Section 20.235(c);
(ll) Section 20.252(a);
(mm) Section 20.261;
(nn) Section 20.262(d);
(oo) Section 20.263(d); and
(pp) Section 20.265(b).

Par. 8. Section 20.22(c) is amended by removing the phrase ''or the regional director (compliance)'' each place it appears.

Par. 9. Section 20.25 is revised to read as follows:

§ 20.25 Permits.

The appropriate ATF officer must issue permits for the United States or a Governmental agency as provided in § 20.241 and industrial alcohol user permits, Form 5150.9, required under this part.

§ 20.27, 20.28, 20.37, 20.117, 20.166, 20.170, 20.213, 20.261, 20.262, 20.263 and 20.265 [Amended].

Par. 10. Part 20 is further amended by adding the word ''appropriate'' before the words ''ATF officer'' or ''ATF officers'' each place it appears in the following places:
(a) Section 20.27;
(b) Section 20.28(a);
(c) Section 20.37;
(d) Section 20.117(d)(2)(iv);
(e) Section 20.166;
(f) Section 20.170;
(g) Section 20.213(b);
(h) Section 20.261;
(i) Section 20.262(c);
(j) Section 20.263(c); and
(k) Section 20.265(a) introductory text.

Par. 11. The last sentence of § 20.45(c)(1) is revised to read as follows:

§ 20.45 Organizational Documents.

* * * * *

(c) *Statement of interest.* (1) * * * If a corporation is wholly owned or controlled by another corporation, persons owning 10% or more of each of the classes of stock of the parent corporation are considered to be the persons interested in the business of the subsidiary, and the names and addresses of such persons must be submitted to the appropriate ATF officer if specifically requested.

* * * * *

§§ 20.53 and 20.205 [Amended]

Par. 12. Part 20 is further amended by removing the phrase ''with the regional director (compliance)'' each place it appears in the following places:
(a) Section 20.53; and
(b) Section 20.205 introductory text.

Par. 13. The first sentence of § 20.62(a) is amended to remove the phrase ''within the same region''.

Par. 14. Paragraph (c) of § 20.92 is revised to read as follows:

§ 20.92 Samples.

* * * * *

(c) The appropriate ATF officer may, at any time, require submission of samples of:
(1) Any ingredient used in the manufacture of an article, or;
(2) Any article.

* * * * *

Par. 15. Paragraph (a) of § 20.95 is amended to remove the phrase ''on request by the Director''.

Par. 16. Paragraph (b) of § 20.100 is revised to read as follows:

§ 20.100 General.

* * * * *

(b) Approval by the appropriate ATF officer of formulas, samples, or statements of process means only that they meet the standards of the Bureau of Alcohol, Tobacco and Firearms. The approval does not require the issuance of a permit under subpart D of this part to withdraw and use specially denatured spirits in those formulas, articles, or statements of process.

* * * * *

Par. 17. Paragraph (d)(2)(v) of § 20.117 is amended by removing the phrase ''which may be conditions of approval by the regional director (compliance)''.

Par. 18. Paragraph (b)(1)(ii) of § 20.134 is amended by removing the phrase ''regional director (compliance) of the region where the manufacturing site is located'' and adding in substitution, the words ''appropriate ATF officer''.

Par. 19. Paragraph (b) of § 20.147 is amended by removing the word ''Director's'' and adding, in substitution, the words ''appropriate ATF officer's.''

Par. 20. Paragraph (e) of § 20.189 is amended by removing the phrase ''by the Director'' and adding, in substitution, the phrase ''in accordance with subpart F of this part''.

Par. 21. Section 20.190 is revised to read as follows:

§ 20.190 Diversion of articles for internal human use or beverage use.

An appropriate ATF officer who has reason to believe that the spirits in any article are being reclaimed or diverted to beverage or internal human use may direct the permittee to modify an approved formula to prevent the reclamation or diversion. The appropriate ATF officer may require the permittee to discontinue the use of the formula until it has been modified and again approved.

Par. 22. The second sentence of § 20.241 is amended to remove the phrase ''from the Director'' and adding, in substitution, the phrase ''as provided in § 20.25''.

Par. 23. The first sentence of § 20.242(b) is amended by removing the phrase ''to the Director'' and the preceding comma.

§§ 20.244 and 20.252 [Amended]

Par. 24. Part 20 is further amended by removing the phrase ''regional director (compliance) of the region'' and adding in substitution, the words ''appropriate ATF officer'' each place it appears in the following places:

(a) Section 20.244; and (b) Section 20.252(b).

Par. 25. The first sentence of § 20.251 is amended by removing the phrase ''for submission on request by the Director'' and adding, in substitution, the phrase ''as required by § 20.92''.

Par. 26. The first sentence of paragraph (a) of § 20.267 is amended by removing the phrase ''submitted to the regional director (compliance)'' and adding, in substitution, the phrase ''as required by this part''.

Par. 27. The second sentence of paragraph (a) of § 20.267 is amended by removing the words ''regional director (compliance)'' and adding, in substitution, the words ''appropriate ATF officer''.

PART 21—FORMULAS FOR DENATURED ALCOHOL AND RUM

Par. 28. The authority citation for part 21 continues to read as follows:

Authority: 5 U.S.C. 552(a); 26 U.S.C. 5242, 7805.

§§ 21.2, 21.3, 21.5, 21.31 and 21.91 [Amended]

Par. 29. Part 21 is further amended by removing the word ''Director'' each place it appears and adding, in its place, the words ''appropriate ATF officer'' in the following places:

(a) Section 21.2(a);
(b) Section 21.3(d);
(c) Section 21.5 introductory text;
(d) Section 21.31(b); and
(e) Section 21.91.

Par. 30. Section 21.2 is further amended by adding a sentence at the end of paragraph (a) and revising paragraph (b) to read as follows:

§ 21.2 Forms prescribed.

(a) * * * The form will be filed in accordance with the instructions for the form.

(b) Forms may be requested from the ATF Distribution Center, P.O. Box 5950, Springfield, Virginia 22150–5950, or by accessing the ATF web site (http://www.atf.treas.gov/).

21.3, 21.21, 21.31, 21.33, 21.34, 21.56 and 21.65 [Amended]

Par. 31. Part 21 is further amended by removing the words ''Chief, Chemical Branch'' each place it appears and, in substitution, adding the words ''appropriate ATF officer'' in the following places:

(a) Section 21.3(b);
(b) Section 21.21(b) and (c);
(c) Section 21.31(c);
(d) Section 21.33(c);
(e) Section 21.34(c);
(f) Section 21.56(a);
(g) Section 21.65(a);

Par. 32. Paragraph (c) of § 21.3 is revised to read as follows:

§ 21.3 Stocks of discontinued formulas.

* * * * *

(c) On approval of an application, filed with the appropriate ATF officer and approved by such officer, destroy those stocks under whatever supervision the appropriate ATF officer requires; or

* * * * *

Par. 33. Paragraph (d) of § 21.3 is further amended by removing the phrases ''to be filed with the regional director (compliance) for transmittal to the Director'' and the parentheses at the beginning and ending of these phrases.

Par. 34. In Subpart A—General Provisions, a new § 21.7 is added as follows:

§ 21.7 Delegations of the Director.

All of the regulatory authorities of the Director contained Part 21 of the regulations are delegated to appropriate ATF officers. These ATF officers are specified in ATF Order 1130.9, Delegation Order—Delegation of the Director's Authorities in 27 CFR Parts 20, 21 and 22. ATF delegation orders, such as ATF Order 1130.9, are available to any interested person by mailing a request to the ATF Distribution Center, PO Box 5950, Springfield, Virginia 22150–5950, or by accessing the ATF web site ((http://www.atf.treas.gov/).

Par. 35. Section 21.11 is amended by removing the definitions of ''Chief, Chemical Branch'' and ''Regional director (compliance)'' and adding a new definition of ''Appropriate ATF officer'' to read as follows:

§ 21.11 Meaning of Terms.

* * * * *

Appropriate ATF Officer. An officer or employee of the Bureau of Alcohol, Tobacco and Firearms (ATF) authorized to perform any functions relating to the administration or enforcement of this part by ATF Order 1130.9, Delegation Order—Delegation of the Director's Authorities in 27 CFR Parts 20, 21 and 22.

* * * * *

Par. 36. Footnote 1 of § 21.141 is amended by removing the phrase ''by the Chief, Chemical Branch''.

PART 22—DISTRIBUTION AND USE OF TAX-FREE ALCOHOL

Par. 37. The authority citation continues to read as follows:

Authority: 26 U.S.C. 5001, 5121,5142, 5143, 5146, 5206, 5214, 5271–5276, 5311, 5552, 5555, 6056, 6061, 6065, 6109, 6151, 6806, 7011, 7805; 31 U.S.C. 9304, 9306.

Par. 38. Section 22.11 is amended by removing the definitions of ''Area supervisor'', ''ATF officer'', ''Delegate'', ''Region'' and ''Regional director (compliance)'' and adding a new definition of ''Appropriate ATF officer'' as to read as follows:

§ 22.11 Meaning of Terms.

* * * * *

Appropriate ATF Officer. An officer or employee of the Bureau of Alcohol, Tobacco and Firearms (ATF) authorized to perform any functions relating to the administration or enforcement of this part by ATF Order 1130.9, Delegation Order—Delegation of the Director's

Authorities in 27 CFR Parts 20, 21 and 22.

* * * * *

Par. 39. In Subpart C—Administrative Provisions after the undesignated center heading ''Authorities'', a new § 22.20 is added as follows:

§ 22.20 Delegations of the Director.

All of the regulatory authorities of the Director contained in this Part 22 are delegated to appropriate ATF officers. These ATF officers are specified in ATF Order 1130.9, Delegation Order—Delegation of the Director's Authorities in 27 CFR Parts 20, 21 and 22. ATF delegation orders, such as ATF Order 1130.9, are available to any interested person by mailing a request to the ATF Distribution Center, PO Box 5950, Springfield, Virginia 22150–5950, or by accessing the ATF web site ((http://www.atf.treas.gov/).

§ 22.21, 22.22, 22.24, 22.171, 22.175 and 22.176 [Amended]

Par. 40. Part 22 is further amended by removing the word ''Director'' each place it appears and adding, in its place, the words ''appropriate ATF officer'' in the following places:

(a) Section 22.21(a);
(b) Section 22.22(a)(2),(3) and (4);
(c) Section 22.24(a);
(d) Section 22.171(a);
(e) Section 22.175; and
(f) Section 22.176(c).

Par. 41. Section 22.21 is further amended by adding a sentence at the end of paragraph (a) and revising paragraph (b) to read as follows:

§ 22.21 Forms prescribed.

(a) * * * The form will be filed in accordance with the instructions for the form.

(b) Forms may be requested from the ATF Distribution Center, P.O. Box 5950, Springfield, Virginia 22150–5950, or by accessing the ATF web site (http://www.atf.treas.gov/).

Par. 42. The first two sentences of § 22.22(a)(1) and paragraph (c) of § 22.22 are revised to read as follows:

§ 22.22 Alternate methods or procedures; and emergency variations from requirements.

(a) *Alternate methods or procedures*—(1) *Application.* A permittee, after receiving approval from the appropriate ATF officer, may use an alternate method or procedure (including alternate construction or equipment) in lieu of a method or procedure prescribed by this part. A permittee wishing to use an alternate method or procedure may apply to the appropriate ATF officer. * * *

* * * * *

(c) *Withdrawal of approval.* The appropriate ATF officer may withdraw approval for an alternate method or procedure or an emergency variation from requirements, approved under paragraph (a) or (b) of this section, if the appropriate ATF officer finds that the revenue is jeopardized or the effective administration of this part is hindered by the approval.

* * * * *

§§ 22.22, 22.23, 22.24, 22.25, 22.27, 22.41, 22.42, 22.42, 22.43, 22.44, 22.45, 22.50, 22.51, 22.57, 22.58, 22.61, 22.62, 22.63, 22.64, 22.68, 22.72, 22.74, 22.79, 22.80, 22.82, 22.102, 22.103, 22.111, 22.113, 22.122, 22.124, 22.125, 22.154, 22.162 and 22.164 [Amended]

Par. 43. Part 22 is further amended by removing the words ''regional director (compliance)'' each place it appears and adding, in substitution, the words ''appropriate ATF officer'' in the following places:

(a) Section 22.22(b)(1), (2) and (3);
(b) Section 22.23;
(c) Section 22.24(b);
(d) Section 22.25;
(e) Section 22.27(b);
(f) Section 22.41(b);
(g) Section 22.42(a)(11);
(h) Section 22.42(b);
(i) Section 22.43(a) introductory text;
(j) Section 22.44 introductory text;
(k) Section 22.45(c)(1);
(l) Section 22.50;
(m) Section 22.51 introductory text;
(n) Section 22.57(a)(1), (b) and (c)(1) and (3);
(o) Section 22.58(b)(1) and (2);
(p) Section 22.61;
(q) Section 22.62;
(r) Section 22.63(a);
(s) Section 22.64;
(t) Section 22.68(a);
(u) Section 22.72(b);
(v) Section 22.74;
(w) Section 22.79;
(x) Section 22.80;
(y) Section 22.82;
(z) Section 22.102(c) introductory text;
(aa) Section 22.103;
(bb) Section 22.111(c)(3);
(cc) Section 22.113(a)(1);
(dd) Section 22.122(a);
(ee) Section 22.124(b);
(ff) Section 22.125(c);
(gg) Section 22.154(b)(3);
(hh) Section 22.162; and
(ii) Section 22.164(a).

§§ 22.26, 22.27, 22.36, 22.39, 22.113, 22.142 and 22.161 [Amended]

Par. 44. Part 22 is further amended by adding the word ''appropriate'' before the words ''ATF officer'' or ''ATF officers'' each place it appears in the following places:

(a) Section 22.26;
(b) Section 22.27(a);
(c) Section 22.36;
(d) Section 22.39(c);
(e) Section 22.113(c);
(f) Section 22.142(a) and (c); and
(g) Section 22.161(a) and (d).

Par. 45. The last sentence of § 22.45(c)(1) is revised to read as follows:

§ 22.45 Organizational Documents.

* * * * *

(c) *Statement of interest.* (1) * * * If a corporation is wholly owned or controlled by another corporation, persons owning 10% or more of each of the classes of stock of the parent corporation are considered to be the persons interested in the business of the subsidiary, and the names and addresses of such persons must be submitted to the appropriate ATF officer if specifically requested.

* * * * *

§§ 22.53 and 22.125 [Amended]

Par. 46. Part 22 is further amended by removing the phrase ''with the regional director (compliance)'' each place it appears in the following places:

(a) Section 22.53; and
(b) Section 22.125(a) introductory text.

§ 22.142 [Amended]

Par. 47. Part 22 is further amended by removing the words ''area supervisor'' each place it appears and adding, in substitution, the words ''appropriate ATF officer'' in the following places:

(a) Section 22.142(a), (c) and (d).

Par. 48. The first sentence of § 22.63(a) is amended by removing the phrase ''within the same region'.

Par. 49. The first sentence of § 22.172(b) is amended by removing the phrase ''to the Director'.

Par. 50. The second sentence of § 22.174 is amended by removing the words ''regional director (compliance) of the region from which the shipment was consigned'' and adding, in substitution, the words ''appropriate ATF officer.''

Signed: July 13, 2000.

Bradley A, Buckles,

Director.

Approved: August 1, 2000.

John P. Simpson,

Deputy Assistant Secretary (Regulatory, Tariff and Trade Enforcement).

[FR Doc. 01–1163 Filed 1–18–01; 8:45 am]

BILLING CODE 4810–31–P

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

27 CFR Part 25

[T.D. ATF–437]

RIN 1512–AC20

Delegation of Authority for Part 25

AGENCY: Bureau of Alcohol, Tobacco and Firearms (ATF), Treasury.

ACTION: Treasury decision, final rule.

SUMMARY: This final rule places ATF authorities contained in part 25, title 27 Code of Federal Regulations (CFR), with the ''appropriate ATF officer'' and requires that persons file documents required by part 25, title 27 Code of Federal Regulations (CFR), with the ''appropriate ATF officer'' or in accordance with the instructions on the ATF form. Also, this final rule removes the definitions of, and references to, specific officers subordinate to the Director and the word ''region.'' Concurrently with this Treasury Decision, ATF Order 1130.10 is being published. Through this order, the Director has delegated most of the authorities in 27 CFR part 25 to the appropriate ATF officers and specified the ATF officers with whom applications, notices and other reports, which are not ATF forms, are filed.

EFFECTIVE DATE: This rule is effective January 19, 2001.

FOR FURTHER INFORMATION CONTACT: Robert Ruhf, Regulations Division, Bureau of Alcohol, Tobacco and Firearms, 650 Massachusetts Avenue NW, Room 5003, Washington, DC 20226 (telephone 202–927–8210 or e-mail to alctob@atfhq.atf.treas.gov).

SUPPLEMENTARY INFORMATION:

Background

Pursuant to Treasury Order 120–01 (formerly 221), dated June 6, 1972, the Secretary of the Treasury delegated to the Director of the Bureau of Alcohol, Tobacco and Firearms (ATF), the authority to enforce, among other laws, the provisions of chapter 51 of the Internal Revenue Code of 1986 (IRC). The Director has subsequently redelegated certain of these authorities to appropriate subordinate officers by way of various means, including by regulation, ATF delegation orders, regional directives, or similar delegation documents. As a result, to ascertain what particular officer is authorized to perform a particular function under chapter 51, each of these various delegation instruments must be consulted. Similarly, each time a delegation of authority is revoked or redelegated, each of the delegation documents must be reviewed and amended as necessary.

ATF has determined that this multiplicity of delegation instruments complicates and hinders the task of determining which ATF officer is authorized to perform a particular function. ATF also believes these multiple delegation instruments exacerbate the administrative burden associated with maintaining up-to-date delegations, resulting in an undue delay in reflecting current authorities.

Accordingly, this final rule rescinds all authorities of the Director in part 25 that were previously delegated and places those authorities with the ''appropriate ATF officer.'' All of the authorities of the Director that were not previously delegated are also placed with the ''appropriate ATF officer.'' Along with this final rule, ATF is publishing ATF Order 1130.10, Delegation Order—Delegation of the Director's Authorities in 27 CFR part 25, Beer, which delegates certain of these authorities to the appropriate organizational level. The effect of these changes is to consolidate all delegations of authority in part 25 into one delegation instrument. This action both simplifies the process for determining what ATF officer is authorized to perform a particular function and facilitates the updating of delegations in the future. As a result, delegations of authority will be reflected in a more timely and user-friendly manner.

In addition, this final rule also eliminates all references in the regulations that identify the ATF officer with whom an ATF form is filed. This is because ATF forms will indicate the officer with whom they must be filed. Similarly, this final rule also amends part 25 to provide that the submission of documents other than ATF forms (such as letterhead applications, notices and reports) must be filed with the ''appropriate ATF officer'' identified in ATF Order 1130.10. These changes will facilitate the identification of the officer with whom forms and other required submissions are filed.

This final rule also makes various technical amendments to Subpart A—Scope of Regulations of 27 CFR part 25. First, a new § 25.6 is added to recognize the authority of the Director to delegate regulatory authorities in part 25 and to identify ATF Order 1130.10 as the instrument reflecting such delegations. Second, § 25.3 is amended to provide that the instructions for an ATF form identify the ATF officer with whom it must be filed. Third, this rule removes from part 25 of Title 27 of the Code of Federal Regulations the definition of the term ''delegate.'' This term is used only in the definition of Secretary in part 25 of Title 27 of the Code of Federal Regulations. We have removed the definition of ''delegate'' to be consistent with most parts of title 27 of the Code of Federal Regulations and to minimize potential confusion and misunderstanding with the appropriate ATF officers to whom the Director has delegated authority.

ATF has made or will make similar changes in delegations to all other parts of Title 27 of the Code of Federal Regulations through separate rulemakings. By amending the regulations part by part, rather than in one large rulemaking document and ATF Order, ATF minimizes the time expended in notifying interested parties of current delegations of authority.

Paperwork Reduction Act

The provisions of the Paperwork Reduction Act of 1995, Pub. L. 104–13, 44 U.S.C. Chapter 35, and its implementing regulations, 5 CFR part 1320, do not apply to this final rule because there are no new or revised recordkeeping or reporting requirements.

Regulatory Flexibility Act

Because no notice of proposed rulemaking is required for this rule, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 et seq.) do not apply. A copy of this final rule was submitted to the Chief Counsel for Advocacy of the Small Business Administration in accordance with 26 U.S.C. 7805(f). No comments were received.

Executive Order 12866

It has been determined that this rule is not a significant regulatory action because it will not: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866.

Administrative Procedure Act

Because this final rule merely makes technical amendments and conforming changes to improve the clarity of the regulations, it is unnecessary to issue this final rule with notice and public procedure under 5 U.S.C. 553(b). Similarly it is unnecessary to subject this final rule to the effective date limitation of 5 U.S.C. 553(d).

Drafting Information

The principal author of this document is Robert Ruhf, Regulations Division, Bureau of Alcohol, Tobacco and Firearms.

List of Subjects in 27 CFR Part 25

Administrative practice and procedure, Authority delegations, Beer, Claims, Custom duties and inspection, Electronic fund transfers, Excise taxes, Exports, Labeling, Liquors, Packaging and containers, Reporting and recordkeeping requirements, Research, Security measures, Surety bonds, Transportation.

Authority and Issuance

Title 27, Code of Federal Regulations is amended as follows:

PART 25—BEER

Paragraph 1. The authority citation for part 25 continues to read as follows:

Authority: 19 U.S.C. 81c; 26 U.S.C. 5002, 5051–5054, 5056, 5061, 5091, 5111, 5113, 5142, 5143, 5146, 5222, 5401–5403, 5411–5417, 5551, 5552, 5555, 5556, 5671, 5673, 5684, 6011, 6061, 6065, 6091, 6109, 6151, 6301, 6302, 6311, 6313, 6402, 6651, 6656, 6676, 6806, 7011, 7342, 7606, 7805; 31 U.S.C. 9301, 9303–8.

§§ 25.3, 25.23, 25.52, 25.142 and 25.155 [Amended]

Par. 2. In part 25 remove the words ''Director'' each place it appears and add, in substitution, the words ''appropriate ATF officer'' in the following places:

(a) Section 25.3(a);
(b) Section 25.23(b) introductory text and (c);
(c) Section 25.52(a)(1), (3), (4) and (5);
(d) Section 25.142(c); and
(e) Section 25.155.

Par. 3. Part 25 is further amended by adding a sentence at the end of paragraph (a) and revising paragraph (b) of § 25.3 to read as follows:

§ 25.3 Forms prescribed.

(a) * * * The form will be filed in accordance with the instructions for the form.

(b) Forms may be requested from the ATF Distribution Center, P.O. Box 5950, Springfield, Virginia 22150–5950, or by accessing the ATF web site (http://www.atf.treas.gov/).

Par. 4. In Subpart A—Scope of Regulations, a new § 25.6 is added as follows:

§ 25.6 Delegations of the Director.

Most of the regulatory authorities of the Director contained in this part 25 are delegated to appropriate ATF officers. These ATF officers are specified in ATF Order 1130.10, Delegation Order—Delegation of the Director's Authorities in 27 CFR part 25, Beer. ATF delegation orders, such as ATF Order 1130.10, are available to any interested person by mailing a request to the ATF Distribution Center, P.O. Box 5950, Springfield, Virginia 22150–5950, or by accessing the ATF web site (http://www.atf.treas.gov/).

Par. 5. Section 25.11 is amended by removing the definitions of ''Area supervisor'', ''ATF officer'', ''Delegate'', ''Region'' and ''Regional director (compliance)'' and by adding a new definition of ''Appropriate ATF officer'' to read as follows:

§ 25.11 Meaning of Terms.

* * * * *

Appropriate ATF Officer. An officer or employee of the Bureau of Alcohol, Tobacco and Firearms (ATF) authorized to perform any functions relating to the administration or enforcement of this part by ATF Order 1130.10, Delegation Order—Delegation of the Director's Authorities in 27 CFR part 25, Beer.

* * * * *

§§ 25.11, 25.22, 25.24, 25.25, 25.42, 25.52, 25.61, 25.63, 25.66, 25.71, 25.72, 25.74, 25.75, 25.77, 25.81, 25.91, 25.95, 25.96, 25.101, 25.103, 25.104, 25.105, 25.114, 25.144, 25.152, 25.158, 25.165, 25.167, 25.173, 25.182, 25.184, 25.196, 25.223, 25.225, 25.272, 25.274, 25.277, 25.281, 25.282, 25.283, 25.284, 25.291, 25.297 and 25.300 [Amended]

Par. 6. Part 25 is further amended by removing the words ''regional director (compliance)'' each place they appear and adding, in substitution, the words ''appropriate ATF officer'' in the following places:

(a) The definition of Barrel in § 25.11;
(b) Section 25.22;
(c) Section 25.24(a)(7);
(d) Section 25.25(a);
(e) Section 25.42(c);
(f) Section 25.52(a)(2) and (b)(1), (2), (3);
(g) Section 25.61(a) and (c);
(h) Section 25.63;
(i) Section 25.66(c)(1);
(j) Section 25.71(a)(2) and (b)(1);
(k) Section 25.72(b)(2);
(l) Section 25.74;
(m) Section 25.75;
(n) Section 25.77;
(o) Section 25.81(e);
(p) Section 25.91(c) and (d);
(q) Section 25.95;
(r) Section 25.96;
(s) Section 25.101(a) introductory text and (b);
(t) Section 25.103;
(u) Section 25.104;
(v) Section 25.105;
(w) Section 25.114(a);
(x) Section 25.144(b);
(y) Section 25.152(a) undesignated paragraph;
(z) Section 25.158(c);
(aa) Section 25.165(b)(3) and (e);
(bb) Section 25.167(a);
(cc) Section 25.173(a);
(dd) Section 25.182;
(ee) Section 25.184(d);
(ff) Section 25.196(b);
(gg) Section 25.223(a);
(hh) Section 25.225(b)(2);
(ii) Section 25.272(a) introductory text, (b), (c), (d) and (e);
(jj) Section 25.274(a);
(kk) Section 25.277;
(ll) Section 25.281(c);
(mm) Section 25.282(b), (c), (d) and (f);
(nn) Section 25.283(d);
(oo) Section 25.284(b);
(pp) Section 25.291(d)(3);
(qq) Section 25.297(b)(4); and
(rr) Section 25.300(c).

§§ 25.31, 25.42, 25.64, 25.66, 25.68, 25.127, 25.213, 25.251, 25.252, 25.291, 25.294 and 25.300 [Amended]

Par. 7. Part 25 is further amended by adding the word ''appropriate'' before the words ''ATF officer'' or ''ATF officers'' each place they appear in the following places:

(a) Section 25.31;
(b) Section 25.42 introductory text;
(c) Section 25.64;
(d) Section 25.66(d);
(e) Section 25.68(b);
(f) Section 25.127;
(g) Section 25.213(c);
(h) Section 25.251(c);
(i) Section 25.252(c);
(j) Section 25.291(c)(2)(ii);
(k) Section 25.294(c); and
(l) Section 25.300(a) and (d)(3).

Par. 8. Section 25.51 is revised to read as follows:

§ 25.51 Right of Entry and Examination.

An appropriate ATF officer may enter, during normal business hours, a brewery or other place where beer is stored and may, when the premises are open at other times, enter those premises in the performance of official duties. Appropriate ATF officers may

make inspections as the appropriate ATF officer deems necessary to determine that operations are conducted in compliance with the law and this part. The owner of any building or place where beer is produced, made, or kept, or person having charge over such premises, who refuses to admit an appropriate ATF officer acting under 26 U.S.C. 7606, or who refuses to permit an appropriate ATF officer to examine beer must, for each refusal, forfeit $500.

Par. 9. Section 25.52(d) is revised to read as follows:

§ 25.52 Variations from requirements.

* * * * *

(d) *Withdrawal of approval.* The appropriate ATF officer may withdraw approval of an alternate method or procedure, approved under paragraph (a) or (b) of this section, if the appropriate ATF officer finds that the revenue is jeopardized or the effective administration of this part is hindered by the approval.

* * * * *

Par. 10. The first and second sentences of § 25.61(b) are revised to read as follows:

§ 25.61 General requirements for notice.

* * * * *

(b) *Brewer's Notice, Form 5130.10.* Each person must, before commencing business as a brewer, give notice on Form 5130.10. Each person continuing business as a brewer as provided in § 25.71 must give notice on Form 5130.10. * * *

* * * * *

§ 25.62 [Amended]

Par. 11. Section 25.62(b) is amended by removing the words ''the regional director of any ATF region'' and adding, in substitution, the words ''an ATF office'.

§§ 25.65, 25.78, 25.81, 25.276 and 25.286 [Amended]

Par. 12. Part 25 is further amended by removing the phrase ''with the regional director (compliance)'' each place it appears in the following places:

(a) Section 25.65;

(b) Section 25.78;

(c) Section 25.81(b) introductory text;

(d) Section 25.276(b); and (e) The last sentence of § 25.286(a).

Par. 13. Section 25.71 (a)(1) is amended by removing the words ''to the regional director (compliance)'' from the first sentence.

§ 25.81 [Amended]

Par. 14. Section 25.81 (c) is amended by removing from the introductory text the words ''regional director (compliance) through the ATF area supervisor'' and adding, in substitution, the words ''appropriate ATF officer''.

Par. 15. The first through third sentences of § 25.85 are revised to read as follows:

§ 25.85 Notice of permanent discontinuance.

When a brewer desires to discontinue business permanently, he or she must file a notice on Form 5130.10. The brewer must state the purpose of the notice as ''Discontinuance of business'' and give the date of the discontinuance. When all beer has been lawfully disposed of, appropriate ATF officer will approve the Form 5130.10 and return a copy to the brewer. * * *

* * * * *

§ 25.91 [Amended]

Par. 16. Section 25.91(a) is amended by removing from the second sentence the phrase ''with the regional director (compliance)'' and the comma preceding this phrase.

Par. 17. Section 25.101(b) is revised to read as follows:

§ 25.101 Disapproval of bonds or consents of surety.

* * * * * *

(b) *Appeal of disapproval.* If the bond or consent of surety is disapproved, the person giving the bond or consent of surety may appeal the disapproval to the appropriate ATF officer, who will grant a hearing in the matter if requested by the applicant or brewer, and whose decision will be final.

* * * * *

Par. 18. The second and last sentences of § 25.141(b)(2) are revised to read as follows:

§ 25.141 Barrels and kegs.

* * * * *

(b) * * *

(2) * * * The coding system employed will permit an appropriate ATF officer to determine the place of production (including street address if two or more breweries are located in the same city) of the beer. The brewer must notify the appropriate ATF officer prior to employing a coding system.

* * * * *

Par. 19. The second and last sentences of § 25.142(b)(2) are revised to read as follows:

§ 25.142 Bottles.

* * * * *

(b) * * *

(2) * * * The coding system employed will permit an appropriate ATF officer to determine the place of production (including street address if two or more breweries are located in the same city) of the beer. The brewer must notify the appropriate ATF offcer prior to employing a coding system.

* * * * *

§ 25.165 [Amended]

Par. 20. Section 25.165(b)(1) is amended by removing the words ''regional director (compliance), for each region in which taxes are paid'' and adding, in substitution, the words ''appropriate ATF officer''.

§ 25.184 [Amended]

Par. 21. Section 25.184(c) is amended by removing the second sentence.

Par. 22. Section 25.213(b) is amended by revising the first and third sentences of the introductory text to read as follows:

§ 25.213 Beer returned to brewery other than that from which removed.

* * * * *

(b) *Notice.* A brewer need not file notice of intention to return beer to a brewery other than the one from which removed unless required by the appropriate ATF officer. * * * The brewer must file it with the appropriate ATF officer. * * *

* * * * *

Par. 23. Section 25.222 (a) is amended by revising the last sentence to read as follows:

§ 25.222 Notice of brewer.

(a) * * * The brewer must submit this notice to the appropriate ATF officer.

* * * * *

§§ 25.222 and 25.225 [Amended]

Par. 24. Part 25 is further amended by removing the words ''area supervisor'' each place they appear, and adding, in substitution, the words ''appropriate ATF officer'' in the following places:

(a) Section 25.222(b); and

(b) Section 25.225(b)(2).

Par. 25. Section 25.223(b) is revised to read as follows:

§ 25.223 Destruction of beer off brewery premises.

* * * * *

(b) *Destruction with supervision.* The appropriate ATF officer may require that an approriate ATF officer verify the information in the notice of destruction or witness the destruction of the beer. The appropriate ATF officer may also require a delay in the destruction of the beer or, if the place of destruction is not readily accessible to an appropriate ATF

officer, may require that the beer be moved to a more convenient location. In this case, the brewer may not destroy the beer except under the conditions imposed by the appropriate ATF officer.

Par. 26. Section 25.273 is revised to read as follows:

§ 25.273 Action on application.

If the appropriate ATF officer approves the application for a pilot brewing plant, he or she will note approval on the application and forward a copy to the applicant. The applicant must file the copy of the approved application at the premises, available for inspection by an appropriate ATF officer.

Par. 27. Section 25.276 (c) amended by revising the first and last sentences to read as follows:

§ 25.276 Operations and records.

* * * * *

(c) *Records.* The operator of a pilot brewing plant must maintain records which, in the opinion of the appropriate ATF officer, are appropriate to the type of operation being conducted. * * * These records will be available for inspection by an appropriate ATF officer.

* * * * *

Par. 28. Section 25.282(e) is revised to read as follows:

§ 25.282 Beer lost by fire, theft, casualty, or act of God.

* * * * *

(e) *Notification of appropriate ATF officer.* (1) A brewer who sustains a loss of beer before transfer of title of the beer to another person and who desires to adjust the tax on the excise tax return or to file a claim for refund or for relief from liability of tax, must, on learning of the loss of beer, immediately notify in writing the appropriate ATF officer of the nature, cause, and extent of the loss, and the place where the loss occurred. Statements of witnesses or other supporting documents must be furnished if available.

(2) A brewer possessing unmerchantable beer and who desires to adjust the tax on the excise tax return or to file a claim for refund or for relief from liability must notify in writing the appropriate ATF officer, of the circumstances by which the beer became unmerchantable, and must state why the beer cannot be salvaged and returned to the market for consumption or sale.

§ 25.283 [Amended]

Par. 29. Section 25. 283(e) is amended by removing the words ''with the regional director (compliance) of the region in which the beer was lost, returned, destroyed, or rendered unmerchantable''.

Par. 30. Section 25.284(d) is amended by revising the third and last sentences to read as follows:

§ 25.284 Adjustment of tax.

* * * * *

(d) *Beer lost, destroyed or rendered unmerchantable.* * * * A brewer may not make an adjustment prior to notification required under § 25.282(e). When beer appears to have been lost due to theft, the brewer may not make an adjustment to the tax return until establishing to the satisfaction of the regional director (compliance) that the theft occurred before removal from the brewery and occurred without connivance, collusion, fraud, or negligence on the part of the brewer, consignor, consignee, bailee, or carrier, or the employees or agents of any of them.

* * * * *

§ 25.285 [Amended]

Par. 31. Section 25.285(a) is amended by removing from the third sentence the words ''with regional director (compliance) in which the brewer's principal place of business is located'' and the comma following these words.

§ 25.297 [Amended]

Par. 32. Section 25.297(a) is amended by removing the words ''to the regional director (compliance) not later than the 15th day of the month following the close of the month for which prepared''.

Par. 33. Section 25.297(b) is amended by removing from the first sentence the words ''with the regional director (compliance) not later than the 15th day of the month following the close of the calendar quarter for which prepared''.

Signed: July 19, 2000.

Bradley A. Buckles,

Director.

Approved: August 1, 2000.

John P. Simpson,

Deputy Assistant Secretary (Regulatory, Tariff and Trade Enforcement).

[FR Doc. 01–1164 Filed 1–18–01; 8:45 am]

BILLING CODE 4810–31–U

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

27 CFR Part 30

[T.D. ATF–438]

RIN 1512–AC16

Delegation of Authority in 27 CFR Part 30

AGENCY: Bureau of Alcohol, Tobacco and Firearms (ATF), Treasury.

ACTION: Treasury decision, final rule.

SUMMARY: Authority delegation. This final rule places all ATF authorities contained in part 30, title 27 Code of Federal Regulations (CFR), with the ''appropriate ATF officer.'' Also, this final rule removes the definitions of, and references to, specific officers subordinate to the Director. Concurrently with this Treasury Decision, ATF Order 1130.17 is being published. Through this order, the Director has delegated the authorities in 27 CFR part 30 to the appropriate ATF officers.

EFFECTIVE DATE: January 19, 2001.

FOR FURTHER INFORMATION CONTACT: Lisa Gesser, Regulations Division, Bureau of Alcohol, Tobacco and Firearms, 650 Massachusetts Avenue NW., Washington, DC 20226, (202–927–9347) or e-mail at alctob@atfhq.atf.treas.gov.

SUPPLEMENTARY INFORMATION:

Background

Pursuant to Treasury Order 120–01 (formerly 221), dated June 6, 1972, the Secretary of the Treasury delegated to the Director of the Bureau of Alcohol, Tobacco and Firearms (ATF), the authority to enforce, among other laws, the provisions of chapter 51 of the Internal Revenue Code of 1986 (IRC). The Director has subsequently redelegated certain of these authorities to appropriate subordinate officers by way of various means, including by regulation, ATF delegation orders, regional directives, or similar delegation documents. As a result, to ascertain what particular officer is authorized to perform a particular function under chapter 51, each of these various delegation instruments must be consulted. Similarly, each time a delegation of authority is revoked or redelegated, each of the delegation documents must be reviewed and amended as necessary.

ATF has determined that this multiplicity of delegation instruments complicates and hinders the task of determining which ATF officer is

authorized to perform a particular function. ATF also believes these multiple delegation instruments exacerbate the administrative burden associated with maintaining up-to-date delegations, resulting in an undue delay in reflecting current authorities.

Accordingly, this final rule rescinds all authorities of the Director in part 30 that were previously delegated and places those authorities with the ''appropriate ATF officer.'' Most of the authorities of the Director that were not previously delegated are also placed with the ''appropriate ATF officer.'' Along with this final rule, ATF is publishing ATF Order 1130.17, Delegation Order—Delegation of the Director's Authorities in part 30, Gauging Manual, which delegates certain of these authorities to the appropriate organizational level.

The effect of these changes is to consolidate all delegations of authority in part 30 into one delegation instrument. This action both simplifies the process for determining what ATF officer is authorized to perform a particular function and facilitates the updating of delegations in the future. As a result, delegations of authority will be reflected in a more timely and user-friendly manner.

Paperwork Reduction Act

The provisions of the Paperwork Reduction Act of 1995, Public Law 104–13, 44 U.S.C. Chapter 35, and its implementing regulations, 5 CFR part 1320, do not apply to this final rule because there are no new or revised recordkeeping or reporting requirements.

Regulatory Flexibility Act

Because no notice of proposed rulemaking is required for this rule, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply. A copy of this final rule was submitted to the Chief Counsel for Advocacy of the Small Business Administration in accordance with 26 U.S.C. 7805(f). No comments were received.

Executive Order 12866

It has been determined that this rule is not a significant regulatory action because it will not: (1) have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866.

Administrative Procedure Act

Because this final rule merely makes technical amendments and conforming changes to improve the clarity of the regulations, it is unnecessary to issue this final rule with notice and public procedure under 5 U.S.C. 553(b). Similarly it is unnecessary to subject this final rule to the effective date limitation of 5 U.S.C. 553(d).

Drafting Information

The principal author of this document is Lisa Gesser, Regulations Division, Bureau of Alcohol, Tobacco and Firearms.

List of Subjects in 27 CFR Part 30

Alcohol and alcoholic beverages, Measurement standards, Scientific equipment.

Authority and Issuance

Title 27, Code of Federal Regulations is amended as follows:

PART 30—GAUGING MANUAL

Paragraph 1. The authority citation for part 30 continues to read as follows:

Authority: 26 U.S.C. 7805.

Par. 2. Section 30.11 is amended by removing the definitions of ''ATF officer'' and ''Regional director'' and by adding a new definition of ''Appropriate ATF officer'' to read as follows:

§ 30.11 Meaning of terms.

* * * * *

Appropriate ATF Officer. An officer or employee of the Bureau of Alcohol, Tobacco and Firearms (ATF) authorized to perform any functions relating to the administration or enforcement of this part by ATF Order 1130.17, Delegation Order—Delegation of the Director's Authorities in 27 CFR Part 30—Gauging Manual.

* * * * *

§§ 30.11, 30.31, 30.36, 30.43, and 30.51 [Amended]

Par. 3. Part 30 is further amended by removing the words ''Director'' each place it appears and adding, in substitution, the words ''appropriate ATF officer'' in the following places:

(a) The definition of ''Bulk conveyance'' in § 30.11;

(b) Section 30.31(b);

(c) Section 30.36;

(d) The last sentence of § 30.43; and

(e) The first sentence of § 30.51.

Par. 4. Section 30.21(c) is revised to read as follows:

§ 30.21 Requirements.

* * * * *

(c) *Appropriate ATF Officers.* Appropriate ATF officers shall use only hydrometers and thermometers furnished by the Government. However, where this part requires the use of a specific gravity hydrometer, ATF officers shall use precision grade specific gravity hydrometers conforming to the provisions of § 30.24, furnished by the proprietor. However, the appropriate ATF officer may authorize the use of other instruments approved by the appropriate ATF officer as being equally satisfactory for determination of specific gravity and for gauging. From time to time appropriate ATF officers shall verify the accuracy of hydrometers and thermometers used by proprietors.

* * * * *

Par. 5. Section 30.24(a) is amended by adding the word ''appropriate'' before the words ''ATF officers.''

Par. 6. Section 30.24(b) is amended by adding the word ''appropriate'' before the words ''ATF officer.''

Bradley A. Buckles,

Director.

Approved: August 11, 2001.

John P. Simpson,

Deputy Assistant Secretary (Regulatory, Tariff and Trade Enforcement).

[FR Doc. 01–1165 Filed 1–18–01; 8:45 am]

BILLING CODE 4810–31–P

DEPARTMENT OF LABOR

Employment Standards Administration, Wage and Hour Division

29 CFR Part 552

RIN 1215–AA82

Application of the Fair Labor Standards Act to Domestic Service

AGENCY: Wage and Hour Division, Employment Standards Administration, Labor.

ACTION: Notice of proposed rulemaking and request for comments.

SUMMARY: The Department of Labor is proposing to amend several of the existing regulations under the Fair Labor Standards Act (FLSA) pertaining to the exemption for companionship

services. Section 13(a)(15) exempts from the minimum wage and overtime provisions of the FLSA domestic service employees employed ''to provide companionship services for individuals who (because of age or infirmity) are unable to care for themselves (as such terms are defined and delimited by regulations of the Secretary).'' This exemption was enacted in 1974 at the same time that Congress amended the FLSA to cover domestic service employees generally. The pertinent regulations governing this exemption have been unchanged since they were promulgated in 1975. Due to significant changes in the home care industry over the last 25 years, workers who today provide in-home care to individuals needing assistance with activities of daily living are performing types of duties and working in situations that were not envisioned when the companionship services regulations were promulgated. The number of workers providing these services has also greatly increased, and most of these workers are being excluded from the FLSA under the companionship services exemption. The Department has reevaluated the regulations and determined that—as currently written—they exempt types of employees far beyond those whom Congress intended to exempt when it enacted section 13(a)(15). Therefore, the Department proposes to amend the regulations to revise the definition of ''companionship services,'' which sets out the duties that a companion must be employed to perform in order to qualify for the exemption, to more closely mirror Congressional intent. The Department also proposes to amend the regulations to clarify the criteria used to judge whether employees qualify as trained personnel, who are not recognized as exempt companions. Finally, the Department proposes to amend the regulations pertaining to employment by a third party. This change would deny the companionship services exemption if the worker is employed by someone other than a member of the family in whose home he or she works. It would similarly deny the exemption for live-in domestics, who are exempt from the FLSA's overtime requirements pursuant to section 13(b)(21), if they are employed by someone other than a member of the family in whose home they reside and work.

DATES: Comments are due on or before March 20, 2001.

ADDRESSES: Submit written comments to T. Michael Kerr, Administrator, Wage and Hour Division, Employment Standards Administration, U.S. Department of Labor, Attention: Fair Labor Standards Team, Room S–3516, 200 Constitution Avenue NW., Washington, DC 20210. Commenters who wish to receive notification of receipt of comments are requested to include a self-addressed, stamped postcard, or to submit comments by certified mail, return receipt requested. As a convenience, commenters may transmit comments by facsimile (''FAX'') machine to (202) 693–1432. This is not a toll free number. If comments are transmitted by FAX and a hard copy is also submitted by mail, please indicate on the hard copy that it is a duplicate copy of the FAX transmission.

FOR FURTHER INFORMATION CONTACT: Richard M. Brennan, Deputy Director, Office of Enforcement Policy, Wage and Hour Division, Employment Standards Administration, U.S. Department of Labor, Room S–3510, 200 Constitution Avenue, NW., Washington, DC 20210; telephone: (202) 693–0745. This is not a toll free number. Copies of this proposed rulemaking may be obtained in alternative formats by calling (202) 693–0745 or (202) 693–1461 (TTY). The alternative formats available are large print electronic file on computer disk (Word Perfect, ASCII, Mates with Duxbury Braille System) and audiotape.

SUPPLEMENTARY INFORMATION

I. Background

Congress expressly extended coverage to ''domestic service'' workers under the FLSA in 1974, amending the law to apply to employees performing services of a household nature in or about the private home of the person by whom they are employed. 29 U.S.C. 202(a), 206(f), 207(l). Domestic service workers were made subject to the FLSA even though they worked for a private household and not for a covered enterprise. Domestic service workers include, for example, employees working as cooks, butlers, valets, maids, housekeepers, governesses, janitors, laundresses, caretakers, handymen, gardeners, and family chauffeurs. Senate Report No. 93–690, 93d Cong., 2d Sess. (1974), p. 20. Simultaneously with extending coverage under the FLSA to domestic service workers, Congress created a complete exemption from both the minimum wage and overtime requirements for casual babysitters and persons ''employed in domestic service employment to provide companionship services for individuals who (because of age or infirmity) are unable to care for themselves (as such terms are defined and delimited by regulations of the Secretary [of Labor]).'' 29 U.S.C. 213(a)(15). Congress also created a more limited exemption from the overtime requirements for domestic service employees in a household who reside in that household. 29 U.S.C. 213(b)(21).

Congressional committee reports describe the reasons for extending the minimum wage protections to domestics as ''so compelling and generally recognized as to make it hardly necessary to cite them.'' Senate Report No. 93–690, p. 18. Private household work had been one of the least attractive fields of employment. Wages were low, work hours were highly irregular, and non-wage benefits were few. Senate Report No. 93–690, p. 18.

The U.S. House of Representatives, Committee on Education and Labor stated its expectation ''that extending minimum wage and overtime protection to domestic workers will not only raise the wages of these workers but will improve the sorry image of household employment. * * * Including domestic workers under the protection of the Act should help to raise the status and dignity of this work.'' House Report No. 93–913, 93d Cong., 2d Sess., (1974), pp. 33–34. The legislative history states that the 1974 Amendments were intended to include all employees whose vocation was domestic service, but to exempt from coverage babysitters and companions who were not regular bread-winners or responsible for their families' support. It was not intended that the statute exclude trained personnel such as nurses, whether registered or practical, from the protections of the Act. Senate Report No. 93–690, p. 20. Senator Williams, Chairman of the Senate Subcommittee on Labor and the Senate floor manager of the 1974 FLSA Amendments, described companions as ''elder sitters'' whose main purpose of employment is to watch over an elderly or infirm person in the same manner that a babysitter watches over children. All other work (such as occasionally making a meal or washing clothes for the person) must be incidental to that main purpose. 119 Cong. Rec. 24773, 24801 (1973).

The Department promulgated implementing regulations in 1975 that define ''companionship services'' as including ''fellowship, care, and protection'' provided to a person who, because of advanced age or physical or mental infirmity, could not care for his or her own needs. The regulation defined such exempt services as including household work related to the person's care (such as meal preparation, bed making, washing of clothes, and other similar services). A companion could also perform additional general

household work without losing the exemption if it was incidental and comprised not more than 20 percent of the total weekly hours worked. Finally, a companion could be exempt even if employed solely by a third-party employer or agency, rather than by an individual or family directly. 29 CFR 552.6; 552.109(a). Similarly, live-in domestic service workers could be exempt even if employed solely by a third-party employer or agency, rather than by the individual or family in whose home they resided and worked. 29 CFR 552.109(c).

The home care industry has changed dramatically since the Department published the 1975 regulations implementing the exemption for companionship services. There has been a growing demand for long-term in-home care for persons of all ages, in part because of the rising cost of and increasing dissatisfaction with traditional institutional care, and because of the availability of public funding assistance for in-home care under Medicare and Medicaid. According to the National Association of Home Care (NAHC) publication, *Basic Statistics About Home Care (March 2000)*, data from the Department of Health and Human Services' Health Care Financing Administration (HCFA) show that the number of Medicare-certified home care agencies increased over three-fold from 2,242 in 1975 to 7,747 in 1999. The number of for-profit agencies not associated with a hospital, rehabilitation facility, or skilled nursing facility, *i.e.*, freestanding agencies, increased more than any other category of agency from 47 in 1975 to 3,129 in 1999. These for-profit agencies grew from 2 percent of total Medicare-certified agencies to over 40 percent by 1999, and now represent the greatest percentage of certified agencies. Public health agencies, which constituted over half of the certified agencies in 1975, now represent only 12 percent.

The Federal Government pays for much of the cost of providing home care services to care recipients. Medicare provides a notable portion of the industry's total revenues; other payment sources include Medicaid, insurance plans, and direct pay. Based on data from ''A Profile of Medicare Home Health''—a HCFA publication—Medicare and Medicaid together account for more than half of the revenues paid to freestanding agencies (40 and 15 percent, respectively). Other private funds (philanthropy) account for 12 percent, while private health insurance accounts for 11 percent. Out-of-pocket funds account for 22 percent of agency revenues.

There has been a similarly dramatic increase in the employment of home health aides and personal and home care aides in the private homes of individuals who need assistance with basic daily living or health maintenance activities. Bureau of Labor Statistics' (BLS) national occupational employment and wage estimates from the Occupational Employment Statistics (OES) survey show that the number of workers in these jobs tripled during the decade between 1988 and 1998, and by 1998 there were 430,440 people working as home health aides and 255,960 people working as personal and home care aides. The combined occupations of personal care and home health aides constitute the seventh most rapidly growing occupational group, and BLS estimates that their number will increase by another 150 percent from 1998 to 2008. The earnings of both categories of employees remain among the lowest in the service industry—a 1998 mean annual wage of $16,250 for home health aides and $14,920 for personal and home care aides according to the OES data. Based on the same data source, ten percent of home health aides and personal and home care aides earn below $12,300 a year—lower than the 1999 poverty threshold level of $13,880 for a family of three.

Home health aides generally received more than personal and home care aides—$7.51 per hour (mean hourly wage) for personal and home care aides, and $8.17 per hour for home health aides. However, 10 percent of home health aides were paid less than $5.87 an hour, while 10 percent of personal and home care aides received less than $5.60 per hour. Although 90 percent of home health aides and personal and home care aides received hourly wages at or above $5.87 or $5.60, nearly 70,000 of these workers received hourly wages at or below such rates, and possibly below the minimum wage.

According to the BLS National Industry-Occupation Employment Matrix (1998), the largest percentage (38 percent) of personal care and home health care aides are employed in the home health care services industry. Others are employed by miscellaneous social service agencies, residential care facilities, personnel supply service agencies, nursing homes and hospitals. Only about two percent were self-employed and another two percent were employed in private households.

Current data suggest that many workers in the home care industry are now employed in their primary occupation. BLS National Current Employment Statistics for 1999 show an average weekly number of hours worked among non-supervisory employees in the home health care services industry (SIC 808) of 29.1 hours. Workers in the individual and family social services industry (SIC 832) averaged 31.2 hours per week. In the residential care industry (SIC 836), workers averaged 32.4 weekly hours worked. To the extent that time spent traveling from one client to the next has not been considered hours worked and thus captured in the above data, home care workers may actually be working longer than revealed by the BLS statistics. As indicated earlier, it clearly was Congress' intent under the 1974 FLSA Amendments to cover all workers who performed domestic services as a *vocation*, excluding casual babysitters and providers of companionship services who were *not* regular bread winners or responsible for their families' support.

These workers perform a variety of housekeeping, personal care, and medical duties for individuals who need assistance with activities of daily living to enable them to remain in their homes. Home health aides perform duties such as preparing meals, dressing patients, administering medication and performing medical procedures under a doctor's or nurse's direction. Personal and home care aides perform a variety of tasks in the home, including household work and assistance with nutrition and cleanliness. Employers have generally treated workers employed as home health aides and personal and home care aides as exempt companions, based upon the Department's current regulations. To the extent that the current regulations allow for the exemption of an employee who provides very little fellowship, and whose duties involve almost exclusively the performance of household chores or medical services, they do not appropriately implement Congress' limited exemption for employees who provide companionship services. As a result, the Department believes it is necessary to amend the regulations to focus them on the fellowship and protection duties that Congress originally intended the companion exemption to cover.

II. Proposed Regulatory Revisions

A. Duties of a Companion (29 CFR 552.6)

The Department proposes to amend the definition of ''companionship services'' in section 552.6 to clarify the focus on the element of fellowship, to align the regulation more closely with Congressional intent. The dictionary definition of ''companionship'' is

instructive in revising the regulation to conform to the concept of a companion as originally intended in the legislative history: someone in the home primarily to watch over and care for the elderly or infirm person, much as a neighbor or babysitter would. The dictionary defines companionship as the ''relationship of companions; fellowship.'' And the term ''companion'' is defined as a ''person who accompanies or associates with another; comrade'' and as a person ''employed to assist, live with, or travel with another.'' It further defines ''fellowship'' as including ''the condition of being together,'' ''friendship'' and coming together ''in a congenial atmosphere.'' The American Heritage Dictionary of the English Language, 1976 Edition. Thus, we propose a revision of the regulation that requires that fellowship be a significant, important and fundamental aspect of the job under the companionship services exemption. Only where the worker and the person being served or assisted interact on a close personal basis, for a significant percentage of the time, would the companionship services exemption be applicable. Of course, the precise nature of what activities constitute fellowship will vary, depending upon the needs, capabilities, and interests of the care recipient. For example, fellowship might involve reading a book or a newspaper to the person, chatting with him or her about family or other events, playing cards, watching television, or going for a walk. Whatever the specific activity, it must involve personal interaction between the in-home care provider and the care recipient in order for the proposed companionship services exemption to apply.

The regulatory definition of companionship services cannot be so broad as to include someone who essentially is serving as a maid or household worker. In 1974, Congress amended the FLSA specifically to include domestic service workers (such as maids, cooks, valets and laundresses) among those intended to be covered by the Act. Congress simultaneously created a narrowly-tailored exemption for casual babysitters and those providing companionship services to the elderly and infirm. The regulations implementing the exemption should strike a balance that implements Congress' twin goals by recognizing that the fellowship and protection provided by a companion are very different from the household chores performed by a maid or cook or laundress. Furthermore, the regulations should also reflect that coverage under the FLSA is construed broadly and exemptions narrowly to effectuate the Act's remedial purposes.

The Department recognizes that it is possible to define companionship services in several different ways, with the options arrayed along a spectrum. The definitions may vary in the degree to which they require the provision of fellowship only, or allow the provision of fellowship in conjunction with hands-on care. The percentage of time that must be spent in fellowship as compared to other care duties also may vary. The Department proposes three alternatives for defining companionship services and seeks comments on all three alternatives. The three possible definitions involve variations in the specific types of duties the employee may perform and the amount of time the employee may spend in performing such duties. All of the alternatives increase the emphasis on fellowship as a critical component of a companion's duties, and narrow or eliminate the type of care that may comprise a companion's duties. In all three alternatives, we also propose to eliminate the current regulatory provision that allows the exemption to apply when the worker spends up to 20 percent of his or her time performing general household work which is unrelated to the care of the person, such as general vacuuming and dusting. Such general household work is precisely the sort of work that Congress sought to cover when it amended the Act in 1974 to reach domestic service workers, and therefore would be precluded.

The first proposal requires that fellowship be a significant part of the person's duties for the companionship services exemption to apply, but does not require fellowship duties to occupy a set percentage of the worker's time. This proposal anticipates that fellowship would occur in conjunction with the performance of other intimate personal care chores, such as bathing, grooming, and dressing, which also would constitute exempt duties. The first proposal also would allow the exemption if the worker performs a limited amount (up to 20 percent of the hours worked per week) of work of a household nature that is directly related to the client's personal care, such as cooking the person's meal, making the person's bed, or washing the dishes for that person.

The second proposal focuses on fellowship and protection as the primary duties in order for the companionship services exemption to apply. Thus, an employee must spend more than 50 percent of his or her time engaging in fellowship or protection duties to be exempt. Such fellowship and protection duties would include activities providing only fellowship or protection as well as activities in which fellowship or protection is provided concurrently with the performance of other intimate personal care chores, such as bathing, grooming, and toileting. However, only one-half the time spent providing fellowship or protection simultaneously with such other intimate personal care chores would count when determining if the employee's primary duty was providing fellowship or protection. The second proposal also would allow the exemption if the worker performs a limited amount (up to 20 percent of the weekly hours) of work of a household nature that is directly related to the person's care.

The third proposal would require that fellowship and protection be the sole core duties in order for the exemption to apply. To qualify for the exemption, the individual would have to spend at least 80 percent of his or her time in activities that provide fellowship or protection, not in conjunction with other personal care duties. The 20 percent tolerance for other types of work would apply to other intimate care and related chores. Thus, under this proposal, time spent on intimate personal care chores (such as grooming, toileting, and feeding) and on directly related work for the person (such as cooking the person's meal) may not exceed 20 percent of the weekly hours worked for the companionship services exemption to apply.

B. Trained Personnel (29 CFR 552.6)

There has also been a dramatic change since the enactment of the 1974 FLSA Amendments in the nature of the duties performed by many employees classified as exempt under the companionship services exemption. Because many individuals who were formerly institutionalized or moved to nursing homes are able, with assistance, to stay in their homes, home care providers have taken on a broader range of medically-related duties. For example, individuals treated as exempt in providing companionship services may now perform duties such as medication management, taking vital signs (pulse, temperature, respiration), routine skin and back care, and assistance with exercise and the performance of simple procedures as an extension of physical therapy service.

The training necessary for an employee to perform such duties, while less than the training of a physician or nurse, means that such individuals are not acting simply as elder sitters or as babysitters watching over their charge.

Some courts, interpreting the current regulations, have allowed employees to qualify for exemption under the present regulatory definition of companionship services despite the fact that they had extensive training, on the theory that they did not have the two or more years of training generally required for LPNs and RNs. For example, in *McCune* v. *Oregon Senior Services Division*, 894 F.2d 1107 (9th Cir. 1990), the court found that certified nursing assistants who had to pass a 60-hour training class were exempt despite their extensive medical training. Similarly, in *Cox* v. *Acme Health Services, Inc.*, 55 F.3d 1304 (7th Cir. 1995), the court held that certified home health aides with 75 hours of state-required training were exempt. The court in *Terwilliger* v. *Home of Hope, Inc.*, 21 F. Supp. 2d 1294 (N.D. Okla. 1998), also found that employees with 160 hours of training, who had to obtain 40 additional hours of training each year, were exempt.

The Department believes that Congress did not intend for the companionship services exemption to apply to employees with the level of training necessary to perform medically-related duties such as medication management and assistance with physical therapy. Duties being performed that require such extensive training are beyond what Congress envisioned when it stated that persons providing companionship services are present in the home, as a neighbor might be, to watch over an elderly person the way a babysitter watches over a child. Thus, the Department proposes to clarify the regulatory definition of companionship services in section 552.6 to exclude personnel trained in the performance of such medically related duties from the companion exemption.

C. Third Party Employment (29 CFR 552.109)

The Department also proposes to amend section 552.109, the regulation pertaining to employment by a third party. People providing in-home care and assistance to individuals with activities of daily living may be employed, or jointly employed, by various parties such as the family or household using the companionship services, State or local governments, private for-profit agencies, and hospital-related and not-for-profit agencies.

Under the existing regulation, employees who are employed by an employer or agency other than the family or household using the companionship services may still qualify for the exemption. Similarly, under the current regulation live-in workers who are employed by a third party, rather than by the family in whose household they work and reside, nevertheless may qualify for an overtime exemption under section 13(b)(21) of the FLSA.

The Department believes that employment by a party other than the family or household using the companionship services is inconsistent with the status of a companion, because the exemption for companionship services in section 13(a)(15) of the FLSA is limited to employees who are domestic service employees. The overtime exemption in section 13(b)(21) for live-in employees who reside in the household is similarly limited to domestic service employees. While domestic service was not defined by Congress in the Act, the Senate report reflects Congress' view that ''the generally accepted meaning of domestic service relates to service of a household nature performed by an employee in or about a private home of the person by whom he or she is employed.'' Senate Report No. 93–690, p. 20 (emphasis added). The regulations mirror Congressional intent in defining domestic service employment as services of a household nature performed by an ''employee in or about a private home (permanent or temporary) of the person by whom he or she is employed.'' 29 CFR 552.3. Thus, the current regulations contain an internal inconsistency, because they allow the companion and live-in domestic exemptions to be applied to an employee employed by someone other than the person in whose private home the work is being performed.

In 1993, the Department published a proposal to amend this regulation in light of the statutory requirement that the exemptions for companionship services and live-ins only applied to domestic service employees. The proposal provided that the companionship services exemption would not apply unless the person receiving the companionship services acted, alone or jointly, as an employer. 58 FR 69310, December 30, 1993. The subsection pertaining to live-in employees was similarly proposed for amendment. In 1995 the rule was reproposed, suggesting that the exemption might apply if either the person receiving the services or a family member or state agency acted as an employer of the person providing companionship services, if the care recipient was unable to act on his or her own behalf. 60 FR 46797, September 8, 1995. The Department received very few comments on either of those proposals, and many of the comments indicated that there was confusion about the impact and effect of the proposals.

The Department continues to believe that the current regulation impermissibly extends the exemption for companionship services and for live-in workers to employees who do not qualify as domestic service employees, because they are not working *in* the home of their employer, *i.e.*, the third party employer. In addition, as discussed above, changes in the industry and in the nature of the duties being performed in peoples' homes by this segment of the work force have resulted in increasing numbers of employees working for third-party employers. Under the 1974 Amendments, Congress extended coverage of the FLSA to domestic service employees who were not previously covered, *i.e.,* those who worked only for a private family and not for a covered enterprise. Anyone who prior to 1974 had worked for a covered placement agency, for example, but who was assigned to work in someone's home, would have been covered previously by the FLSA. The Department believes that Congress did not intend the 1974 amendments to change the status of workers already covered by the FLSA, but only intended to exclude casual babysitters and companions from those newly covered by the law, that is, those exclusively employed by the homeowner or family member.

Accordingly, we propose to amend section 552.109 (a) and (c) to make the exemptions in sections 13(a)(15) and 13(b)(21) of the FLSA applicable only with respect to the family or household using the worker's services. For employees who are employed, whether solely or jointly, by an employer *other than* the family or household, such workers would *not* be engaged in ''domestic service employment'' with respect to those third party employers, and those third party employers, therefore, would *not* be able to avail themselves of the exemptions. A corresponding revision is made to the definition of *domestic service employment* in section 552.103.

III. Paperwork Reduction Act

This proposed regulation does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act.

IV. Executive Order 12866

The proposed rule is not an ''economically significant'' regulatory action within the meaning of section 3(f)(1) of Executive Order 12866 on

''Regulatory Planning and Review.'' The rule is not likely to: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; or (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof. As a result, the Department concluded that a full economic impact and cost/benefit analysis was not required for the rule under Section 6(a)(3) of the Order. However, because of its importance to the public and to the Administration's priorities, the rule was treated as a significant regulatory action and it was, therefore, reviewed by the Office of Management and Budget.

Based on our preliminary analysis of the data, it is our conclusion that the proposals to change how the companionship services exemption is applied under the FLSA will not produce a significant economic or budgetary impact on affected entities. The data indicate that more than 90 percent of the workers employed in the potentially affected occupational categories already receive the current federal minimum wage of $5.15 an hour or higher, and changing their status under the FLSA from exempt to non-exempt would not impose any new wage costs to meet minimum wage requirements. Similarly, because it appears that most of the workers in these occupational categories do not regularly work overtime (*i.e.,* more than 40 hours per week), there would be little impact from overtime wage costs if their status were changed from exempt to non-exempt. Our analysis suggests that most of the likely impact, although small, will be limited to the less than 10 percent of workers who do not receive at least $5.15 an hour and to those workers who may be entitled to additional compensation (minimum wage or overtime) for time spent traveling between multiple client work sites during the day. Some employers may not now pay for such travel time. For those few workers who may be paid at or near the $5.15 minimum wage or who work overtime hours once the travel time is included, some employers could incur minor additional wage costs to meet FLSA's minimum wage or overtime requirements. However, there are many scheduling options available to employers to enable them in that event to limit the total hours worked by an employee to 40 or fewer hours per week to ensure that overtime costs are not incurred if paying overtime wages is not in their own economic self-interests.

The Department of Health and Human Services' Health Care Finance Administration informally estimates that the proposal will have a negligible effect on Medicare costs as the types of services at issue are not a significant component of the Medicare program. Annual Medicaid program expenditures may increase somewhere within a $30 to $40 million range, of which 57 percent would be the Federal share. An equivalent percent increase in private expenditures for home health services would suggest the possibility of a maximum additional increase of $35 million in total private expenditures. The combined private and public total would likely be no greater than $75 million.

Accordingly, it is our conclusion that this rulemaking is not an economically significant regulatory action for purposes of Executive Order 12866.

V. Small Business Regulatory Enforcement Fairness Act

For similar reasons as noted above, the Department has concluded that this proposed rule is not a ''major'' rule requiring approval by the Congress under the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*). It will not likely result in (1) an annual effect on the economy of $100 million or more; (2) a major increase in costs or prices for consumers, individual industries, Federal, State or local government agencies, or geographic regions; or (3) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

VI. Unfunded Mandates Reform Act

For similar reasons for purposes of the Unfunded Mandates Reform Act of 1995, this rule does not include a Federal mandate that may result in increased expenditures by State, local, and tribal governments in the aggregate of more than $100 million, or increased expenditures by the private sector of more than $100 million.

VII. Executive Order 13132 (Federalism)

The Department has reviewed this rule under the terms of Executive Order 13132 regarding federalism and has determined that it does not have federalism implications. Because the economic effects under the rule will not be substantial for the reasons noted above, the rule does not have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

VIII. Effects on Families

The Department has assessed this rule under section 654 of the Treasury and General Government Appropriations Act, 1999, for its effect on family well-being and hereby certifies that it will not adversely affect the well-being of families.

IX. Regulatory Flexibility Act

The Department has determined for similar reasons that this proposed regulation will not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, and the Department has so certified to the Chief Counsel for Advocacy of the Small Business Administration. As discussed above in the analysis under Executive Order 12866, more than 90 percent of the workers employed in occupational categories addressed by this rulemaking already receive wages at rates above the current federal minimum wage, and they typically work fewer than 40 hours per week. Furthermore, employers are reimbursed by the Federal government or insurance companies for most of the cost of providing these benefits. Thus, even assuming that the alternative covering the most additional (and therefore exempting the fewest) workers is adopted, the rule will not have a significant economic impact. The following regulatory flexibility analysis supports this determination.

(1) Reasons Why Action is Being Considered

Section 13(a)(15) of the Fair Labor Standards Act (29 U.S.C. 213(a)(15)) contains an exemption from both the minimum wage and overtime pay requirements for ''3 any employee employed in domestic service employment to provide companionship services for individuals who (because of age or infirmity) are unable to care for themselves (as such terms are defined and delimited by regulations of the Secretary)'' (emphasis added). Due to considerable growth in home care and the home health care industry since the implementing regulations were promulgated in 1975, the Department's

more recent experience indicates that the ''companionship services'' exemption is being asserted in an expansive way for many more workers than we believe the Congress originally intended based on a careful analysis of the background and legislative history to the exemption. Vast numbers of workers employed in regular vocations to provide domestic services and care for individuals in their private homes are being excluded from FLSA coverage as a result of this misapplication of this exemption, which we believe is contrary to the intent and specific purposes of the 1974 FLSA Amendments. The Department is therefore issuing this proposal to invite public comments on possible clarifications to the definitional terms describing the companionship services exemption to bring it more in line with original Congressional intent.

(2) Objectives of and Legal Basis for Rule

This proposed rule is issued under the authority provided by section 13(a)(15) of the FLSA (29 U.S.C. 213(a)(15)), which grants the Secretary of Labor legislative rulemaking authority to define and delimit the terms ''employee employed in domestic service employment to provide companionship services'' for purposes of exempting such workers from the minimum wage and overtime pay requirements of the FLSA.

(3) Number of Small Entities Covered Under the Rule

A small business profile obtained from the U.S. Small Business Administration's Office of Advocacy web site indicates that the health services industry is among the top small business industries in the United States according to employment figures. The SBA small business size standard for Home Health Care Services, NAICS 6216, applies a $10 million threshold in annual receipts for defining a small business. Based on data from the U.S. Census Bureau's 1997 Economic Census, there were 16,895 home health care establishments (both exempt from and subject to federal income tax) in 1997 that operated for the entire year. Of that number, 16,486 (or 98%) had revenues (in the case of tax exempt firms) or receipts (in the case of non-exempt firms) of less than $10,000,000. For purposes of this analysis, we have assumed that most of the entities potentially affected by this proposal would likely meet the applicable criteria defining a small business in the home health care industry.

(4) Reporting, Recordkeeping, and Other Compliance Requirements of the Rule

The rule contains no reporting, recordkeeping or other compliance requirements. All employers covered by the FLSA must comply with its minimum wage, overtime pay, child labor, and generally applicable recordkeeping requirements with respect to each employee who is not otherwise exempt from the FLSA's requirements.

(5) Relevant Federal Rules Duplicating, Overlapping, or Conflicting With the Rule

There are no Federal rules that duplicate, overlap, or conflict with this rule governing the scope of the companionship services exemption under the FLSA. Regulations issued under the Medicare and Medicaid programs govern qualifying reimbursements for eligible expenses under those programs.

(6) Differing Compliance or Reporting Requirements for Small Entities

This proposed rule contains no reporting, recordkeeping, or other compliance requirements specifically applicable to small entities or that differ from FLSA requirements generally applicable to all employers subject to the FLSA. Furthermore, since this is a question of application of the basic minimum wage and overtime requirements of the Act, and most affected employers would be small, no special treatment would be appropriate for small entities. However, the Department has prepared three alternative definitions of the scope of exempt duties and requested comments on all three.

(7) Clarification, Consolidation, and Simplification of Compliance and Reporting Requirements

There is continuing confusion, among both employees and employers, over the scope of the companionship services exemption as it relates to the home health care industry. This proposal is intended to delimit how the exemption applies in a manner that conforms more fully with Congressional intent. Compliance requirements—*i.e.*, payment of not less than the minimum wage for all hours worked and overtime pay, computed at time-and-one-half the regular rate for hours worked over 40 per week to all covered employees—are imposed by statute but are also relatively simple and easy to comply with. Under the recordkeeping requirements generally applicable to all FLSA-covered employers, no particular order or form of records is prescribed by regulation and employers are free to use any format that assures the essential records are kept that meets compliance needs.

(8) Use of Other Standards

This proposed regulation addresses only statutory coverage and definitional terms used in applying the ''companionship services'' exemption. Different standards for a statutory exemption are not appropriate for small businesses. It should be noted, however, that the proposed modification to the exemption to exclude from the exemption those workers who are employed by an employer or agency other than the family or household using their services would have the effect of excluding all large employers (as well as small employers other than the family or household).

(9) Exemption of Small Entities From Coverage of the Rule

An exemption based on the size of the entity/employer would not be permitted by the terms of the statute. Coverage and applicability of the wage and hours provisions of the FLSA are based on engagement in interstate commerce, production of goods for interstate commerce, employment in domestic service employment in private households (per se), and employment by certain enterprises named in the statute as subject to its provisions.

X. Document Preparation

This document was prepared under the direction and control of Thomas M. Markey, Deputy Administrator for Operations, Wage and Hour Division, Employment Standards Administration, U.S. Department of Labor.

List of Subjects in 29 CFR Part 552

Domestic service workers, Employment, Labor, Minimum wages, Overtime pay, Wages.

Signed at Washington, DC on this 12th day of January, 2001.

T. Michael Kerr,

Administrator, Wage and Hour Division.

For the reasons set forth above, part 552 of title 29 of the Code of Federal Regulations is proposed to be amended as follows:

PART 552—APPLICATION OF THE FAIR LABOR STANDARDS ACT TO DOMESTIC SERVICE

1. The authority citation for part 552 continues to read as follows:

Authority: Secs. 13(a)(15) and 13(b)(21) of the Fair Labor Standards Act, as amended (29 U.S.C. 213(a)(15), (b)(21)), 88 Stat. 62; Sec. 29(b) of the Fair Labor Standards

Amendments of 1974 (Pub. L. 93–259, 88 Stat. 76), unless otherwise noted.

2. § 552.3 is proposed to be revised by adding a sentence to the end of the section to read as follows:

§ 552.3 Domestic service employment.

* * * Employees who are employed, whether solely or jointly, by an employer or agency other than the family or household using their services are not engaged in domestic service employment within the meaning of this part with respect to such third-party employer.

3. § 552.6 is proposed to be revised to read as follows:

Alternative 1 for § 552.6

§ 552.6 Companionship services for the aged or infirm.

As used in section 13(a)(15) of the Act, the term companionship services shall mean those services which provide fellowship, care and protection for a person who, because of advanced age or physical or mental infirmity, cannot care for his or her own needs. Although no specific percentage of time must be devoted exclusively to fellowship, fellowship must be a significant component of a companion's duties. Protection generally involves being present in the home of the individual to ensure the safety and well being of that individual. Care generally involves providing intimate personal care services to that individual, such as feeding the person or assisting the person with bathing, dressing, grooming, or toileting. A companion may also perform household work but only insofar as it is directly related to the care of the individual, such as preparing the individual's meal, making the individual's bed, washing the individual's clothes and other similar services for the person, provided, however, that such work is incidental, *i.e.*, does not exceed 20 percent of the total weekly hours worked. The term ''companionship services'' does not include services relating to the care and protection of the individual which require and are performed by personnel with training in medical procedures, including, but not limited to, catheter and ostomy care, injections, and tube feeding, regardless of whether the caregiver is a registered or practical nurse. While such trained personnel do not qualify as companions, this fact does not remove them from the category of covered domestic service employees when employed in or about a private household.

Alternative 2 for § 552.6

§ 552.6 Companionship services for the aged or infirm.

As used in section 13(a)(15) of the Act, the term companionship services shall mean those services which provide fellowship, care and protection for a person who, because of advanced age or physical or mental infirmity, cannot care for his or her own needs. Fellowship and protection must be a companion's primary duties and the companion must spend at least 50% of his or her weekly hours worked providing fellowship or protection. A companion's time may be devoted exclusively to fellowship or protection, or fellowship and protection may be provided in conjunction with and concurrently with intimate personal care activities; however, only one-half of the time spent providing fellowship or protection in the context of and concurrently with intimate personal care activities may count towards the 50 percent requirement. Protection generally involves being present in the home of the individual to ensure the safety and well being of that individual. Care generally involves providing intimate personal care services to that individual, such as feeding the person or assisting the person with bathing, dressing, grooming, or toileting. A companion may also perform household work but only insofar as it is directly related to the care of the individual, such as preparing the individual's meal, making the individual's bed, washing the individual's clothes and other similar services for the person, provided, however, that such work is incidental, *i.e.*, does not exceed 20 percent of the total weekly hours worked. The term ''companionship services'' does not include services relating to the care and protection of the individual which require and are performed by personnel with training in medical procedures, including, but not limited to, catheter and ostomy care, injections, and tube feeding, regardless of whether the caregiver is a registered or practical nurse. While such trained personnel do not qualify as companions, this fact does not remove them from the category of covered domestic service employees when employed in or about a private household.

Alternative 3 for § 552.6

§ 552.6 Companionship services for the aged or infirm.

As used in section 13(a)(15) of the Act, the term companionship services shall mean those services which provide fellowship and protection for a person who, because of advanced age or physical or mental infirmity, cannot care for his or her own needs. Fellowship and protection are a companion's sole core duties and a companion must spend at least 80% or his or her weekly hours worked exclusively providing fellowship or protection. Protection generally involves being present in the home of the individual to ensure the safety and well being of that individual. A companion may also perform duties that provide care, which generally involves providing intimate personal care services to the individual, such as feeding the person or assisting the person with bathing, dressing, grooming, or toileting. A companion also may perform household work but only insofar as it is directly related to the care of the individual, such as preparing the individual's meal, making the individual's bed, washing the individual's clothes and other similar services for the person. However, all intimate personal care services and household work directly related to the individual must be incidental, i.e., may not exceed 20 percent of the total weekly hours worked. The term ''companionship services'' does not include services relating to the care and protection of the individual which require and are performed by personnel with training in medical procedures, including, but not limited to, catheter and ostomy care, injections, and tube feeding, regardless of whether the caregiver is a registered or practical nurse. While such trained personnel do not qualify as companions, this fact does not remove them from the category of covered domestic service employees when employed in or about a private household.

4. In § 552.109, paragraphs (a) and (c) are proposed to be revised to read as follows:

§ 552.109 Third party employment.

(a) Employees who are employed, whether solely or jointly, by an employer or agency other than the family or household using their services are not engaged in ''domestic service employment'' within the meaning of these regulations with respect to such third party employer. Consequently, such a third party employer may not avail itself of the minimum wage and overtime pay exemption provided by section 13(a)(15) of the Act for employees employed in domestic service employment to provide companionship services.

(b) * * *

(c) Household workers who are employed, whether solely or jointly, by an employer or agency other than the

family or household using their services are not engaged ''in domestic service employment'' within the meaning of these regulations with respect to such third party employer. Consequently, such a third party employer may not avail itself of the overtime pay exemption provided by section 13(b)(21) of the Act for employees employed in domestic service who reside in the household.

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 229

[Docket No. 001128334–0334–01; I.D. 111300E]

RIN 648–AN40

Taking of Marine Mammals Incidental to Commercial Fishing Operations; Atlantic Large Whale Take Reduction Plan Regulations

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Interim final rule; delay of effective date.

SUMMARY: This interim final rule delays the effective date of an interim final rule amending the Atlantic Large Whale Take Reduction Plan (ALWTRP) from January 22, 2001, until February 21, 2001. Due to the rough January weather conditions in the Gulf of Maine, the affected fishers have not been able to implement the gear modifications in the interim final rule in time to meet the January 22, 2001 effective date. The intent of this delay of effective date is to allow fishers 30 additional days to implement the gear modifications.

DATES: The effective date of the interim final rule amending 50 CFR part 229 published at 65 FR 80368, December 21, 2000, is delayed until February 21, 2001.

ADDRESSES: Send comments on this interim final rule to the Chief, Marine Mammal Division, NMFS, Office of Protected Resources, 1315 East-West Highway, Silver Spring, MD 20910. Copies of the Environmental Assessment, Atlantic Large Whale Take Reduction Team (ALWTRT) meeting summaries, progress reports on implementation of the ALWTRP, and a map and table of the changes to the ALWTRP may be obtained by writing Douglas Beach, NMFS/Northeast Region, 1 Blackburn Dr., Gloucester, MA 01930 or Katherine Wang, NMFS/Southeast Region, 9721 Executive Center Dr., St. Petersburg, Fl 33702–2432.

Send comments regarding any ambiguity or unnecessary complexity arising from the language used in this interim final rule to the Marine Mammal Division Chief at the previously listed address. See **SUPPLEMENTARY INFORMATION,** under the heading Electronic Access, for Internet addresses pertaining to this interim final rule.

FOR FURTHER INFORMATION CONTACT: Douglas Beach, NMFS, Northeast Region, 978–281–9254; Katherine Wang, NMFS, Southeast Region, 727–570–5312; or Patricia Lawson, NMFS, Office of Protected Resources, 301–713–2322.

SUPPLEMENTARY INFORMATION:

Electronic Access

Several of the background documents for this interim final rule and the take reduction planning process can be downloaded from the ALWTRP web site at http://www.nero.nmfs.gov/whaletrp/.

Background

The ALWTRP was developed pursuant to the Marine Mammal Protection Act (MMPA) to reduce the level of serious injury/mortality of all large whale species in East Coast lobster trap and finfish gillnet fisheries. The background for the take reduction planning process and development of the ALWTRP is set out in the preamble to the proposed (62 FR 16519, April 7, 1997), interim final (62 FR 39157, July 22, 1997), and final (64 FR 7529, February 16, 1999) rules implementing the ALWTRP. Additional information is available in the report from the ALWTRT after its recent series of meetings in 2000. Copies of these documents and supporting Environmental Assessments (EAs) are available from the NMFS/Northeast Region contact in the **ADDRESSES** section of this document.

Because of the status of the right whale population, there is a need to further reduce entanglement. The interim final rule published December 21, 2000, (65 FR 80368), with an effective date of January 22, 2001, implemented gear modifications (buoy line weak links, net panel weak links with anchoring systems, restrictions on number of buoy lines, and gear marking) that were initially discussed in the 1997 proposed and 1999 final rules and recommended by the TRT after the 2000 meetings. NMFS responded to these recommendations by promulgating the gear modifications in the December 21, 2000, interim final rule. It was agreed that the regulations implementing these gear modifications should be issued as soon as practicable. However, due to rough January weather conditions in the Gulf of Maine, effected fishers will be unable to retrieve and modify active gear by the January 22, 2001 effective date. This interim final rule delays the effective date until February 21, 2001, to allow fishers time to implement the gear modifications.

NMFS expects that a delay of the rule to February 21, 2001 will have minimal impact on the North Atlantic right whale population. Available sighting data for the January through February period suggests that most right whales in New England are congregated in Cape Cod Bay. Data reported by the NE Right Whale Alert System during 1999–2001, included only two sightings of right whales in New England waters outside of Cape Cod Bay. Whales do not begin to leave the Bay until late March (when they move to Stellwagen Bank and then perhaps on to the Great South Channel Area) by which time gear will have been modified as per the Interim Final Rule. Thus, the 30 day delay is not expected to adversely affect right whales in these waters.

Classification

An Environmental Assessment (EA) describing the impacts to the environment that would result from the implementation of the ALWTRP was prepared for the July 22, 1997, interim final rule (62 FR 39157). Supplemental EAs were also prepared for the April 9, 1999, final rule (64 FR 17292) and the December 21, 2000, interim final rule (65 FR 80368). The conclusion of those EAs was that the ALWTRP's actions would pose no significant adverse environmental impact. The delay of the effective date by 30 days does not change the determination of those EAs. This action is categorically excluded from further review because it is an action of limited size and magnitude that does not result in a significant change in the original action.

This interim final rule has been determined to be not significant for purposes of Executive Order 12866.

Given the status of the species to be protected and the fact that entanglements continue to occur under the existing regulations, the Assistant Administrator for Fisheries (AA) NOAA, for good cause under 5 U.S.C. 553(b)(3)(B), found that extending the December 21, 2000, interim final rule (65 FR 80368) to allow for prior notice and an opportunity for public comment

would be contrary to the public interest. In addition, the AA finds for good cause under 5 U.S.C. 553(b)(3) that extending this interim final rule for prior notice and an opportunity for public comment would be contrary to the public interest. It would be unfair to subject fishers to changes in gear requirements under the December 21, 2000 interim final rule (65 FR 80368) when, due to weather, the affected fishers have been unable to implement these changes. Because prior notice and an opportunity for public comment are not required to be provided for this interim final rule by 5 U.S.C. 553 or by any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, are inapplicable.

This interim final rule delays implementation of a collection-of information requirement subject to the Paperwork Reduction Act that has already been approved by Office of Management and Budget (OMB control number: 0648–0364).

A biological opinion (BO) on the ALWTRP was finalized on July 15, 1997. That opinion concluded that implementation of the ALWTRP and continued operation of fisheries conducted under the American Lobster, Northeast Multispecies, and Shark Fishery Management Plans (FMPs), as modified by the ALWTRP, may adversely affect, but are not likely to jeopardize the continued existence of any listed species or adversely modify critical habitat. A further determination was made that the February 16, 1999, final rule (64 FR 7529) did not change the basis for that BO. NMFS also determined that the December 21, 2000, interim final rule (65 FR 80368) does not change the basis for the 1997 and 1999 ESA determinations. Because this interim final rule simply delays the effective date of the December 21, 2000, interim final rule, NMFS finds this action also does not change the basis for that BO.

This interim final rule should have no adverse impacts on marine mammals. Whale entanglement rates are not expected to increase significantly as a result of this action.

This interim final rule does not change the determination for the December 21, 2000, interim final rule (65 FR 80368) that the ALWTRP will be implemented in a manner that is consistent to the maximum extent practicable with the approved coastal zone management programs of the U.S. Atlantic coastal states.

This interim final rule does not contain policies with federalism implications sufficient to warrant preparation of a federalism assessment under Executive Order 12612.

This interim final rule is promulgated in compliance with all procedural requirements established by the Administrative Procedure Act.

Plain Language Requirement for Rulemaking

The President has directed Federal agencies to use plain language in their communications with the public, including regulations. To comply with this directive, we seek public comment on any ambiguity or unnecessary complexity arising from the language used in this interim final rule. Send comments to the NMFS Marine Mammal Division Chief (see **ADDRESSES**).

List of Subjects in 50 CFR Part 229

Administrative practice and procedure, Confidential business information, Fisheries, Marine mammals, Reporting and recordkeeping requirements.

Dated: January 12, 2001.

William T. Hogarth,

Deputy Assistant Administrator for Fisheries, National Marine Fisheries Service.

[FR Doc. 01–1589 Filed 1–18–01; 8:45 am]

BILLING CODE 3510–22–S

Proposed Rules

Federal Register
Vol. 66, No. 13
Friday, January 19, 2001

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 575

RIN 3206–AJ08

Recruitment and Relocation Bonuses and Retention Allowances

AGENCY: Office of Personnel Management.

ACTION: Proposed rule with request for comments.

SUMMARY: The Office of Personnel Management (OPM) is issuing proposed regulations to provide agencies with greater flexibility to use recruitment and relocation bonuses and retention allowances. These proposed regulations would provide agencies with the flexibility to pay retention allowances to employees who are likely to leave their positions for other Federal employment under certain limited circumstances. This proposal also would allow agencies to pay recruitment and relocation bonuses and retention allowances to prevailing rate (wage) employees.

DATES: Comments must be received on or before March 20, 2001.

FOR FURTHER INFORMATION CONTACT: Jeanne Jacobson, (202) 606–2858; FAX: (202) 606–0824; email: payleave@opm.gov.

ADDRESSES: Comments may be sent or delivered to Donald J. Winstead, Assistant Director for Compensation Administration, Workforce Compensation and Performance Service, Office of Personnel Management, Room 7H31, 1900 E Street NW., Washington, DC 20415, FAX: (202) 606–0824, or email: *payleave@opm.gov.*

SUPPLEMENTARY INFORMATION: The Office of Personnel Management (OPM) is proposing to amend the recruitment and relocation bonus and retention allowance regulations in 5 CFR part 575, subparts A, B, and C, to provide agencies with additional flexibility to use these incentives. The proposed regulations would allow agencies to grant a retention allowance to a current employee likely to leave for other Federal employment under certain limited circumstances. The proposed regulations also would allow agencies to pay recruitment and relocation bonuses and retention allowances to prevailing rate (wage) employees.

Retention Allowances for Employees Likely To Leave for Other Federal Employment

Under current law (5 U.S.C. 5754), OPM may authorize agencies to grant a retention allowance to an employee if the unusually high or unique qualifications of the employee or a special need for the employee's services makes it essential to retain the employee, and the agency determines that the employee would be likely to leave in the absence of an allowance. Our regulations initially authorized agencies to grant retention allowances only if the employee was likely to leave the Federal service for employment outside the executive, legislative, or judicial branch of the Federal Government (60 FR 12833, March 28, 1991). Later, we broadened this authority to provide agencies with the flexibility to grant retention allowances to employees who were likely to leave the Federal service for any reason (60 FR 33323, June 28, 1995). We did not authorize agencies to pay retention allowances to employees likely to leave for other Federal employment because of concerns about potentially disruptive and costly bidding wars among Federal agencies competing for employees with highly desired skills or competencies.

Agencies have recently requested that OPM amend its regulations to authorize retention allowances for employees likely to leave for other Federal employment in certain limited circumstances. We recognize that agencies may experience significant staffing problems that hinder their ability to meet mission objectives when their employees leave for other Federal jobs. In some cases, the retention allowance authority may be the most effective way to resolve such problems. However, we must also continue to be cognizant of the potential costs of interagency competition.

We propose to amend the regulations at 5 CFR 575.304(b) to allow agencies to pay a retention allowance to an employee likely to leave for other Federal employment when (1) the other Federal position is under a different pay system (with certain exceptions) or (2) it is essential to retain the employee during a temporary but critical work situation. (Agencies would continue to have authority under § 575.304(b)(1) to pay retention allowances to employees who are likely to leave the Federal service for any reason.)

Section 575.304(b)(2) of the proposed regulations would authorize an agency to pay a retention allowance to an employee likely to leave for another Federal position that is under a pay system that is different from the pay system of the employee's current position. The proposed regulations would prohibit agencies from using this authority to pay retention allowances to an employee likely to leave for a General Schedule (GS), prevailing rate (wage), senior-level and scientific or professional (SL/ST), Senior Executive Service (SES), administrative law judge (ALJ), Executive Schedule (EX), or Board of Contract Appeals (BCA) position when his or her current position is also under any of these pay systems. (See proposed § 575.304(d).)

For example, using this new authority an agency could pay a retention allowance to a General Schedule employee likely to leave for a higher-paying position under a pay system outside of title 5, United States Code, (*e.g.,* the Federal Aviation Administration). In this situation, the recruiting agency may have independent statutory authority to offer salaries or other incentives that are greater than those available under the General Schedule, making it very difficult for the employee's current agency to compete effectively. We believe allowing agencies to grant retention allowances in such situations will help level the playing field among agencies with similar staffing needs.

Section 575.304(b)(3) of the proposed regulations would allow Federal agencies to grant retention allowances to an employee likely to leave for other Federal employment (under the same or different pay system) during temporary but critical staffing situations. Private sector organizations pay ''staying-on'' or ''retention bonuses'' to help retain employees and keep operations running smoothly during ''crisis'' situations, such as mergers, acquisitions, and plant closings. We believe it would be reasonable to allow Federal agencies to use the retention allowance authority on

a temporary basis to help retain experienced employees who otherwise would be likely to leave during similar critical periods.

For example, an agency may need to retain an employee until the completion of a project critical to the mission of the agency or during the closure of a facility or office or the relocation of an office or facility to a different commuting area. Such employees may be likely to leave for other Federal employment if, for example, the agency has announced that it will eliminate or substantially change the duties of the employee's position as a result of the critical situation or upon completion of the important project or if the office relocation will compel the employee to change his or her residence to continue employment. A retention allowance may help entice an employee to stay through the temporary but critical work period.

To help ensure that agencies use this new authority only for temporary staffing difficulties, § 575.307(b) would limit payment of retention allowances to an employee working on a critical project to a period of no longer than 1 year. On a case-by-case basis, the head of an agency may ask OPM to extend this time limit. The proposed regulations would allow an agency to pay retention allowances to an employee likely to leave for other Federal employment prior to an office closure or relocation as long as the agency continues to have an essential need for the employee's services.

When authorizing a retention allowance for an employee likely to leave for other Federal employment under § 575.304(b)(2) and (3), the proposed regulations would require agencies to follow the payment criteria and documentation provisions currently prescribed in § 575.305(c). In addition, before approving a retention allowance for an employee who is likely to leave during a critical work period, § 575.305(c)(2) of the proposed regulations would require the agency to determine how the employee's departure would affect its ability to function effectively during the critical period.

The proposed regulations at § 575.305(c)(3)(iii) also would require agencies to consider other relevant factors when authorizing a retention allowance and determining the amount for an employee who is likely to leave for other Federal employment. These factors may include the likelihood of attracting candidates to fill the employee's position if the agency has announced that it will relocate the position, the cost and time required to hire and train a new employee to complete a critical project, or the salaries typically paid by another Federal agency.

To help avoid unwarranted and possibly costly interagency competition, § 575.305(c)(4) of the proposed regulations also would require agencies to consider the use of non-pay alternatives to help resolve staffing problems before paying a retention allowance to an employee likely to leave for another Federal position. Such non-pay alternatives may include alternative recruitment strategies; use of temporary or term appointments or appointments with varying work schedules, such as part-time, intermittent, and seasonal schedules; employment of experts and consultants; alternative work schedules (*i.e.,* flexible or compressed work schedules), job sharing, and telecommuting arrangements; paying or sharing the cost of employee training and higher education; or redesigning jobs so that a larger pool of candidates may qualify for a position or to make a job more appealing to candidates by adding desirable duties or eliminating undesirable duties.

All other conditions and requirements for paying a retention allowance under 5 CFR part 575, subpart C, would continue to apply to employees who receive an allowance on the basis of being likely to leave for other Federal employment. For example, §§ 575.306(c) and 575.307(b) would require agencies to reduce or terminate a retention allowance paid to an employee likely to leave for other Federal employment when the conditions giving rise to the original determination to pay the allowance have changed. In addition, under § 575.307(d)(4), an agency could authorize a retention allowance of up to 10 percent (or up to 25 percent with OPM approval) of an employee's rate of basic pay for a group or category of employees likely to leave for other Federal employment. (In response to agency inquiries, the proposed regulations at § 575.305(c)(1) clarify that, when the group retention allowance authority is not used, agencies must make likely-to-leave determinations (for any reason, including for other Federal employment) only on an individual, case-by-case basis.)

Recruitment, Relocation, and Retention Payments for Prevailing Rate (Wage) Employees

Sections 5753(e) and 5754(e) of title 5, United States Code, permit the President to authorize the application of recruitment, relocation, and retention payments to one or more categories of employees in an agency who would not otherwise be covered by these provisions of law upon the request of the head of the agency. Under section 6 of Executive Order 12748 of February 1, 1991, the President delegated this authority to the Director of OPM. In response to an agency request, these proposed regulations would provide agencies with discretionary authority to pay recruitment and relocation bonuses and retention allowances to an employee in a prevailing rate (wage) position, as defined in 5 U.S.C. 5342(a)(3). This would include Federal Wage System or ''wage grade'' employees. Under the proposed regulations, the same payment criteria, procedures, and documentation requirements that apply to other covered groups of employees also would apply to wage employees.

E.O. 12866, Regulatory Review

This rule has been reviewed by the Office of Management and Budget in accordance with E.O. 12866.

Regulatory Flexibility Act

I certify that these regulations would not have a significant economic impact on a substantial number of small entities because they would apply only to Federal agencies and employees.

List of Subjects in 5 CFR Part 575

Government employees, Wages.

U.S. Office of Personnel Management.

Janice R. Lachance,

Director.

Accordingly, OPM is proposing to amend part 575 of title 5, Code of Federal Regulations, as follows:

PART 575—RECRUITMENT AND RELOCATION BONUSES; RETENTION ALLOWANCES; SUPERVISORY DIFFERENTIALS

1. The authority citation for part 575 continues to read as follows:

Authority: 5 U.S.C. 1104(a)(2), 5753, 5754, and 5755; secs. 302 and 404 of the Federal Employees Pay Comparability Act of 1990 (FEPCA) (Pub. L. 101–509), 104 Stat. 1462 and 1466, respectively; E.O. 12748, 3 CFR, 1992 Comp., p. 316.

Subpart A—Recruitment Bonuses

2. In § 575.102, paragraph (a)(5) is amended by removing ''or''; paragraph (a)(6) is amended by removing ''.'' and inserting in its place ''; or''; and a new paragraph (a)(7) is added to read as follows:

§ 575.102 Delegation of authority.

(a) * * *

(7) A prevailing rate position, as defined in 5 U.S.C. 5342(a)(3).

* * * * *

Subpart B—Relocation Bonuses

3. In § 575.202, paragraph (a)(5) is amended by removing ''or''; paragraph (a)(6) is amended by removing ''.'' and inserting in its place ''; or''; and a new paragraph (a)(7) is added to read as follows:

§ 575.202 Delegation of authority.

(a) * * *

(7) A prevailing rate position, as defined in 5 U.S.C. 5342(a)(3).

* * * * *

Subpart C—Retention Allowances

4. In § 575.302, paragraph (a)(5) is amended by removing ''or''; paragraph (a)(6) is amended by removing ''.'' and inserting in its place ''; or''; and paragraph (a)(7) is added to read as follows:

§ 575.302 Delegation of authority.

(a) * * *

(7) A prevailing rate position, as defined in 5 U.S.C. 5342(a)(3).

* * * * *

5. In § 575.303, the definition of *commuting area* is added in alphabetical order to read as follows:

§ 575.303 Definitions.

* * * * *

Commuting area has the meaning given that term in § 575.203.

* * * * *

6. In § 575.304, paragraph (d) is redesignated as paragraph (e), paragraphs (b) and (c) are revised, and a new paragraph (d) is added, to read as follows:

§ 575.304 Conditions for payment.

* * * * *

(b) An agency may consider an employee likely to leave if he or she is—

(1) Likely to leave the Federal service for any reason;

(2) Likely to leave his or her position for another Federal position under a different pay system (except as provided in paragraph (c) of this section); or

(3) Likely to leave his or her position for a position under the same or different Federal pay system prior to the closure of the employee's office or facility; relocation of the employee's office or facility to a different commuting area; or the completion of a project critical to the mission of an agency.

(c) An agency may not pay a retention allowance under paragraph (b)(2) of this section to an employee likely to leave for a General Schedule, prevailing rate (wage), senior-level and scientific or professional, Senior Executive Service, administrative law judge, Executive Schedule, or Board of Contract Appeals position when his or her current position is also under any of these pay systems.

(d) An agency may not pay a retention allowance to an employee who is likely to leave his or her position for another Federal position other than under the conditions described in paragraphs (b)(2) and (3) of this section.

* * * * *

7. In § 575.305, paragraphs (a)(2)(iii), (c), and (d)(1)(i) are revised to read as follows:

§ 575.305 Agency retention allowance plans; higher level review and approval; and criteria for payment.

(a) * * *

(2) * * *

(iii) Procedures for paying allowances; and

* * * * *

(c) *Criteria for payment.* (1) An agency must base each allowance paid under this subpart on a written determination that the unusually high or unique qualifications of the employee or a special need of the agency for the employee's services makes it essential to retain the employee and that, in the absence of such an allowance, the employee would be likely to leave under one of the conditions specified in § 575.304(b). Except when using the group retention allowance authority under paragraph (d) of this section, an agency must make the determination that an employee is likely to leave on an individual, case-by-case basis.

(2) An agency must base the determination required by paragraph (c)(1) of this section on a written description of the extent to which the employee's departure would affect the agency's ability to carry out an activity or perform a function that the agency deems essential to its mission or to operate effectively during a critical period.

(3) An agency must consider the following factors, as applicable in the case at hand, in determining whether to pay a retention allowance and the amount of any such payment:

(i) The success of recent efforts to recruit candidates and retain employees with qualifications similar to those possessed by the employee for positions similar to the position held by the employee;

(ii) The availability in the labor market of candidates for employment who, with minimal training or disruption of service to the public, could perform the full range of duties and responsibilities of the employee's position; or

(iii) Other supporting factors, such as the likelihood of attracting candidates to fill the employee's position if the agency has announced that it will soon relocate the position, the cost and time required to hire and train a new employee to complete a critical, time-sensitive project, or the salaries typically paid by another Federal agency.

(4) For an employee likely to leave for other Federal employment under the conditions described in § 575.304(b)(2) and (3), the agency must consider the use of non-pay solutions to help retain the employee before authorizing a retention allowance. Such solutions may include conducting an aggressive recruiting program, using alternative appointing authorities, redesigning jobs, establishing training programs, implementing alternative work schedules, or improving working conditions.

(d) * * *

(1)(i) An agency may authorize a retention allowance of up to 10 percent of an employee's rate of basic pay for a group or category of employees (excluding individuals covered by § 575.302(a)(2), (3), (5), or (6) or those in similar positions to which OPM has delegated authority to approve retention allowances to agency heads under § 575.302(c)). An agency must determine in writing that the category of employees has unusually high or unique qualifications, or that the agency has a special need for the employees' services that makes it essential to retain the employees in that category. The agency must also determine in writing that it is reasonable to presume that there is a high risk that a significant number of employees in the targeted category are likely to leave under one of the conditions specified in § 575.304(b) in the absence of an allowance.

* * * * *

8. In § 575.306, paragraph (c) is revised to read as follows:

§ 575.306 Payment of retention allowance.

* * * * *

(c) An agency may continue paying a retention allowance as long as the conditions giving rise to the original determination to pay the allowance still exist, except as provided in § 575.307(a) and (b). However, at least annually, the agency must review each determination to pay an allowance to determine whether payment is still warranted. The agency approving official must certify this determination in writing.

* * * * *

9. In § 575.307, paragraphs (b) and (c) are redesignated as paragraphs (c) and

(d), respectively, and a new paragraph (b) is added to read as follows:

§ 575.307 Reduction or termination of retention allowance.

* * * * *

(b) An agency must terminate a retention allowance paid to an employee (or group of employees) under § 575.304(b)(3) (for work on a project critical to the mission of the agency) not later than 1 year after the initial allowance payment. On a case-by-case basis, the head of an agency may ask OPM to extend this time limit.

* * * * *

[FR Doc. 01–1486 Filed 1–18–01; 8:45 am]

BILLING CODE 6325–01–P

SOCIAL SECURITY ADMINISTRATION

20 CFR Parts 404, 416, and 422

[Regulations Nos. 4 and 16]

RIN 0960–AF44

New Disability Claims Process

AGENCY: Social Security Administration (SSA).

ACTION: Notice of proposed rulemaking.

SUMMARY: We are proposing to revise our regulations that pertain to the processing of initial claims for disability benefits under title II (Social Security Disability Insurance) and title XVI (Supplemental Security Income) of the Social Security Act (the Act). The proposed rules would incorporate modifications to our administrative review process and disability determination procedures based on testing that we are conducting. The changes, which would apply to initial applications for disability benefits, would:

- First, permit disability examiners in our State agencies the flexibility to decide whether input from a medical or psychological consultant is needed to make a disability determination, so that our State agencies may use the expertise of the disability examiners and medical and psychological consultants more effectively;
- Second, provide claimants with an opportunity for an informal disability conference with the adjudicators of their claims at the initial level in cases in which it appears that the evidence does not support a fully favorable determination; and
- Third, eliminate the reconsideration step of the administrative review process.

We plan to phase in these changes over a period of 1 year until they apply in every State.

DATES: To be sure that your comments are considered, we must receive them no later than March 20, 2001.

ADDRESSES: Comments should be submitted to the Commissioner of Social Security, P.O. Box 17703, Baltimore, Maryland 21235–7703; sent by telefax to (410) 966–2830; sent by e-mail to *regulations@ssa.gov;* or delivered to the Office of Process and Innovation Management, Social Security Administration, L2109 West Low Rise Building, 6401 Security Boulevard, Baltimore, MD 21235–6401, between 8:00 a.m. and 4:30 p.m. on regular business days. During these same hours, you may inspect the comments that we receive by making arrangements with the contact person shown below.

FOR FURTHER INFORMATION CONTACT: Georgia E. Myers, Regulations Officer, Office of Process and Innovation Management, L2109 West Low Rise Building, 6401 Security Boulevard, Baltimore, MD 21235–6401, (410) 965–3632 or TTY (410) 966–5609, for information about this notice. For information on eligibility or claiming benefits, call our national toll-free number, 1–800–772–1213 or TTY 1–800–325–0778, or visit our Internet web site, Social Security Online, at www.ssa.gov.

SUPPLEMENTARY INFORMATION:

In Brief, What Are We Proposing To Do?

We are proposing to change our rules in three ways:

1. We are proposing to change our rules for how State agencies make disability determinations for us. The change would allow State agency adjudicators, called ''disability examiners,'' to decide whether input from a medical or psychological consultant is needed to make a disability determination. The medical or psychological consultant would not be responsible for the determination; *i.e.,* would not be an adjudicator of the claim.
2. We are proposing to add rules providing that disability examiners will offer claimants an opportunity for an informal conference whenever it appears that the evidence does not support a fully favorable determination.
3. We are proposing to eliminate the reconsideration step of our administrative review process.

On August 30, 1999, we published a notice in the **Federal Register** announcing a ''prototype'' involving these three major modifications to our disability determination process for initial applications under titles II and XVI of the Act. (See 64 FR 47218.) In the notice, we stated that, before proceeding to national implementation, we expected that the prototype would provide a body of information about the impact of these modifications on agency operations, notice and other procedures, and the quality and timeliness of our determinations and decisions. Although the prototype is continuing and we continue to gather information and gain operational experience, we believe that we now have sufficient information to propose changes to our regulations. Public comments received on these proposed changes will assist us in fine-tuning these changes.

Because we now know that implementation of the process in each State agency requires support during the period of transition, we are considering a plan by which we would implement the process in groups of State agencies until all States use the new process. Our projected completion date will be in 2003. We explain our current plan in more detail later in this preamble, and invite public comment.

What Is the Current Process?

Sections 404.1503 and 416.903 of our regulations provide that State agencies make disability and blindness determinations, following rules that we provide. Sections 404.1615(c) and 416.1015(c) of our regulations provide with respect to initial disability claims that, in most cases, these disability determinations must be made by a State agency medical or psychological consultant and a State agency disability examiner, a lay adjudicator with expertise in evaluating disability. The medical or psychological consultant and the disability examiner work together as a team and are jointly responsible for the determination. Under current rules, a disability examiner alone may make a determination only in the very unusual circumstance in which:

- There is no medical evidence to be evaluated (*i.e.,* no medical evidence exists or we are unable, despite making every reasonable effort, to obtain any medical evidence that may exist); and
- The individual fails or refuses, without good reason, to attend a consultative examination.

State agency determinations in initial claims are generally based on review of the written information in a claimant's case record. Although our procedures permit disability examiners and medical and psychological consultants to speak to claimants to obtain more information, there are no formal requirements for such contact. Also, we have no procedures requiring a State agency adjudicator to explain and discuss our disability standards with claimants or to

explain the determination, apart from the information that we provide in the written notice of determination; *i.e.,* after we have already made the determination.

Sections 205(b)(1) and 1631(c)(1)(A) of the Act provide that an individual who disagrees with our initial determination has a right to a hearing. However, §§ 404.900 and 404.907 (for title II) and 416.1400 and 416.1407 (for title XVI) of our regulations have long provided that, when an individual is dissatisfied with an initial determination, he or she may appeal the determination first to the ''reconsideration'' level of our administrative review process. In initial disability claims, the reconsideration determination consists of a case review of evidence from the initial claim as well as evidence obtained subsequently. Only after the reconsideration determination may individuals who are dissatisfied with their determinations appeal to a hearing before an administrative law judge.

What Led Us to These Proposed Rules?

For many years, we have been exploring methods for improving the disability determination process to make it more consistent, accurate, efficient, and timely. For example, for several years we have engaged in what we call ''process unification'' activities aimed at improving our ability to achieve similar results in similar cases at all stages of the administrative review process. In 1995, we also published § § 404.906 and 416.1406, ''Testing modifications to the disability determination procedures,'' which permitted us to test a number of variations to our current processes. We called the various test processes ''models.'' (See 60 FR 20023, April 24, 1995.)

Among the models that we included in § § 404.906 and 416.1406 were revisions to our current process that would permit a disability examiner in the State agency to assume sole authority for making disability determinations in certain cases, thereby giving examiners the flexibility to decide whether to obtain input from a medical or psychological consultant when making the disability determination. One of the models also included a ''predecision interview'' with the claimant to ensure that the case record was complete and that the claimant understood our disability standards. In the preamble to the Notice of Proposed Rulemaking (NPRM) for these rules, we indicated that in recent years we had conducted various studies on how to improve the disability determination process, and that we had a number of goals in proposing the models. We stated that our goals were:

- To provide assistance to the disability applicant by making the filing of a disability claim simpler;
- To promote fairness in each disability determination by ensuring that each disability applicant is given an opportunity to provide all of the necessary information to complete the claim and is aware of his or her rights under the program; and
- To ensure that our determination is equitable. (See 58 FR 54532, 54533, October 22, 1993.)

In 1994, we included a number of similar features in our proposal to redesign the disability claims process and the subsequent final redesign plan. (See 59 FR 18188, April 15, 1994, and 59 FR 47887, September 19, 1994.) Both the redesign proposal and the final plan were especially critical of:

- The time it takes for us to adjudicate some disability claims,
- The number of SSA and State agency employees who may be involved in processing a claim initially and throughout the appeals process,
- The lack of interaction between the claimant and the decisionmaker, and
- The lack of thorough explanations, in many cases, of the basis for the disability determinations.

Therefore, the redesign of the disability process included the following goals that are important to this NPRM:

- To ensure that claims that should be allowed are allowed at the earliest point in the process;
- To provide more opportunity for claimant interaction with the decisionmaker; and
- To reduce the amount of time required processing a claim to a final disability determination or decision.

Over the years since 1994, we have tested various ideas for addressing these goals and improving the claims process. For example, in 1997, we integrated several of the redesign proposals into what we called the ''Full Process Model.'' We tested this model in eight States and got especially positive results from several features of the model:

- We allowed disability examiners the flexibility to decide whether to obtain medical or psychological consultant input in making a disability determination. (This did not apply to certain cases, described below, in which the Act requires a medical or psychological consultant or other health care professional to participate in making the determination.) This process change revised the role of the medical and psychological consultants to act as true consultants in these cases, to be used as needed.
- We provided claimants with an opportunity for a conference with the disability examiners who were deciding their claims when it appeared that the evidence was not sufficient to support a fully favorable determination. This gave claimants an opportunity to provide additional explanations and evidence, or sources of evidence. The disability examiners also explained the Social Security definition of disability and why it appeared that the claimants did not meet that definition or why it did not appear that the evidence supported a fully favorable determination.
- Finally, we eliminated the reconsideration step of the administrative review process. Claimants who were dissatisfied with their initial determinations appealed directly to the administrative law judge hearing level.

We found that these actions resulted in better determinations at the initial level, with more allowances of claims that should have been allowed. We believe that many claims that would have been allowed only after appeal under the old process were allowed at the initial step under the new process. These claimants were able to receive benefits months sooner than they otherwise would have, an important protection for individuals who are unable to work. By eliminating the reconsideration step, claimants who appealed reached the hearing level an average of 2 months sooner than claimants who went through the reconsideration step and therefore had an opportunity to receive their hearing decisions sooner. Also, the quality of our determinations improved. Reviews of disability determinations from the FPM by SSA's Office of Quality Assessment indicated that the new process improved the accuracy of initial decisions to deny claims from 92.6 percent to 94.8 percent. If implemented nationally, this would translate to approximately 34,000 fewer disabled claimants being erroneously denied benefits and facing the prospect of a lengthy appeal.

We believe that these positive results were due to a number of factors. For example, we know that removing the reconsideration step permitted the State agencies to redirect their resources so that the individuals who formerly worked on reconsideration claims could work on initial claims. This permitted increased contact with the claimants and improved documentation of the disability determinations.

The success of the Full Process Model provided the impetus for our current

prototype, which includes the three most successful elements of the Full Process Model, the elements we are proposing in this Notice of Proposed Rulemaking (NPRM). We have been operating the prototype in 10 States since October 1999. The States are: Alabama, Alaska, California, Colorado, Louisiana, Michigan, Missouri, New Hampshire, New York, and Pennsylvania. In New York at this time, the prototype applies only to residents in areas served by the Albany and Brooklyn branches of the State agency. In California, it applies only to residents in areas served by the Los Angeles North and Los Angeles West branches of the State agency.

This notice pertains to features that have been used in these Prototype States. We continue testing other features that were part of the 1995 proposal separately from the prototype process, but this notice does not pertain to those features.

What Are the Key Features of the Proposed Rules?

The process we are proposing in this NPRM is similar to the prototype process with some modifications based on our experience with the Full Process Model and in the prototype States. The following are the key features and our reasons for proposing them. We explain the specific changes in the proposed rules in detail later in this preamble.

1. Enhanced Roles of State Agency Disability Examiners and Medical and Psychological Consultants

By ''enhanced roles'' of these individuals, we mean that disability examiners would be responsible for making the disability determination in many claims, and may decide whether medical consultant or psychological consultant input is needed. We also mean that medical or psychological consultants will serve as true consultants in these claims by providing review and advice in cases with difficult or complex medical issues. Medical and psychological consultants would be expected to participate in training and mentoring the disability examiners. This change would let us better use the expertise of our adjudicators and medical resources, minimize file handoffs and allow State agencies to make disability determinations in a more timely and cost-effective manner.

However, the proposed rules provide two situations in which a medical or psychological consultant must be involved in assessing disability because of requirements in the Act:

- Sections 221(h) and 1614(a)(3)(H) of the Act, and §§ 404.1503(e), 404.1615(d), 416.903(e), and 416.1015(e) of our regulations require that, before we may find an individual ''not disabled'' in any case in which there is evidence of a mental impairment, we will make every reasonable effort to ensure that a qualified psychiatrist or psychologist has completed the medical portion of the case review and any applicable residual functional capacity assessment. Therefore, the proposed rules provide that a disability examiner alone may make a fully favorable determination, but that any determination that is less than fully favorable must be made by a team that includes a medical or psychological consultant, as under current procedures. However, in these cases, the disability examiner will still offer a claimant conference, and the first stage of appeal will be to the administrative law judge hearing level.
- Section 1614(a)(3)(I) of the Act and §§ 416.903(f) and 416.1015(e) of our regulations require that, for all claims for childhood disability benefits under title XVI, we will make reasonable efforts to ensure that a qualified pediatrician or other individual who specializes in a field of medicine appropriate to the child's impairment(s) evaluates the case of the child. Therefore, the proposed rules provide that we must use disability examiners and medical or psychological consultants as a team in all determinations of childhood disability under title XVI, including fully favorable determinations. However, the disability examiner will still offer a claimant conference, and appeal will be to the administrative law judge hearing level.

We also provide that, in addition to these two mandatory situations in which a determination is made by a disability examiner and medical or psychological consultant team, State agencies may require medical or psychological consultant involvement in other cases. For example, we would expect a State agency to require its trainees and other less experienced disability examiners to work in teams with medical and psychological consultants until they have become sufficiently expert to determine cases alone.

- We are proposing this change because our experience in the prototype States continues to affirm the successes we had in the Full Process Model. We believe that enhancing the roles of disability examiners and medical and psychological consultants will maximize the effectiveness of adjudicative resources, focusing State agency medical and psychological consultants on duties and responsibilities commensurate with their training and experience. Furthermore, evidence from the Full Process Model as well as the prototype States shows that the accuracy of initial determinations improves, reducing the likelihood that a disabled claimant will have to go through the appeals process in order to receive benefits for which he or she is eligible.

2. Increased Contact Between Claimants and Adjudicators

The proposed rules would require disability examiners to provide claimants with an opportunity for an ''informal disability conference'' in any claim in which the evidence does not appear to support a fully favorable determination. By ''fully favorable'' we mean a determination that the claimant is (1) disabled and (2) that the determination matches the claimant's allegations about onset of disability and (3) that the claimant is still disabled at the time of the determination.

The purpose of the conference would be to:

- Explain our disability requirements to the claimant;
- Explain why the facts currently in the case record indicate that the determination should be less than fully favorable; and
- Ensure that we have identified and made every reasonable effort to obtain relevant evidence from all appropriate sources.

The proposed rules do not prohibit a disability examiner from contacting a claimant at other times. For example, a disability examiner may contact a claimant before he or she requests any evidence to ensure that the information in the case file about the claimant's medical sources is complete. However, under the proposed rules, the disability examiner must still make contact with the claimant at or near the end of the process, when the disability examiner believes that he or she has obtained sufficient evidence on which to base a determination and it appears that the determination will be less than fully favorable.

Our experience in the Full Process Model and the prototype States has shown that increased interaction between claimants and disability examiners makes the process more personal, and it changes the determinations in some claims because of new information provided by claimants during their conferences.

3. Eliminate the Reconsideration Step of the Administrative Review Process for Initial Disability Claims

We are proposing to remove the reconsideration step of our administrative review process in all determinations on initial disability applications except appeals of determinations based on a finding that the claimant is engaging in, or has engaged in, substantial gainful activity. Findings about substantial gainful activity are made in our field offices, not in the State agencies, and the appropriate appeal will continue to be to the reconsideration level.

We are proposing this change primarily because evidence indicates that the reconsideration step adds little value to the disability determination process, at a great cost of staffing resources and processing time. Eliminating the reconsideration step permits State agencies to use their resources to make better determinations at the initial level, thereby increasing the accuracy of initial determinations. It will also provide an opportunity for denied claimants to request a hearing sooner than under the current process and, therefore, result in earlier administrative law judge decisions in many claims.

How Do We Plan To Implement the New Disability Claims Process?

We have determined that it is not feasible to change over to the new process in all of our State agencies all at once. As we have already noted, it is clear from both the Full Process Model and the Prototype that each State will need substantial lead time for training and preparation, and we must retain our capacity to process new claims as timely as possible during implementation.

We believe that our only option for accomplishing this goal is to implement the redesigned process in smaller groups of States in several stages over approximately a 1-year period beginning with the publication of the final rules that result from this NPRM. This will permit us to plan and conduct critical activities in each group of States, such as training, systems enhancement, staffing, and workload management. Most importantly, a staged implementation will also allow us to minimize delays in processing claims. Our goal is to ensure to the extent possible that, while we implement the new process, we continue to make all of our disability determinations timely.

Therefore, the proposed rules explain that only individuals whose cases are adjudicated by State agencies that have implemented the new process will be subject to the new rules. In the proposed revisions, we have described which cases are subject to the new rules and which will continue to be adjudicated under the current rules.

To make clear which cases will be handled using the new rules, we are proposing to include a new temporary appendix 1 to subpart J of part 404 that lists participating State agencies and the criteria for identifying which cases will be handled under the proposed rules. We are printing the appendix only in part 404 to save space; the proposed rules in part 416 cross-refer to the appendix in part 404. As we add more State agencies, we will publish an appropriate notice in the **Federal Register** changing the appendix to include them.

When all State agencies are using the new rules, we will publish rules removing the appendix and all language in the proposed rules that indicates that there are two processes.

What Are the Specific Provisions of the Proposed Rules?

The following are the major revisions of the proposed rules:

Proposed §§ 404.904 and 416.1404 Informal Disability Conference

We are proposing to redesignate current §§ 404.904 and 416.1404, ''Notice of the initial determination,'' as §§ 404.904a and 416.1404a so that we can insert these new provisions. Proposed §§ 404.904 and 416.1404 would provide our rules explaining:

- Who will be offered an informal disability conference;
- What a disability conference is; and
- The procedures associated with the informal disability conference.

Paragraph (a), ''What is an informal disability conference?'' explains that we will offer a claimant an informal disability conference in a case of an initial application for benefits if the individual meets all of the following factors:

1. Based on the evidence in the individual's case record, it appears that we will not be able to make a ''fully favorable'' determination, except if the determination will be based on a finding that the individual is, or was, engaging in substantial gainful activity. We provide an explanation of what we mean by a ''fully favorable'' determination and to specify what is ''not fully favorable'' for purposes of this section. We adopted the language for the definition of a ''fully favorable'' determination from §§ 404.948(a) and 416.1448(a).

2. The individual's case is being determined according to the identifying criteria listed in proposed appendix 1 to subpart J of part 404. These criteria involve people who have filed applications for benefits based on disability and whose claims are handled by one of the State agencies that is using the new rules. As already noted, we intend this proposed provision to be temporary. When all State agencies are participating in the new process, we will delete appendix 1 to subpart J.

Other paragraphs in these proposed sections provide more information about the procedures we would require in connection with the informal disability conference.

- In paragraph (b)—''How will I be contacted?''—we explain how we will notify the individual of the date, time, and place or method (*e.g.,* telephone) of the informal disability conference. We also explain that we will notify the claimant's representative when he or she is represented.

In paragraph (c)—''Where will my informal disability conference be held?—we explain that we may hold the conference by telephone, in person, or using videoconferencing technology but that in most cases we will hold the conference by telephone. We also explain that we will decide the method we will use for the conference.

- In paragraph (d)—''Can an attorney or other representative participate in the informal disability conference?''—we indicate that the individual has the right to have an attorney or other representative present at the informal disability conference.

Sections 404.908 and 416.1408 Parties to a Reconsideration

We propose to revise the first sentence of paragraph (a), ''Who may request a reconsideration,'' to add an exception to the statement that the first level of appeal from an initial determination is a reconsideration. The proposed language includes cross-references to the new appendix and to § 404.930.

Sections 404.930 and 416.1430 Availability of a Hearing Before an Administrative Law Judge

We propose to add a new subparagraph (a)(2) to explain that individuals who meet the criteria in the new appendix appeal their initial determinations to the administrative law judge hearing level. Because of this, we would redesignate the numbers of the other subparagraphs within these paragraphs.

Sections 404.948 and 416.1448 Deciding a Case Without an Oral Hearing Before an Administrative Law Judge

We propose to revise the heading of paragraph (a) from ''Decision wholly favorable'' to ''Decision fully favorable.'' This will make the heading consistent with the text of current §§ 404.948(c) and 404.1448(c) and these proposed rules. The change is only editorial.

Proposed Appendix 1 to Subpart J of Part 404

As we explained earlier in this preamble, we are proposing to add this new appendix to list the types of claims that will be handled under the new disability claims process and the State agencies that will be using the new process. The proposed appendix includes three paragraphs. In paragraph (a)—''What is this appendix for?''—we briefly note the three major differences between the new process and the current process.

In paragraph (b)—''Why aren't all State agencies using the new disability claims process?''—we explain briefly how we are implementing the rules gradually in the States. We also explain that the appendix is temporary and that we will remove it when all State agencies are using the new process.

Paragraph (c)—''Which claims will be handled under the new disability claims process?''—explains that applications for benefits based on disability processed in certain state agencies come under the new rules. It is central to all of the other rules in this NPRM because we refer back to it to provide the basic criteria for all three of the major features of these proposed rules: The informal disability conference, no reconsideration appeal step, and permitting disability examiners the flexibility to decide whether to obtain medical or psychological consultant input when making the disability determination except in cases in which the Act requires that a medical or psychological consultant participate in making the determination. For example, in proposed §§ 404.930(a)(2) and 416.1430(a)(2), we explain that the first level of appeal for a person who meets the criteria in the proposed appendix is the administrative law judge hearing. (We also include this provision in proposed §§ 404.904(g) and 416.1404(g).) Likewise, we explain in proposed §§ 404.1615(c)(1) and 416.1015(c)(1) that a disability examiner may make the determination in the case of an individual who meets the criteria in the proposed appendix, except in cases requiring by statute participation by a medical or psychological consultant.

Paragraph (d)—''Which State agencies are using the new disability claims process?''—lists the participating State agencies. The State agencies listed in this NPRM are the same State agencies and branches of State agencies that have been participating in the Prototype test. When we decide which State agencies will be in the next group to begin using the new process, we will publish an appropriate notice in the **Federal Register** revising the list.

Sections 404.1512 and 416.912 Evidence of Your Impairment

We propose to revise paragraph (b)(6) of these sections for consistency with the changes we are proposing in §§ 404.1615 and 416.1015. In current §§ 404.1527(f) and 416.927(f), we recognize that State agency medical and psychological consultants are members of the teams that make determinations of disability under the current process. Therefore, we do not consider their administrative findings of fact (*e.g.,* about residual functional capacity) at the initial level to be medical opinions that must be weighed together with the evidence in the case record. However, our regulations have long provided that at the administrative law judge hearing and Appeals Council levels of administrative review, administrative law judges and administrative appeal judges must consider these findings as opinions of nonexamining sources. For this reason, current §§ 404.1512(b)(6) and 416.912(b)(6) provide that our term ''evidence'' includes opinions from State agency medical and psychological consultants when a case is at the administrative law judge hearing or Appeals Council level.

Under the proposed rules, there will now be cases in which disability examiners will make initial determinations when there are opinions from state agency medical or psychological consultants in the claims file. In these cases, we will expect disability examiners to consider these opinions as evidence from nonexamining sources in the same way as administrative law judges and administrative appeals judges. Therefore, we propose to revise §§ 404.1512(b)(6) and 416.912(b)(6) to include disability examiners who make decisions alone.

Sections 404.1526 and 416.926 Medical Equivalence

We propose to revise paragraph (b), ''Medical equivalence must be based on medical findings,'' to be consistent with the changes in these proposed rules that provide an enhanced role for disability examiners in making disability determinations. The current provision requires that in every case we must consider the medical opinion given by one or more medical or psychological consultants designated by the Commissioner in deciding medical equivalence. Under the current process, this requirement is always satisfied at the initial level of administrative review because medical and psychological consultants are always members of teams that make the initial determination and are responsible for this finding.

In view of the changes we are proposing to our process, we now propose to remove this requirement for cases that are adjudicated under the new process. Proposed paragraph (b) would provide that we ''may'' consider the opinion of a medical or psychological consultant designated by the Commissioner, *i.e.,* when a medical consultant provides an opinion on equivalency we will consider it. Under the Full Process Model and the Prototype, we found no evidence that omitting a medical or psychological consultant's opinion from the determination whether an impairment(s) medically equaled a listing lowered the quality of the determinations.

The proposed change would also affect adjudication at the administrative law judge hearing and Appeals Council levels of administrative review (when the Appeals Council makes a decision). Under §§ 404.1526(b) and 416.926(b), and Social Security Ruling (SSR) 96–6p, we require that administrative law judges and administrative appeals judges (when the Appeals Council makes a decision) must also consider the opinion of a medical or psychological consultant designated by the Commissioner when they consider whether an individual's impairment or combination of impairments medically equals a listing. See SSR 96–6p, ''Titles II and XVI: Consideration of Administrative Findings of Fact by State Agency Medical and Psychological Consultants and Other Program Physicians and Psychologists at the Administrative Law Judge and Appeals Council Levels of Administrative Review; Medical Equivalence,'' (61 FR 34466, July 2, 1996). In many cases, this requirement is satisfied because State agency medical and psychological consultants have already considered the issue and provided this opinion in connection with the initial and reconsideration determinations. SSR 96–6p provides that their signatures on the determinations satisfy the

requirement to obtain an opinion from a medical or psychological consultant designated by the Commissioner at the administrative law judge hearing and Appeals Council levels of administrative review when an administrative law judge or the Appeals Council finds that an individual's impairment(s) does not medically equal a listing.

However, SSR 96–6p requires that, when an administrative law judge or administrative appeals judge determines that he or she may make a finding that an individual's impairment(s) medically equals a listing, he or she must obtain an updated medical opinion from a medical expert. If the proposed revision in §§ 404.1526(b) and 416.926(b) becomes final, we will remove this requirement for administrative law judges and the Appeals Council, in order to be consistent with the changes for disability examiners.

In current § 416.926, we include a paragraph (d), ''Responsibility for determining medical equivalence,'' which we do not now include in § 404.1526. We propose to add a new paragraph (d) in § 404.1526 that is identical to the paragraph in § 416.926, and to revise the paragraph to incorporate reference to disability examiners who make determinations. The new language would explain that in such cases, the disability examiner is responsible for determining medical equivalence.

Sections 404.1527 and 416.927 Evaluating Opinion Evidence

We propose to revise paragraph (f), ''Opinions of nonexamining sources,'' to include disability examiners when they make disability determinations. As we have already explained under the explanation of the proposed revisions to §§ 404.1512(b)(6) and 416.912(b)(6), these individuals must consider opinions from medical and psychological consultants to be opinion evidence from nonexamining sources in the same way that administrative law judges and the administrative appeals judges do (when the Appeals Council makes a decision).

To reflect this change, we propose to add a new paragraph (f)(2) for disability examiners who make disability determinations. The language in the proposed provision is similar to the provisions for administrative law judges in current paragraph (f)(2). Because we would add a new paragraph (f)(2), we would redesignate current paragraphs (f)(2) and (f)(3) as paragraphs (f)(3) and (f)(4).

We propose minor revisions in paragraph (f)(1) to make clear that the current rules would continue to apply to cases that are adjudicated in State agencies that are not using the new process.

Sections 404.1546 and 416.946 Responsibility for Assessing and Determining Residual Functional Capacity

We propose to revise this section to clarify the responsibility for making assessments of a claimant's residual functional capacity.

The existing, unnumbered paragraph will be replaced by numbered paragraphs that will clarify the responsibility for making assessments of residual functional capacity in various types of claims. We will add a paragraph that will state that a State agency disability examiner may make assessments of residual functional capacity.

Sections 404.1615 and 416.1015 Making Disability Determinations

In paragraph (c) of these sections, we propose to add the rules that will permit disability examiners to make disability determinations in certain cases.

In proposed paragraph (c)(1)(i), we explain that a State agency disability examiner may make the disability determination in cases of individuals who meet the criteria in the appendix and that are not excluded in proposed paragraph (c)(2). We explain that this is not an absolute rule, because each State agency will have the option to decide whether to permit a disability examiner to make these determinations. Our intent is to provide each State agency with the authority to determine whether a given disability examiner is sufficiently skilled to make disability determinations without working in a team with a medical or psychological consultant.

We also provide in the third sentence of the proposed paragraph a reminder that a disability examiner may still request assistance from a medical or psychological consultant. In the prototype States, there have been many cases in which disability examiners sought opinions from medical and psychological consultants on various aspects of claims.

Proposed paragraph (c)(1)(ii) is the same as current paragraph (c)(2).

In the proposed rule, we would redesignate current paragraph (c)(1) as paragraph (c)(2). The current paragraph provides the requirement that a disability examiner and a medical or psychological consultant must make the determination in almost all cases. In the proposed paragraph, we would retain this provision for States that are not yet using the new process in proposed §§ 404.1615(c)(2)(iii) and 416.1015(c)(2)(iv). The reason the part 404 and part 416 sections have different numbers is that there is an additional section (proposed paragraph (c)(2)(iii)) containing the requirement of title XVI of the Act that in any case of a child claiming SSI disability benefits, we must make reasonable efforts to ensure that a qualified pediatrician or other individual who specializes in a field of medicine appropriate to a child's impairment(s) evaluates the case of the child. We decided to make the paragraphs providing the current rule for using teams last so that when we need to revise the rules again after all State agencies are using the new process, we can delete them without having to renumber the paragraphs.

In proposed paragraph (c)(2)(i), we would provide, as required by the Act, that a team must make the determination in any case in which the State agency determines that the individual is not disabled and there is evidence that indicates the existence of a mental impairment. In proposed paragraph (c)(2)(ii) we provide that a State agency may at its option require any disability examiner to work in a team with a medical or psychological consultant.

We are also proposing two changes to current paragraph (c) that are not related to the Prototype. At the end of § 404.1615(c), are two undesignated paragraphs. There is one undesignated paragraph at the end of § 416.1015(c) that contains the same text as the two undesignated paragraphs at the end of § 404.1615(c). The first sentence of both versions provides cross-references to the rules defining ''medical or psychological consultant'' and ''disability hearing officer.'' In the proposed rules, we have moved those cross-references to the appropriate sections of paragraph (c) that address these individuals.

The second sentence explains that State agency disability examiners and disability hearing officers must be qualified to interpret and evaluate medical reports and other evidence as necessary to determine the capacities of the claimant to perform substantial gainful activity. We propose to designate this sentence as paragraph (d) so that it can be cited, and to redesignate all the subsequent paragraphs in the sections. We are not proposing any changes to this sentence.

The second undesignated paragraph at the end of current § 404.1615(c), which is the third sentence in the single undesignated paragraph in current § 416.1015(c), provides a cross-reference to § 404.1572 (in § 404.1615(c)) and to

§ 416.972 (in § 416.1015(c)) ''for what we mean by substantial gainful activity.'' Although these rules do in fact define the term ''substantial gainful activity'' for purposes of evaluating a person's earnings and work activity, the cross-references are misleading in the context of the preceding text. Disability examiners and disability hearing officers do not determine whether claimants who are working are engaging in ''substantial gainful activity'' and do not use the rules in §§ 404.1572 and 416.972. This determination is made in our field offices. Disability examiners and disability hearing officers make determinations about whether an individual is able to work using other rules regarding medical and vocational factors. Therefore, we propose to delete these sentences since they could be confusing.

Other Changes

We are proposing changes to other rules in subparts J, P, and Q of part 404, subparts I, J, and N of part 416, and subparts B and C of part 422. These changes are intended to make these other rules consistent with the proposed changes we have explained above.

Clarity of This Regulation

Executive Order (E.O.) 12866 and the President's memorandum of June 1, 1998, require each agency to write all rules in plain language. In addition to your substantive comments on these proposed rules, we invite your comments on how to make these proposed rules easier to understand.

For example:

- Have we organized the material to suit your needs?
- Are the requirements in the rules clearly stated?
- Do the rules contain technical language or jargon that is unclear?
- Would a different format (grouping and order of sections, use of headings, paragraphing) make the rules easier to understand?
- Would more (but shorter) sections be better?
- Could we improve clarity by adding tables, lists, or diagrams?
- What else could we do to make the rules easier to understand?

Electronic Version

The electronic file of this document is available on the date of publication in the **Federal Register** on the Internet site for the Government Printing Office: *http://www.access.gpo.gov/su_docs/aces/aces140.html.* It is also available on the Internet site for SSA (*i.e., Social Security Online*): *http://www.ssa.gov/.*

Regulatory Procedures

Executive Order 12866 and the Congressional Review Act

We have consulted with the Office of Management and Budget (OMB) and determined that these proposed regulations meet the criteria of an economically significant regulatory action under E.O. 12866 because the impact in any single year exceeds $100 million. Thus, they were subject to OMB review. We have provided below an assessment of the costs and benefits of these proposed rules. It should also be noted that this proposed rule is a major rule under the criteria of the Congressional Review Act (Chapter 8 of 5 U.S.C.).

Program Savings

We do not expect any program savings to result from these regulations.

Program Costs

1. Title II

We estimate that these rules will result in increased program outlays resulting in the following costs (in millions of dollars) to the title II program:

[Million of dollars]

FY2001	FY2002	FY2003	FY2004	FY2005	FY2001–2005	FY2001–2010
70	155	360	751	1,247	2,583	17,105

Related Medicare Costs

[Millions of dollars]

FY2001	FY2002	FY2003	FY2004	FY2005	FY2001–2005	FY2001–2010
	3	26	75	174	277	4,420

2. Title XVI

We estimate that these rules will result in increased program outlays resulting in the following costs (in millions of dollars) to the title XVI program:

[Millions of dollars]

	FY2001	FY2002	FY2003	FY2004	FY2005	FY2001–2005	FY2001–2010
Federal	4	30	81	188	335	638	3,922
State	.....	3	8	19	34	64	392

[Millions of dollars]

	FY2001	FY2002	FY2003	FY2004	FY2005	FY2001–2005	FY2001–2010
Federal	3	40	120	310	576	1,049	8,940
State	2	30	91	234	435	791	6,743

Administrative Savings

We do not expect any administrative savings to result from these regulations.

Administrative Costs

We expect there will be some administrative costs associated with the transition to these rules.

Policy Alternatives

We considered, but did not select, the following policy alternative:

Keep the Current Disability Claim Process

As noted above, the initiative to redesign the disability claim process was critical of several aspects of the current process, including: the time it takes for a final agency decision; the lack of interaction between the claimant and the decisionmaker; and the lack of thorough explanations, in many cases, of the basis for the disability determination. Based on the Full Process Model test and our experience with the prototype so far, we found that the proposed new process results in better determinations at the initial level, with more allowances of claims that should be allowed. Many claims that would have been allowed only after appeal under the old process, were allowed at the initial step of the new process. Eliminating the reconsideration step enables claimants who appeal to reach the hearing level sooner than under the old process, and the resources previously used at the reconsideration step can be used to ensure a more complete determination process at the initial level. These positive results support implementation of the redesigned claim process.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments, and on the private sector. This final rule would not impose any Federal mandates on any State, local, or tribal governments, or on the private sector, within the meaning of the Unfunded Mandates Reform Act of 1995.

Regulatory Flexibility Act

We certify that these proposed rules will not have a significant economic impact on a substantial number of small entities because they affect only individuals. Thus, a regulatory flexibility analysis as provided in the Regulatory Flexibility Act, as amended, is not required.

Paperwork Reduction Act

These proposed regulations would impose no new reporting or recordkeeping requirements requiring OMB clearance.

(Catalog of Federal Domestic Assistance Programs No. 96.001, Social Security—Disability Insurance; 96.002, Social Security—Retirement Insurance; 96–004, Social Security—Survivors Insurance; 96.006, Supplemental Security Income)

List of Subjects

20 CFR Part 404

Administrative practice and procedure, Blind, Disability benefits, Old-Age, Survivors and Disability Insurance, Reporting and recordkeeping requirements, Social Security.

20 CFR Part 416

Administrative practice and procedure, Aged, Blind, Disability benefits, Public assistance programs, Reporting and recordkeeping requirements, Supplemental Security Income (SSI).

20 CFR Part 422

Administrative practice and procedure, Freedom of information, Organization and functions (Government agencies), Social Security.

Dated: January 11, 2001.

Kenneth S. Apfel,

Commissioner of Social Security.

For the reasons set out in the preamble, we propose to amend subparts J, P, and Q of part 404, subparts I, J, and N of part 416, and subparts B and C of part 422 of 20 CFR, chapter III as set forth below:

PART 404—FEDERAL OLD-AGE, SURVIVORS AND DISABILITY INSURANCE (1950–)

1. The authority citation for subpart J of part 404 continues to read as follows:

Authority: Secs. 201(j), 204(f), 205(a), (b), (d)–(h), and (j), 221, 225, and 702(a)(5) of the Social Security Act (42 U.S.C. 401(j), 404(f), 405(a), (b), (d)–(h), and (j), 421, 425, and 902(a)(5)); 31 U.S.C. 3720A; sec. 5, Pub. L. 97–455, 96 Stat. 2500 (42 U.S.C. 405 note); secs. 5, 6(c)–(e), and 15, Pub. L. 98–460, 98 Stat. 1802 (42 U.S.C. 421 note).

2. Section 404.900 is amended by revising paragraphs (a)(2) and (a)(3) to read as follows:

§ 404.900 Introduction.

(a) * * *

(2) *Reconsideration.* If you are dissatisfied with an initial determination, except for certain determinations about whether you are disabled (see paragraph (a)(3)(ii) of this section), you may ask us to reconsider it.

(3) *Hearing before an administrative law judge.* You may request a hearing before an administrative law judge if you are dissatisfied with:

(i) A reconsideration determination; or

(ii) Certain initial determinations on your application for benefits based on disability, if you are a person entitled to an informal disability conference, as explained in § 404.904 and appendix 1 to this subpart.

* * * * *

3. Section 404.901 is amended by adding the following definition to the alphabetical list of definitions:

§ 404.901 Definitions

* * * * *

''Fully favorable,'' with respect to a disability determination, means that we determine that: the claimant is disabled; the beginning date of disability is no later than the date alleged by the claimant; and either disability has not ended or, if the claimant alleges that disability has ended, it ended no earlier than the date alleged by the claimant.

* * * * *

4. Section 404.904 is redesignated as Section 404.904a and revised to read as follows:

§ 404.904a Notice of the initial determination.

We will mail a written notice of the initial determination to you at your last known address. The notice will state the reasons for the initial determination and the effect of the initial determination.

The notice also will explain your right to appeal the determination and whether the appeal should be for a reconsideration or a hearing before an administrative law judge. (See §§ 404.900(a), 404.904(g), 404.907, and 404.930, and appendix 1 to this subpart.) We will not mail a notice if the beneficiary's entitlement to benefits has ended because of his or her death.

5. A new section 404.904 is added to read as follows:

§ 404.904 Informal disability conference.

(a) *What is an informal disability conference?* When you file an application for disability benefits, the disability examiner may offer you an opportunity to have an informal disability conference. If your claim is decided by a component of our office other than a State agency, the disability examiner in that component may offer you an opportunity to have an informal disability conference. The purpose of the informal disability conference is to explain how your medical condition relates to our disability requirements, and to make sure that we have all of the information we need to make a determination about whether you are disabled. We will offer you an informal disability conference if all of the following apply in your case:

(1) Based on the evidence in your case record, it appears that we will not be able to make a fully favorable disability determination. However, we will not offer you an informal disability conference if the determination is less than fully favorable because:

(i) You are, or were, engaging in substantial gainful activity; or

(ii) You fail to cooperate in the processing of your claim; or

(iii) You fail to meet one or more eligibility requirement that is not related to your medical condition (*e.g.,* insured status).

(2) Your claim meets the requirements in paragraphs (c) and (d) of Appendix 1 of this subpart (claims for disability being determined by certain State agencies).

(b) *Notification.* We will notify you in writing to offer you the conference. You may choose to have a conference or not have a conference. If you have an attorney or other representative, we will also notify that person about the conference. The attorney or representative may participate in the conference.

(c) *How will my informal disability conference be held?* In most cases, we will hold your informal disability conference by telephone. In some cases, we may ask you to come to the State agency for a conference in person. We may also ask you to go to a location near you for a videoconference. We will decide how your conference will be held.

(d) *What happens during the informal disability conference?* The disability examiner will have an informal conversation with you. If he or she has not already done so in earlier conversations, the disability examiner will explain our disability standard. He or she also will tell you why the evidence in your case does not appear to support a fully favorable determination. You will have a chance to give us any information that we may not have. If you want to give us information that we need to make a determination, we will give you a chance to get the information or we will try to get it for you, following our rules in § 404.1512.

(e) *What happens if I decide not to have an informal disability conference?* If you decide not to have a conference, we will make an initial determination based on the information that we have.

6. Section 404.905 is revised to read as follows:

§ 404.905 Effect of an initial determination.

Our initial determination is final unless you request appeal (see § 404.907) within the stated time period, or we revise the determination.

7. Section 404.907 is revised to read as follows:

§ 404.907 Reconsideration—general.

(a) If you are dissatisfied with the initial determination, reconsideration is the first step in the administrative review process that we provide, except for the following determinations. In these cases, the next step in the administrative review process is to the administrative law judge hearing level.

(1) Determinations described in § § 404.930(a)(6) and (a)(7), where you appeal an initial determination denying your request for waiver or adjustment or recovery of an overpayment (see § 404.506).

(2) If you meet the requirements in paragraphs (c) and (d) of Appendix 1 of this subpart, an initial determination about whether you are disabled that is not fully favorable to you, except for a determination based on a finding that you are, or were, engaging in substantial gainful activity. (See appendix 1 to this subpart.)

(b) If you are dissatisfied with our reconsidered determination, you may request a hearing before an administrative law judge.

8. Section 404.908 is amended by revising paragraph (a) to read as follows:

§ 404.908 Parties to a reconsideration.

(a) *Who may request a reconsideration.* If you are dissatisfied with our initial determination, you may request that we reconsider it, unless you are entitled to request a hearing before an administrative law judge, as we explain in § 404.930 and Appendix 1 of this subpart. In addition, a person who shows in writing that his or her rights may be adversely affected by the initial determination may request a reconsideration.

* * * * *

9. Section 404.930 is amended by redesignating existing paragraphs (a)(2) through (a)(7) as paragraphs (a)(3) through (a)(8), and adding a new paragraph (a)(2) to read as follows:

§ 404.930 Availability of a hearing before an administrative law judge.

(a) * * *

(2) an initial determination about whether you are disabled that is not fully favorable to you, unless that determination was about whether you are engaging or were engaging in substantial gainful activity, if your claim meets the requirements in paragraphs (c) and (d) of Appendix 1 of this subpart;

* * * * *

10. Section 404.948 is amended by revising the heading of paragraph (a) to read as follows:

§ 404.948 Deciding a case without an oral hearing before an administrative law judge.

(a) *Decision fully favorable.* * * *

* * * * *

11. A new appendix 1 to subpart J is added to read as follows:

Appendix 1—Claims That Will Be Handled Under the New Disability Claims Process

(a) *What is this appendix for?* This appendix lists the types of claims that will be handled under the new disability claims process, and which State agencies will participate in the process. Individuals who meet the criteria in paragraphs (c) and (d) of this appendix, except for individuals whose determinations of disability are based on a finding that they are, or were, engaging in substantial gainful activity, may appeal to an administrative law judge hearing if they are dissatisfied with their initial determinations. In the States listed in paragraph (d), a disability examiner is responsible for making the disability determination in certain cases. The disability examiner will have the flexibility to decide whether input from a medical or psychological consultant is needed in making the disability determination. See §§ 404.1615 and 416.1015. Individuals who also meet the criteria in § 404.904(a) of this section or § 416.1404 of part 416 and whose State agencies are using the new claims process

will be offered an informal disability conference.

(b) *Why aren't all State agencies using the new disability claims process?* We are phasing in the new process gradually, because each State will need substantial lead time for training and preparation, and we must retain our capacity to process new claims as timely as possible during implementation. This means that we will add more State agencies to this list from time-to-time until all State agencies are using the new process. When all State agencies are using the new process, we will delete this appendix and the new process will apply to everyone.

(c) *Which claims will be handled under the new disability claims process?* Your claim will be handled under the new process if you filed an application for benefits (disability insurance benefits or Supplemental Security Income) based on disability or blindness and if your case is processed in one of the State agencies listed in paragraph (d) of this appendix.

(d) *Which State agencies are using the new disability claims process?* The following State agencies are using the new process:

Alabama; Alaska; California (North Los Angeles and West Los Angeles branches); Colorado; Louisiana; Michigan; Missouri; New Hampshire; New York (Brooklyn and Albany branches); Pennsylvania.

12. The authority citation for subpart P of part 404 continues to read as follows:

Authority: Secs. 202, 205(a), (b), and (d)–(h), 216(I), 221(a) and (i), 222(c), 223, 225, and 702(a)(5) of the Social Security Act (42 U.S.C. 402, 405(a), (b), and (d)–(h), 416(i), 421(a) and (i), 422(c), 423, 425, and 902(a)(5)); sec. 211(b), 104–193, 110 Stat. 2105, 2189.

13. Section 404.1512 is amended by revising paragraph (b)(6) to read as follows:

§ 404.1512 Evidence of your impairment.

* * * * *

(b) * * *

(6) Findings, other than the ultimate determination about whether you are disabled, made by State agency medical or psychological consultants and other program physicians or psychologists, and opinions expressed by medical experts we consult based on their review of the evidence in your case record. See § § 404.1527(f)(2) and (f)(3).

* * * * *

14. Section 404.1526 is amended by revising the last sentence of paragraph (b) and by adding a new paragraph (d) to read as follows:

§ 404.1526 Medical equivalence.

* * * * *

(b) * * * We may request, and will consider if requested, any medical opinion from one or more medical or psychological consultants designated by the Commissioner when we decide medical equivalence. (See § 404.1616.)

* * * * *

(d) *Responsibility for determining medical equivalence.* In cases where the State agency or other designee of the Commissioner makes the initial disability determination, a disability examiner is responsible for determining medical equivalence in cases in which a medical or psychological consultant does not make the determination together with the disability examiner (see § 404.1615 and Appendix 1 of subpart J). In cases in which a medical or psychological consultant makes the determination together with the disability examiner, the medical or psychological consultant is responsible for assessing medical severity, and the disability examiner and medical or psychological consultant are jointly responsible for determining medical equivalence. For cases in the disability hearing process or otherwise decided by a disability hearing officer, the responsibility for determining medical equivalence rests with either the disability hearing officer or, if the disability hearing officer's reconsideration determination is changed under § 404.918, with the Associate Commissioner for Disability or his or her delegate. For cases at the Administrative Law Judge or Appeals Council level, the responsibility for deciding medical equivalence rests with the administrative law judge or Appeals Council.

15. Section 404.1527 is amended by revising paragraph (f)(1), by redesignating existing paragraphs (f)(2) and (f)(3) as paragraphs (f)(3) and (f)(4) and by adding a new paragraph (f)(2) to read as follows:

§ 404.1527 Evaluating opinion evidence.

* * * * *

(f) * * *

(1) In some cases, State agency medical and psychological consultants are members of teams that make initial determinations of disability (see § 404.1615(c)(2)). In these cases, a State agency medical or psychological consultant will consider the evidence in your case record and make findings of fact about the medical issues, including, but not limited to, the existence and severity of your impairment(s), the existence and severity of your symptoms, whether your impairment(s) meets or equals the requirements for any impairment listed in appendix 1 to this subpart, and your residual functional capacity. These administrative findings of fact are based on the evidence in your case record but they are not themselves evidence at this step.

(2) In other cases, a State agency disability examiner is responsible for making the initial determination (see § 404.1615(c)(1)). In these cases, the disability examiner may obtain the opinion of a State agency medical or psychological consultant with respect to issues, including, but not limited to, the existence and severity of your impairment(s), the existence and severity of your symptoms, whether your impairment(s) meets or equals the requirements for any impairment listed in appendix 1 to this subpart, and your residual functional capacity. In these cases, State agency disability examiners weigh any opinions provided by State agency medical or psychological consultants in accordance with these rules. State agency medical and psychological consultants are highly qualified and are also experts in Social Security disability evaluation. See § 404.1512(b)(6). When a State agency disability examiner considers findings of a State agency medical or psychological consultant, the State agency disability examiner will evaluate the findings using relevant factors in paragraphs (a) through (e) of this section, such as the medical or psychological consultant's medical specialty and expertise in our rules, the supporting explanations provided by the medical or psychological consultant, and any other factors relevant to the weighing of the opinions.

* * * * *

16. Section 404.1529 is amended by revising the third sentence of paragraph (b) and by adding a new fourth sentence to paragraph (b) to read as follows:

§ 404.1529 How we evaluate symptoms, including pain.

* * * * *

(b) *Need for medically determinable impairment that could reasonably be expected to produce your symptoms, such as pain.* * * * In some cases at the initial step in the administrative review process, and all cases at the reconsideration step, a State agency medical or psychological consultant (or other medical or psychological consultant designated by the Commissioner) directly participates in determining whether your medically determinable impairment(s) could reasonably be expected to produce your alleged symptoms (see § 404.1615(c)(2)). In other cases at the initial step of the administrative review process, a State agency disability examiner may ask for and consider the opinion of a State agency medical or psychological consultant in determining whether your medically determinable impairment(s) could reasonably be expected to

produce your alleged symptoms (see § 404.1615). * * *

* * * * *

17. Section 404.1546 is revised to read as follows:

§ 404.1546 Responsibility for assessing and determining residual functional capacity.

(a) *Initial determinations.* (1) In cases in which a State agency disability determination is made by a team consisting of a State agency disability examiner and a medical or psychological consultant, the medical or psychological consultant is responsible for assessing your residual functional capacity (see § 404.1615(c)(2)).

(2) In cases in which a State agency disability examiner makes the disability determination, the State agency disability examiner is responsible for assessing your residual functional capacity (see § 404.1615(c)(1)).

(b) *Disability hearing cases.* For cases in the disability hearing process, the responsibility for deciding your residual functional capacity rests with either the disability hearing officer or, if the disability hearing officer's reconsidered determination is changed under § 404.918, with the Associate Commissioner for Disability or his or her delegate.

(c) *Administrative law judge or Appeals Council cases.* For cases at the Administrative Law Judge or Appeals Council level, the administrative law judge or Appeals Council is responsible for assessing your residual functional capacity.

18. The authority citation for subpart Q of part 404 continues to read as follows:

Authority: Secs. 205(a), 221, and 702(a)(5) of the Social Security Act (42 U.S.C. 405(a), 421, and 902(a)(5)).

19. Section 404.1615 is amended by revising paragraph (c), by redesignating the first undesignated paragraph following paragraph (c)(3) as paragraph (d), by removing the second undesignated paragraph following paragraph (c)(3), by revising new paragraph (d), and by redesignating existing paragraphs (d), (e), (f), and (g), as paragraphs (e), (f), (g), and (h), to read as follows:

§ 404.1615 Making disability determinations.

* * * * *

(c) The following individuals in the State agency will make disability determinations:

(1)(i) If your claim meets the requirements in paragraphs (c) and (d) of Appendix 1 of subpart J, a State agency disability examiner is responsible for making the disability determination in your claim, unless it is a claim described in (c)(2) of this section. The State agency disability examiner may request advice from a State agency medical or psychological consultant on the medical aspects of your impairment.

(ii) In any State agency, a State agency disability examiner may make the disability determination when there is no medical evidence to be evaluated (i.e., no medical evidence exists or we are unable, despite making every reasonable effort, to obtain any medical evidence that may exist) and the individual fails or refuses, without a good reason, to attend a consultative examination (see § 404.1518).

(2) A State agency medical or psychological consultant (see § 404.1616) and a State agency disability examiner together will make the disability determination in the following situations:

(i) Any case in which the State agency determines that you are not disabled and there is evidence that indicates the existence of a mental impairment, as described in paragraph (e) of this section;

(ii) Any case in which the State agency decides to require a State agency medical or psychological consultant and a State agency disability examiner to make the disability determination together; and

(iii) Any case, if your claim does not meet the requirements in paragraphs (c) and (d) of Appendix 1 of subpart J.

(3) A State agency disability hearing officer (see § 404.915).

(d) The State agency disability examiner and disability hearing officer must be qualified to interpret and evaluate medical reports and other evidence relating to the claimant's physical or mental impairments and as necessary to determine the capacities of the claimant to perform substantial gainful activity.

* * * * *

20. Section 404.1616 is amended by revising paragraph (a) to read as follows:

§ 404.1616 Medical or psychological consultants.

(a) *What is a medical consultant?* A medical consultant is a person who is a member of a team that makes disability determinations in a State agency, as explained in § 404.1615(c)(2), or who provides advice to a State agency disability examiner, as explained in § 404.1615(c)(1). A medical consultant may also be a person who serves the same functions for us when a federal component makes the disability determination.

* * * * *

PART 416—SUPPLEMENTAL SECURITY INCOME FOR THE AGED, BLIND, AND DISABLED

21. The authority citation for subpart I of part 416 continues to read as follows:

Authority: Secs. 702(a)(5), 1611, 1614, 1619, 1631(a), (c), and (d)(1), and 1633 of the Social Security Act (42 U.S.C. 902(a)(5), 1382, 1382c, 1382h, 1383(a), (c), and (d)(1), and 1383b); secs. 4(c) and 5, 6(c)–(e), 14(a), and 15, Pub. L. 98–460, 98 Stat.1794, 1801, 1802, and 1808 (42 U.S.C. 421 note, 423 note, 1382h note).

22. Section 416.912 is amended by revising paragraph (b)(6) to read as follows:

§ 416.912 Evidence of your impairment.

* * * * *

(b) * * *

(6) Findings, other than the ultimate determination about whether you are disabled, made by State agency medical or psychological consultants and other program physicians or psychologists, and opinions expressed by medical experts we consult based on their review of the evidence in your case record. See §§ 416.1527(f)(2) and (f)(3).

* * * * *

23. Section 416.926 is amended by revising the last sentence of paragraph (b) and by adding a new paragraph (d) to read as follows:

§ 416.926 Medical equivalence for adults and children.

* * * * *

(b) * * * We may request, and will consider if requested, any medical opinion from one or more medical or psychological consultants designated by the Commissioner when we decide medical equivalence. (See § 416.1016.)

* * * * *

(d) *Responsibility for determining medical equivalence.* In cases where the State agency or other designee of the Commissioner makes the initial disability determination, a disability examiner is responsible for determining medical equivalence in cases in which a medical or psychological consultant does not make the determination together with the disability examiner (see § 416.1015 and Appendix 1 of subpart J). In cases in which a medical or psychological consultant makes the determination together with the disability examiner, the medical or psychological consultant is responsible for assessing medical severity, and the disability examiner and medical or

psychological consultant are jointly responsible for determining medical equivalence. For cases in the disability hearing process or otherwise decided by a disability hearing officer, the responsibility for determining medical equivalence rests with either the disability hearing officer or, if the disability hearing officer's reconsideration determination is changed under § 416.1418, with the Associate Commissioner for Disability or his or her delegate. For cases at the Administrative Law Judge or Appeals Council level, the responsibility for deciding medical equivalence rests with the administrative law judge or Appeals Council.

24. Section 416.927 is amended by revising paragraph (f)(1), by redesignating existing paragraphs (f)(2) and (f)(3) as paragraphs (f)(3) and (f)(4) and by adding a new paragraph (f)(2) to read as follows:

§ 416.927 Evaluating opinion evidence.

* * * * *

(f) * * *

(1) In some cases, State agency medical and psychological consultants are members of teams that make initial determinations of disability (see § 416.1015(c)(2)). In these cases, a State agency medical or psychological consultant will consider the evidence in your case record and make findings of fact about the medical issues, including, but not limited to, the existence and severity of your impairment(s), the existence and severity of your symptoms, whether your impairment(s) meets or equals the requirements for any impairment listed in appendix 1 to subpart P of part 404 of this chapter, and your residual functional capacity. These administrative findings of fact are based on the evidence in your case record but they are not themselves evidence at this step.

(2) In other cases, a State agency disability examiner is responsible for making the initial determination (see § 416.1015(c)(1)). In these cases, the disability examiner may obtain the opinion of a State agency medical or psychological consultant with respect to issues, including, but not limited to, the existence and severity of your impairment(s), the existence and severity of your symptoms, whether your impairment(s) meets or equals the requirements for any impairment listed in appendix 1 to subpart P of part 404 of this chapter, and your residual functional capacity. In these cases, State agency disability examiners weigh any opinions provided by State agency medical or psychological consultants in accordance with these rules. State agency medical and psychological consultants are trained and are also experts in Social Security disability evaluation. See § 416.912(b)(6). When a State agency disability examiner considers findings of a State agency medical or psychological consultant, the State agency disability examiner will evaluate the findings using relevant factors in paragraphs (a) through (e) of this section, such as the medical or psychological consultant's medical specialty and expertise in our rules, the supporting explanations provided by the medical or psychological consultant, and any other factors relevant to the weighing of the opinions.

* * * * *

25. Section 416.929 is amended by revising the third sentence of paragraph (b) and by adding a new fourth sentence to paragraph (b) to read as follows:

§ 416.929 How we evaluate symptoms, including pain.

* * * * *

(b) *Need for medically determinable impairment that could reasonably be expected to produce your symptoms, such as pain.* * * * In some cases at the initial step in the administrative review process, and all cases at the reconsideration step, a State agency medical or psychological consultant (or other medical or psychological consultant designated by the Commissioner) directly participates in determining whether your medically determinable impairment(s) could reasonably be expected to produce your alleged symptoms (see § 416.1015(c)(2)). In other cases at the initial step of the administrative review process, a State agency disability examiner may ask for and consider the opinion of a State agency medical or psychological consultant in determining whether your medically determinable impairment(s) could reasonably be expected to produce your alleged symptoms (see § 416.1015). * * *

* * * * *

26. Section 416.946 is revised to read as follows:

§ 416.946 Responsibility for assessing and determining residual functional capacity.

(a) *Initial determinations.* (1) In cases in which a State agency disability determination is made by a team consisting of a State agency disability examiner and a medical or psychological consultant, the medical or psychological consultant is responsible for assessing your residual functional capacity (see § 416.1015(c)(2)).

(2) In cases in which a State agency disability examiner makes the disability determination, the State agency disability examiner is responsible for assessing your residual functional capacity (see § 416.1015(c)(1)).

(b) *Disability hearing cases.* For cases in the disability hearing process, the responsibility for deciding your residual functional capacity rests with either the disability hearing officer or, if the disability hearing officer's reconsidered determination is changed under § 416.1418, with the Associate Commissioner for Disability or his or her delegate.

(c) *Administrative law judge or Appeals Council cases.* For cases at the Administrative Law Judge or Appeals Council level, the administrative law judge or Appeals Council is responsible for assessing your residual functional capacity.

27. The authority citation for subpart J of part 416 continues to read as follows:

Authority: Secs. 702(a)(5), 1614, 1631, and 1633 of the Social Security Act (42 U.S.C. 902(a)(5), 1382c, 1383, and 1383b).

28. Section 416.1015 is amended by redesignating paragraphs (d) through (h) as paragraphs (e) through (i), by redesignating the undesignated paragraph following paragraph (c)(3) as paragraph (d) and revising it, and by revising paragraph (c) to read as follows:

§ 416.1015 Making disability determinations.

* * * * *

(c) The following individuals in the State agency will make disability determinations:

(1) (i) If your claim meets the requirements of paragraphs (c) and (d) of Appendix 1 of subpart J, part 404 of this chapter, a State agency disability examiner is responsible for making the disability determination in your claim, unless it is a claim described in (c)(2) of this section. The State agency disability examiner may request advice from a State agency medical or psychological consultant on the medical aspects for your impairment.

(ii) In any State agency, a State agency disability examiner may make the disability determination when there is no medical evidence to be evaluated (*i.e.,* no medical evidence exists or we are unable, despite making every reasonable effort, to obtain any medical evidence that may exist) and the individual fails or refuses, without a good reason, to attend a consultative examination (see § 416.918).

(2) A State agency medical or psychological consultant (see § 416.1016) and a State agency disability examiner together will make the disability determination in the following situations:

(i) Any case in which the State agency determines that you are not disabled and there is evidence that indicates the existence of a mental impairment, as described in paragraph (e) of this section;

(ii) Any case in which the State agency decides to require a State agency medical or psychological consultant and a State agency disability examiner to make the disability determination together; and

(iii) Any case of a child claiming disability benefits, as described in paragraph (f) of this section;

(iv) Any case, if your claim does not meet the requirements in paragraphs (c) and (d) of Appendix 1 of subpart J, part 404 of this chapter.

(3) A State agency disability hearing officer (see § 416.1015).

(d) The State agency disability examiner and disability hearing officer must be qualified to interpret and evaluate medical reports and other evidence relating to the claimant's physical or mental impairments and as necessary to determine the capacities of the claimant to perform substantial gainful activity.

* * * * *

29. Section 416.1016 is amended by revising paragraph (a) to read as follows:

§ 416.1016 Medical or psychological consultants.

(a) *What is a medical consultant?* A medical consultant is a person who is a member of a team that makes disability determinations in a State agency, as explained in § 416.1015(c)(2), or who provides advice to a State agency disability examiner, as explained in § 416.1015(c)(1). A medical consultant may also be a person who serves the same functions for us when a federal component makes the disability determination.

* * * * *

30. The authority citation for subpart N of part 416 continues to read as follows:

Authority: Secs. 702(a)(5), 1631, and 1633 of the Social Security Act (42 U.S.C. 902(a)(5), 1383, and 1383b); 31 U.S.C. 3720A.

31. Section 416.1400 is amended by revising paragraphs (a)(2) and (a)(3) to read as follows:

§ 416.1400 Introduction.

(a) * * *

(2) *Reconsideration.* If you are dissatisfied with an initial determination, except for certain determinations about whether you are disabled (see (a)(3)(ii) of this section), you may ask us to reconsider it.

(3) *Hearing before an administrative law judge.* You may request a hearing before an administrative law judge if you are dissatisfied with:

(i) A reconsideration determination; or

(ii) Certain initial determinations on your application for benefits based on disability, if you are a person entitled to an informal disability conference, as explained in § 416.1404 and appendix 1 to subpart J of part 404 of this chapter.

* * * * *

32. Section 416.1401 is amended by adding the following definition to the alphabetical listing of definitions in this section, to read as follows:

§ 416.1401 Definitions.

* * * * *

''Fully favorable'' with respect to a disability determination, means that we determine that: the claimant is disabled; the beginning date of disability is no later than the date alleged by the claimant; and either disability has not ended or, if the claimant alleges that disability has ended, it ended no earlier than the date alleged by the claimant.

* * * * *

33. Section 416.1404 is redesignated as Section 416.1404a and revised to read as follows:

§ 416.1404a Notice of the initial determination.

(a) We will mail a written notice of the initial determination to you at your last known address. Generally, we will not send a notice if your benefits are stopped because of your death, or if the initial determination is a redetermination that your eligibility for benefits and the amount of your benefits have not changed.

(b) The written notice that we send will tell you:

(1) What our initial determination is;

(2) The reasons for our determination; and

(3) What rights you have to a reconsideration of the determination or a hearing before an administrative law judge. (See § § 416.1400(a), 416.1404(g), 416.1407, and 416.1430, and appendix 1 to subpart J of part 404 of this chapter.)

(c) If our initial determination is that we must suspend, reduce or terminate your benefits, the notice will also tell you that you have a right to a reconsideration before the determination takes effect (see § 416.1336).

34. A new section 416.1404 is added to read as follows:

§ 416.1404 Informal disability conference.

(a) *What is an informal disability conference?* When you file an application for disability benefits, the disability examiner may offer you an opportunity to have an informal disability conference. If your claim is decided by a component of our office other than a State agency, the disability examiner in that component may offer you an opportunity to have an informal disability conference. The purpose of the informal disability conference is to explain how your medical condition relates to our disability requirements, and to make sure that we have all of the information we need to make a determination about whether you are disabled. We will offer you an informal disability conference if all of the following apply in your case:

(1) Based on the evidence in your case record, it appears that we will not be able to make a fully favorable disability determination. However, we will not offer you an informal disability conference if the determination is less than fully favorable because:

(i) You are, or were, engaging in substantial gainful activity; or

(ii) You fail to cooperate in the processing of your claim; or

(iii) You fail to meet one or more eligibility requirement that is not related to your medical condition (e.g., limitations on income and resources).

(2) Your claim meets the requirements of paragraphs (c) and (d) of appendix 1, subpart J of part 404.

(b) *Notification* We will notify you in writing to offer you the conference. You may choose to have a conference or not have a conference. If you have an attorney or other representative, we will also notify that person. The attorney or representative may participate in the conference.

(c) How *will my informal disability conference be held?* In most cases, we will hold your informal disability conference by telephone. In some cases, we may ask you to come to the State agency for a conference in person. We may also ask you to go to a location near you for a videoconference. We will decide how your conference will be held.

(d) *What happens during the informal disability conference?* The disability examiner will have an informal conversation with you. If he or she has not already done so in earlier conversations, he or she will explain our disability standard. He or she also will tell you why the evidence in your case does not appear to support a fully favorable determination. You will have a chance to provide information that we may not have. If you want to give us information that we need to make a determination, we will give you a chance to get the information or we will try to get it for you, following our rules in § 416.912.

(e) *What happens if I decide not to have an informal disability conference?* If you decide not to have a conference, we will make an initial determination based on the information that we have.

35. Section 416.1405 is revised to read as follows:

§ 416.1405 Effect of an initial determination.

Our initial determination is final unless you request a reconsideration or an administrative law judge hearing within the stated time period, or we revise the determination.

36. Section 416.1407 is revised to read as follows:

§ 416.1407 Reconsideration—general.

If you are dissatisfied with the initial determination, reconsideration is the first step in the administrative review process that we provide, with one exception. If your claim meets the requirements of paragraphs (c) and (d) of Appendix 1, subpart J, part 404 of this chapter, and we make an initial determination about whether you are disabled that is not fully favorable to you, except for a determination based on a finding that you are, or were, engaging in substantial gainful activity, the next step in the administrative review process is to the administrative law judge hearing level. If you are dissatisfied with our reconsidered determination, you may request a hearing before an administrative law judge.

37. Section 416.1408 is amended by revising paragraph (a) to read as follows:

§ 416.1408 Parties to a reconsideration.

(a) *Who may request a reconsideration.* If you are dissatisfied with our initial determination, you may request that we reconsider it, unless you are entitled to request a hearing before an administrative law judge, as we explain in § 416.1430 and appendix 1 of subpart J, part 404 of this chapter. In addition, a person who shows in writing that his or her rights may be adversely affected by the initial determination may request a reconsideration.

* * * * *

38. Section 416.1430 is amended by redesignating existing paragraphs (a)(2), (a)(3), and (a)(4) as paragraphs (a)(3), (a)(4), and (a)(5), and by adding a new paragraph (a)(2) to read as follows:

§ 416.1430 Availability of a hearing before an administrative law judge.

(a) * * *

(2) An initial determination about whether you are disabled that is not fully favorable to you, unless that determination was about whether you are engaging or were engaging in substantial gainful activity, if your claim meets the requirements of paragraphs (c) and (d) of appendix 1 of subpart J, part 404 of this chapter;

* * * * *

39. Section 416.1448 is amended by revising the heading of paragraph (a) to read as follows:

§ 416.1448 Deciding a case without an oral hearing before an administrative law judge.

(a) *Decision fully favorable.* * * *

* * * * *

PART 422—ORGANIZATION AND PROCEDURES

40. The authority citation for subpart B of part 422 continues to read as follows:

Authority: Secs. 205, 232, and 702(a)(5), 1131, and 1143 of the Social Security Act (42 U.S.C. 405, 432, 902(a)(5), 1320b–l, and 1320b–13).

41. Section 422.140 is amended by revising the first sentence to read as follows:

§ 422.140 Reconsideration of initial determination.

Except in the case of certain determinations regarding disability (see § 404.930 and appendix 1 of subpart J, part 404 of this chapter), any party who is dissatisfied with an initial determination with respect to entitlement to monthly benefits, a lump-sum death payment, a period of disability, a revision of an earnings record, with respect to any other right under title II of the Social Security Act, or with respect to entitlement to hospital insurance benefits or supplementary medical insurance benefits, or the amount of hospital insurance benefits, may request that the Social Security Administration reconsider such determination. * * *

42. The authority citation for subpart C of part 422 continues to read as follows:

Authority: Secs. 205, 221, and 702(a)(5) of the Social Security Act (42 U.S.C. 405, 421, and 902(a)(5)); 30 U.S.C. 923(b).

43. Section 422.203 is amended by revising the first sentence of paragraph (a)(1), by redesignating paragraph (c) as paragraph (c)(1), and by adding paragraph (c)(2) to read as follows:

§ 422.203 Hearings.

(a) * * * (1) After certain determinations regarding disability (see § 404.930 and appendix 1 of subpart J, part 404 of this chapter), and after a reconsidered or a revised determination (i) of a claim for benefits or any other right under title II of the Social Security Act; or (ii) of eligibility or amount of benefits or any other matter under title XVI of the Act, except where an initial or reconsidered determination involving an adverse action is revised, after such revised determination has been reconsidered; or (iii) as to entitlement under part A or part B of title XVIII of the Act, or as to the amount of benefits under part A of such title XVIII (where the amount in controversy is $100 or more); or of health services to be provided by a health maintenance organization without additional costs (where the amount in controversy is $100 or more); or as to the amount of benefits under part B of title XVIII (where the amount in controversy is $500 or more); or as to a determination by a peer review organization (PRO) under title XI (where the amount in controversy is $200 or more); or as to certain determinations made under section 1154, 1842(1), 1866(f)(2), or 1879 of the Act; any party to such a determination may, pursuant to the applicable section of the Act, file a written request for a hearing on the determination. * * *

* * * * *

(c) * * *

(2) Unless for good cause shown on extension of time has been granted, a request for hearing must be filed within 60 days after the receipt of the notice of the reconsidered or revised determination, or after an initial determination described in § 404.900(a)(3)(ii), 42 CFR 498.3(b) and (c) (see §§ 404.933, 410.631, and 416.1433 of this chapter and 42 CFR 405,722, 498.40, and 417.260.)

* * * * *

[FR Doc. 01–1442 Filed 1–18–01; 8:45 am]

BILLING CODE 4191–02–P

Notices

Federal Register

Vol. 66, No. 13

Friday, January 19, 2001

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Forest Service

Information Collection; Request for Comments; Improve Management of the Tongass National Forest and Service to Southeast Alaska Residents

AGENCY: Forest Service, USDA.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Forest Service announces its intention to establish a new information collection. The collected information will help the Forest Service identify and meet the needs of southeast Alaska residents who use, visit, or benefit in other ways from the Tongass National Forest in southeast Alaska. Information will be collected from southeast Alaska residents.

DATES: Comments must be received in writing on or before March 20, 2001.

ADDRESSES: All comments should be addressed to Robert F. Schroeder, Forestry Sciences Lab, Forest Service, USDA, 2770 Sherwood Lane, Suite 2A, Juneau, AK 99801.

Comments also may be submitted via facsimile to (907) 586–7848 or by email to: rschroeder@fs.fed.us.

The public may inspect comments received at the Office of the Forestry Sciences Lab, Forest Service, USDA, 2770 Sherwood Lane, Suite 2A, Juneau, Alaska. Visitors are asked to call (907) 586–8811, extension 240, to facilitate entrance into the building.

FOR FURTHER INFORMATION CONTACT: Robert F. Schroeder, Forestry Sciences Lab, at (907) 586–8811, extension 240.

SUPPLEMENTARY INFORMATION:

Background

The Tongass National Forest encompasses nearly 85 percent of the land in southeast Alaska, and activities conducted on the Forest form the basis for the regional economy. Commercial fishing, timber production, mineral extraction, and the quickly growing tourism industry depend on the renewable and non-renewable natural resources of this National Forest. The Forest Service completed a revision of the Tongass Land Management Plan in 1997 and published a revised Record of Decision in the **Federal Register** on May 11, 1999 (64 FR 25274). The Tongass Land Management Plan and Record of Decision will serve as a blueprint for how the Forest Service will manage the Tongass National Forest over the next 10 to 15 years.

While revising the Tongass Land Management Plan in 1997, the Forest Service identified critical information needs. Some of these information needs were associated with the human component of Tongass National Forest ecosystems, that is the people and social systems that benefit from these ecosystems.

The collected data, by addressing the human component, will provide the Forest Service with a better understanding of how forest management practices influence community well-being and social change within the southeast Alaska geographic area and will help the agency meet the needs of residents of southeast Alaska who are affected by forest management actions on a day-to-day basis.

The agency will gain a better understanding of the demands that southeast Alaska residents make on the Tongass National Forest programs and services, how well information about agency programs and services are communicated to southeast Alaska residents, and how well the agency meets the needs and expectations of the residents of southeast Alaska.

Forest Service personnel from the Pacific Northwest Research Station Forestry Sciences Lab in Juneau, Alaska, will work in cooperation with University of Alaska research staff to design, administer, and evaluate these surveys. Interviewers will conduct surveys by telephone. Persons interviewed will be asked to respond to questions that include their perceptions of how the Tongass National Forest is managed by the agency, their preferences for how this National Forest should be managed, their perceptions of Tongass National Forest ecosystems, their past and planned visits to the Tongass National Forest, their use of the forest's resources, their vision of the forest of the future, their household and community economic dependence on the forest, and their attitudes and values concerning timber management.

University of Alaska and Forestry Sciences Lab scientists will tabulate the results from this information collection. The results will be available to the public and to State and Federal agencies in printed and electronic formats. The results also will be published in the Pacific Northwest Research Station's General Technical Report series and in referenced journals.

This data collection will provide information on how southeast Alaska residents use the Tongass National Forest, the extent of their economic and subsistence reliance on the forest, and their attitudes and values concerning future management of the Tongass National Forest.

Description of Information Collection

The following describes the information collection to be established:

Title: The Tongass Southeast Alaska Resident Survey.

OMB Number: New.

Expiration Date of Approval: New.

Type of Request: This is a new information collection requirement and has not yet received approval from the Office of Management and Budget.

Abstract: The Forest Service, other Federal agencies, and the State of Alaska conducted a survey in 1979 to assess the interaction of the southeast Alaska residents with the Tongass National Forest. This survey also included the perceptions these residents had of the Tongass as a natural resource. The 1979 survey provided the most recent comprehensive information on southeast Alaska residents' subsistence and recreational use of the Tongass, their attitudes and values concerning the Tongass National Forest, their interest in the development of a regional timber economy, and their perceptions of Forest Service land management practices. This important benchmark survey is now 20 years old and may not be an accurate reflection of the views, perceptions, and activities of current southeast Alaska residents.

This new information collection will provide more current data and will identify issues that have become important to the southeast Alaska residents in the intervening years.

Respondents also will be asked questions that relate to issues that were not important at the time of the 1979 survey. These issues include large scale timber harvesting on national forest and private lands; a large increase in tourist and recreational use of the Tongass National Forest; expansion of tourist use into back-country areas; economic restructuring of the area that is moving away from timber, mining, and commercial fishing toward tourism and service industries; and an increasing resident and visitor population competing for limited fish and wildlife resources.

Forest Service personnel and University of Alaska research staff will conduct a random sample survey of southeast Alaska residents, through telephone interviews.

Data gathered in this information collection are not available from other sources.

Estimate of Annual Burden: 30 minutes per respondent.

Type of Respondents: Individual residents of southeast Alaska communities.

Estimated Annual Number of Respondents: 1600 per year.

Estimated Annual Number of Responses per Respondent: 1.

Estimated Total Annual Burden on Respondents: 800 hours.

Comment Is Invited

The agency invites comments on the following: (a) Whether the proposed collection of information is necessary for the stated purposes and the proper performance of the functions of the agency, including whether the information will have practical or scientific utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Use of Comments

All comments received in response to this notice, including names and addresses when provided, will become a matter of public record. Comments will be summarized and included in the request for Office of Management and Budget approval.

Dated: January 9, 2001.

Barbara C. Weber,

Associate Deputy Chief for Research & Development.

[FR Doc. 01–1583 Filed 1–18–01; 8:45 am]

BILLING CODE 3410–11–U

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce (DOC) has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: Bureau of Export Administration (BXA).

Title: Short Supply Regulations—Unprocessed Western Red Cedar.

Agency Form Number: None.

OMB Approval Number: 0694–0025.

Type of Request: Extension of a currently approved collection of information.

Burden: 35 hours.

Average Time Per Response: 60 minutes per response.

Number of Respondents: 35 respondents.

Needs and Uses: The information is collected as supporting documentation for license applications to export western red cedar logs to enforce the Export Administration Act's prohibition against the export of such logs from State or Federal lands.

Affected Public: Individuals, businesses or other for-profit institutions.

Required to obtain or retain a benefit.

OMB Desk Officer: David Rostker.

Copies of the above information collection proposal can be obtained by calling or writing Madeleine Clayton, Departmental Clearance Officer, Office of the Chief Information Officer, (202) 482–3129, Department of Commerce, Room 6086, 14th and Constitution Avenue, NW, Washington, D.C. 20230, or via e-mail at *MClayton@doc.gov.*

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to David Rostker, OMB Desk Officer, Room 10202, New Executive Office Building, Washington, DC 20230.

Dated: January 12, 2001.

Madeleine Clayton,

Departmental Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 01–1563 Filed 1–18–01; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[Docket No. 010111011–1011–01]

RIN 0648–AO99

Announcement of Intent To Initiate the Process To Designate the Northwestern Hawaiian Islands Coral Reef Ecosystem Reserve as a National Marine Sanctuary; Intent To Prepare a Draft Environmental Impact Statement and Management Plan

AGENCY: Marine Sanctuaries Division (MSD), National Ocean Service (NOS), National Oceanic and Atmospheric Administration, Department of Commerce (DOC).

ACTION: Notice

SUMMARY: On December 4, 2000, President William Clinton signed Executive Order 13178 establishing the Northwestern Hawaiian Islands Coral Reef Ecosystem Reserve, pursuant to the National Marine Sanctuaries Amendments Act of 2000. The Reserve extends approximately 1200 nautical miles long and 100 nautical miles wide. Pursuant to this Act and the Executive Order, NOAA, on behalf of the Secretary is initiating the process to designate the Reserve as a national marine sanctuary and will proceed with the subsequent steps of the designation process. In designating the sanctuary, the Executive Order directs NOAA to supplement or compliment the existing Reserve.

NOAA will prepare an environmental impact statement and management plan which will examine the management, boundary and regulatory alternatives associated with sanctuary designation. NOAA will hold scoping meetings to solicit information and comments on the range and significance of issues related to sanctuary designation and management.

FOR FURTHER INFORMATION CONTACT: Helen Golde, (301) 713–3125, ext. 152 or helen.golde@noaa.gov.

SUPPLEMENTARY INFORMATION: The National Marine Sanctuaries Act (NMSA), 16 U.S.C. 1431 *et seq.*, authorizes the Secretary of Commerce (Secretary) to designate discrete areas of the marine environment as national marine sanctuaries to protect their special conservation, recreational, ecological, historical, cultural, archaeological, scientific, educational, or esthetic qualities. The NMSA is administered by the National Oceanic and Atmospheric Administration (NOAA) through the Marine Sanctuaries Division (MSD).

On May 26, 2000, President Clinton directed the Secretaries of Commerce and the Interior, working cooperatively with the State of Hawaii and consulting with the Western Pacific Fishery Management Council, to develop recommendations for a new, coordinated management regime to increase protection of the coral reef ecosystem of the Northwestern Hawaiian Islands and provide for sustainable use of the area. Upon consideration of their recommendations and comments received during the public visioning process on this intiative, President Clinton issued Executive Order 13178 on December 4, 2000, establishing the Northwestern Hawaiian Islands Coral Reef Ecosystem Reserve (Reserve), pursuant to the National Marine Sanctuaries Amendments Act of 2000 (Act), Public Law 106–513.

As described in Executive Order 13178, the approximately 1,200 mile stretch of coral islands, seamounts, banks, and shoals of the Northwestern Hawaiian Islands are some of the healthiest and most extensive coral reefs in the United States. In their own right, the spectacular coral reefs and lands provide an amazing geological record of volcanic and erosive powers that have shaped this area. This vast area supports a dynamic reef ecosystem that supports more that 7,000 marine species, of which approximately half are unique to the Hawaiian Island chain. This incredibly diverse ecosystem is home to many species of coral, fish, birds, marine mammals, and other flora and fauna including the endangered Hawaiian monk seal, the threatened green sea turtle, and others. In addition, this area has great cultural significance to Native Hawaiian as well as linkages to early Polynesian culture—making it additionally worthy of protection and understanding. This is truly a unique and special place, a coral reef ecosystem like no place on earth, and a source of pride, inspiration, and satisfaction for all Americans, especially the people of Hawaii.

The purpose of the Reserve is to ensure the comprehensive, strong, and lasting protection of the coral reef ecosystem and related marine resource and species of the Northwestern Hawaiian Islands. The Reserve extends approximately 1200 nautical miles long and 100 nautical miles wide. The Reserve is adjacent to and seaward of the seaward boundaries of the State of Hawaii and the Midway Atoll National Wildlife Refuge, and overlays the Hawaiian Islands National Wildlife Refuge to the extent that it extends beyond the seaward boundaries of the State of Hawaii.

As required by the Act and Executive Order 13178, NOAA is initiating the process to designate the Reserve as a national marine sanctuary and will proceed with the steps of the designation process pursuant to the applicable provisions of sections 303 and 304 of the NMSA (16 U.S.C. 1433 and 1434). In designating the sanctuary, the Executive Order directs NOAA to supplement or compliment the existing Reserve. As part of the process, NOAA shall, in consultation with the Governor of the State of Hawaii, determine whether State submerged lands and waters should be included as part of the sanctuary. In designating and managing the sanctuary, the Secretary shall consider the advice and recommendations of the Reserve Council established pursuant to paragraph (f) of section 5 of E.O. 13178. The Reserve Council is expected to be established in January, 2001.

NOAA will prepare an environmental impact statement, pursuant to the National Environmental Policy Act, and management plan which will examine the management, boundary and regulatory alternatives associated with sanctuary designation. NOAA will hold scoping meetings, tentatively planned for spring 2001, to solicit information and comments on the range and significance of issues related to sanctuary designation and management. Individuals and representatives of interested organizations and government agencies are invited and encouraged to attend. Opportunities for comment will exist throughout this process and will be announced in the **Federal Register**, the local media, and other appropriate channels.

Authority: 16 U.S.C. Section 1431 *et seq.*, Pub. L. 106–513.

(Federal Domestic Assistance Catalog Number 11.429 Marine Sanctuary Program)

Dated: January 11, 2001.

John Oliver,

Chief Financial Officer/Chief Administrative Officer.

[FR Doc. 01–1475 Filed 1–18–01; 8:45 am]

BILLING CODE 3510–08–U

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 092500B]

Coral, Golden Crab, Shrimp, Spiny Lobster, Red Drum, Coastal Migratory Pelagic Resources, and Snapper-Grouper Fisheries of the South Atlantic

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Issuance of an exempted fishing permit.

SUMMARY: NMFS announces the issuance of an exempted fishing permit (EFP) for the North Carolina Aquariums (applicant), headquartered in Raleigh, NC. The EFP authorizes the applicant, with certain conditions, to collect for public display up to 60 red porgy and up to 500 lb (227 kg) of coral/live rock in Federal waters off North Carolina each year for 2 years. The three North Carolina Aquariums are located at Roanoke Island, Pine Knoll Shores, and Kure Beach, North Carolina. This EFP is similar to a previously approved EFP for North Carolina Aquariums that expired earlier this year.

DATES: The newly issued EFP is effective January 12, 2001, through December 31, 2002.

ADDRESSES: Copies of the EFP are available from Peter Eldridge, Southeast Regional Office, NMFS, 9721 Executive Center Drive N., St. Petersburg, FL 33702.

FOR FURTHER INFORMATION CONTACT: Peter Eldridge, 727-570-5305; fax 727-570-5583; e-mail: peter.eldridge@noaa.gov.

SUPPLEMENTARY INFORMATION: The EFP is issued under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. 1801 *et seq.*), and regulations at 50 CFR 600.745(b) concerning exempted fishing.

The EFP authorizes the applicant, with certain conditions, to collect for public display up to 60 red porgy and up to 500 lb (227 kg) of coral/live rock in Federal waters off North Carolina each year for 2 years.

The North Carolina Aquariums (NCA), with aquariums located at Roanoke Island, Pine Knoll Shores, and Kure Beach, is a public, non-profit, self-supporting institution established to promote an awareness, understanding, and appreciation of the diverse natural and cultural resources associated with North Carolina's ocean, estuaries, rivers,

streams, and other aquatic environments. The several aquariums are major educational and conservation institutions with extensive field study and outreach programs. The specimens will be maintained in the various NCA facilities for public display.

The proposed collection involves activities otherwise prohibited by Federal regulations implementing the Fishery Management Plans for Coral, Coral Reefs, and Live/Hard Bottom Habitats, and the Fishery Management Plan for the Snapper-Grouper Fisheries of the South Atlantic Region. The applicant requests authorization in order to harvest and possess corals, live rock, and red porgy taken from Federal waters off North Carolina.

The EFP has a number of conditions concerning the harvest of prohibited species and corals, the gear that can be employed, and bycatch restrictions. The EFP requires an annual report to NMFS that lists taken specimens.

A notice of receipt of the application for this permit was published in the **Federal Register** on October 2, 2000 (65 FR 58745). In addition to announcing the receipt of the application, public comments were requested. No public comments were received. Also, consistent with the requirements of 50 CFR 600-745(b)(3)(1), NMFS provided copies of the EFP application to the State of North Carolina, the South Atlantic Fishery Management Council, and the U.S. Coast Guard along with information on the EFP's effects on target species. All of the consulted entities supported the issuance of the EFP.

Failure of the permittee to comply with the terms and conditions of the EFP may be grounds for revocation, suspension or modification of this permit, as well as civil or criminal sanctions.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: January 10, 2001.

Bruce C. Morehead,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 01–1379 Filed 1–18–01; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

ACTION: Notice of proposed information collection requests.

SUMMARY: The Acting Leader, Regulatory Information Management, Office of the Chief Information Officer, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1995.

DATES: An emergency review has been requested in accordance with the Act (44 U.S.C. chapter 3507(j)), since public harm is reasonably likely to result if normal clearance procedures are followed. Approval by the Office of Management and Budget (OMB) has been requested by January 31, 2001. A regular clearance process is also beginning. Interested persons are invited to submit comments on or before March 20, 2001.

ADDRESSES: Written comments regarding the emergency review should be addressed to the Office of Information and Regulatory Affairs, Attention: Lauren Wittenberg, Desk Officer: Department of Education, Office of Management and Budget; 725 17th Street, NW., Room 10235, New Executive Office Building, Washington, DC 20503 or should be electronically mailed to the internet address Lauren_Wittenberg@omb.eop.gov.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35) requires that the Director of OMB provide interested Federal agencies and the public an early opportunity to comment on information collection requests. The Office of Management and Budget (OMB) may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The Acting Leader, Information Management Group, Office of the Chief Information Officer, publishes this notice containing proposed information collection requests at the beginning of the Departmental review of the information collection. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, *e.g.,* new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. ED invites public comment. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on respondents, including through the use of information technology.

Dated: January 12, 2001.

Joe Schubart,

Acting Leader, Regulatory Information Management, Office of the Chief Information Officer.

Office of Special Education and Rehabilitative Services

Type of Review: New.

Title: Performance Report—Training Personnel for the Education of Individuals with Disabilities Education Act (IDEA)

Abstract: This package contains instructions and the form necessary for grantees and contractors supported under Training Personnel for the Education of Individuals, CFDA No. 84.325. Data are obtained from grantees and are used to assess and monitor the implementation of IDEA and for Congressional reporting.

Additional Information: This program is a high priority initiative and an essential part of the Administration's overall strategy to allow the Department of Education to better facilitate the availability of an adequate amount of qualified personnel to better serve the needs of our children.

Frequency: Annually.

Affected Public: Not-for-profit institutions

Reporting and Recordkeeping Hour Burden:

Responses: 450

Burden Hours: 2,250

Requests for copies of the proposed information collection request should be addressed to Vivian Reese, Department of Education, 400 Maryland Avenue, SW., Room 4050, Regional Office Building 3, Washington, DC 20202–4651, or should be electronically mailed to the internet address OCIO_IMG_Issues@ed.gov, or should be faxed to 202–708–9346.

Comments regarding burden and/or the collection activity requirements, contact Sheila Carey at (202) 708–6287 or via her internet address Sheila_Carey@ed.gov. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

[FR Doc. 01–1591 Filed 1–18–01; 8:45 am]

BILLING CODE 4000–01–U

DEPARTMENT OF EDUCATION

Revised Sexual Harassment Guidance: Harassment of Students by School Employees, Other Students, or Third Parties

AGENCY: Office for Civil Rights, Department of Education.

ACTION: Notice of availability.

SUMMARY: The Assistant Secretary for Civil Rights, U.S. Department of Education (Department), announces the availability of a document (revised sexual harassment guidance) that replaces the 1997 document entitled ''Sexual Harassment Guidance: Harassment of Students by School Employees, Other Students, or Third Parties,'' issued by the Office for Civil Rights (OCR) on March 13, 1997 (1997 guidance). We revised the guidance in limited respects in light of subsequent Supreme Court cases relating to sexual harassment in schools.

The revised guidance reaffirms the compliance standards that OCR applies in investigations and administrative enforcement of Title IX of the Education Amendments of 1972 (Title IX) regarding sexual harassment. The revised guidance re-grounds these standards in the Title IX regulations, distinguishing them from the standards applicable to private litigation for money damages and clarifying their regulatory basis as distinct from Title VII of the Civil Rights Act of 1964 agency law. In most other respects the revised guidance is identical to the 1997 guidance. Thus, we intend the revised guidance to serve the same purpose as the 1997 guidance. It continues to provide the principles that a school should use to recognize and effectively respond to sexual harassment of students in its program as a condition of receiving Federal financial assistance.

FOR FURTHER INFORMATION CONTACT: Address requests for copies of the revised sexual harassment guidance to Jeanette J. Lim, U.S. Department of Education, 400 Maryland Avenue, SW., room 5212 Switzer Building, Washington, DC 20202–1100. Telephone: (202) 205–5557 or 1–800–421–3481. For all requests submitted by letter, you must include the term ''Revised Sexual Harassment Guidance.''

If you use a telecommunications device for the deaf (TDD), you may call the TDD number at (202) 260–0471. The document is also available through the Internet at the following site: *http://www.ed.gov/ocr/shguide*

If you prefer to send your request through the Internet, use the following address: ocr@ed.gov

You must include the term ''Revised Sexual Harassment Guidance'' in the subject line of your electronic message.

Individuals with disabilities may obtain this document in an alternative format (*e.g.,* Braille, large print, audiotape, or computer diskette) by contacting the OCR Customer Service Team at 1–800–421–3481.

Electronic Access to This Document

You may view this notice, as well as all other Department of Education documents published in the **Federal Register**, in text or Adobe Portable Document Format (PDF) on the Internet at either of the following sites:

http://ocfo.ed.gov/fedreg.htm
http://www.ed.gov/news.html

To use PDF, you must have Adobe Acrobat Reader, which is available free at either of the previous sites. If you have questions about using PDF, call the U.S. Government Printing Office (GPO), toll free, at 1–888–293–6498; or in the Washington, DC, area at (202) 512–1530.

Note: The official version of this notice is the notice published in the **Federal Register**. Free Internet access to the official edition of the Federal Register and the Code of Federal Regulations is available on GPO Access at: http://www.access.gpo.gov/nara/index.html.

Dated: January 16, 2001.

Norma V. Cantú,

Assistant Secretary for Civil Rights.

[FR Doc. 01–1606 Filed 1–18–01; 8:45 am]

BILLING CODE 4000–01–U

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6933–6]

Agency Information Collection Activities: Proposed Collection; Comment Request; Impact of Formal Environmental Policy Statements on the Teaching, Research and Operations of Colleges and Universities

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this document announces that EPA is planning to submit the following proposed Information Collection Request (ICR) to the Office of Management and Budget (OMB): ''Impact of Formal Environmental Policy Statements on the Teaching, Research and Operations of Colleges and Universities''; EPA ICR #2013.01. Before submitting the ICR to OMB for review and approval, EPA is soliciting comments on specific aspects of the proposed information collection as described below.

DATES: Comments must be submitted on or before March 20, 2001.

ADDRESSES: Office of Enforcement and Compliance, EPA Region 10, 1200 6th Ave. (MS OEC–164), Seattle, WA 98101. Interested persons may obtain a copy of the ICR without charge; to do so, see the following Further Information Contact section.

FOR FURTHER INFORMATION CONTACT: Clark L. Gaulding; Academic Program Manager and Senior Policy Advisor; (206) 553–1849; fax (206) 553–7176. E-mail at <gaulding.clark@epa.gov>

SUPPLEMENTARY INFORMATION:

Affected entities: Entities potentially affected by this action are institutions providing college or university education leading to bachelors and graduate degrees.

Title: ''Impact of Formal Environmental Policy Statements on the Teaching, Research and Operations of Colleges and Universities''; EPA ICR #2013.01.

Abstract: Many universities and colleges have adopted formal statements of environmental policy, and more are being adopted all the time. This is probably good, but little is known about the impacts that these statements have on the actual behavior of our academic institutions. Do they make a difference, and, if so, how? Where's the evidence? Is articulated environmental policy a prophesy of future behavior at the schools that adopt them, or is it rhetoric, however well intended?

This survey study is intended to develop some possible answers to these questions. Written surveys and selected follow-up interviews will be conducted on a representative number of the approximately 4,000 campuses across the U.S. Part of the inquiry is statistical in nature; how many schools have a formal policy on the environment, and how many do not; does it make a difference whether the school is public or private, large or small, urban or rural? Does region make a difference? Of the schools with policies, when were they adopted and is there a trend? Finally, can anything be made of the numbers?

Beyond the numbers, the survey, and especially the interviews, will focus on (1) substance and (2) impact. A random cross-section of written policy statements will be analyzed in comparative fashion to understand not only who wrote them, but what topics they literally address (especially,

teaching, research and operations) and what tone they impart (especially, how purely philosophical or action-oriented are they).

The impact of articulated environmental policy on institutional behavior will be weighed in two ways. The institutions themselves will be asked to explain and document the impacts across the full range of university activities. In parallel, EPA data will be used to look at environmental compliance at schools both with and without written policy to see whether there is any inferential relationship. Response to the study will be voluntary, and results will be reported in statistical fashion rather than with reference to any particular school. The analytical information and conclusions resulting from this study will be useful to academic institutions as they consider their role and responsibility toward society with respect to the natural environment, and to EPA in its policy deliberations regarding its relationship with higher education as an important element of society.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR Chapter 15.

The EPA would like to solicit comments to:

(i) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(ii) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(iii) Enhance the quality, utility, and clarity of the information to be collected; and

(iv) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Burden statement: Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

There are two elements to this proposed study: a written survey questionnaire and a follow-up interview for a selected sub-set of those responding to the questionnaire. Using the burden definition above, it is estimated that the total hour burden for an institution to respond to the written survey questionnaire will be between five (5) and fifteen (15) hours depending on the size and organization of the respondent institution. The hour burden for an institution to participate in a follow-up interview is estimated not to exceed two (2) hours. It is not expected that any institution will incur any capital or recurring costs to participate in the study. Therefore, the dollar cost burden of participation will be directly related to the hour burden and the wage or salary rate of the individuals who handle the response at each institution.

Dated: January 8, 2001.

Lauris Davies,

Director, Office of Enforcement and Compliance, Region 10.

[FR Doc. 01–1345 Filed 1–18–01; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–6614–8]

Environmental Impact Statements and Regulations; Availability of EPA Comments

Availability of EPA comments prepared pursuant to the Environmental Review Process (ERP), under Section 309 of the Clean Air Act and Section 102(2)(c) of the National Environmental Policy Act as amended. Requests for copies of EPA comments can be directed to the Office of Federal Activities at (202) 564–7167. An explanation of the ratings assigned to draft environmental impact statements (EISs) was published in FR dated April 14, 2000 (65 FR 20157).

Draft EISs

ERP No. D–AFS–L65367–AK Rating EC2, Chugach National Forest, Proposed Revised Land and Resource Management Plan, Implementation, Glacier, Seward and Cordora Ranger Districts, Kenai Peninsula Borough, AK.

Summary: EPA expressed environmental concerns with the lack of clarity in the direction and protections in the proposed Standards and Guidelines and the lack of detail in the proposed monitoring and evaluation plan. EPA recommended that the FEIS be revised clarifying how the new plan would conform with the new planning rule, clarify and strengthen the standards and guidelines, revise and refine the monitoring plan, and provide information to support conclusions of the predicted effects.

Final EISs

ERP No. F–AFS–L65327–WA Stimson Alaska National Interest Lands Conservation Act (ANILCA) Access Easement Project, Easement Authorization Grant for Construction, Reconstruction and Use of Seven Road Segments for Hauling Logs and Resource Management, Colville National Forest, Sullivan Ranger District, Pend Oreille County, WA.

Summary: No formal comment letter was sent to the preparing agency.

ERP No. F–AFS–L65353–ID Lakeface-Lamb Fuel Reduction Project, To Reduce the Risk of Lethal Fires within a Wildland/Urban Interface, Implementation, Idaho Panhandle National Forests, Priest Lake Ranger District, Bonner County, ID.

Summary: No formal comment letter was sent to the preparing agency.

ERP No. F–AFS–L65365–ID Swan Flat Timber Sale, Proposal to Cut and Haul Sawtimber, Caribou National Forest, Land Resource Management Plan (LRMP), Montpelier Ranger District, Bear Lake County, ID.

Summary: No formal comment letter was sent to the preparing agency.

ERP No. F–BLM–K67040–CA Imperial Project, Open-Pit Precious Metal Mining Operation Utilizing Heap Leach Processes, Updated Information concerning ''Endangered, Rare or Threatened'' Biological Resources, Plan of Operations and Reclamation Plan Approvals, Right-of-Way Grants, Conditional Use/U.S. COE Permits, El Centro Resource Area, Desert District.

Summary: EPA commended BLM on its consideration of the unique characteristics of the project area within the California Desert Conservation Area, and the proposed project's potential irreparable degradation of sacred and historic values of the Indian Pass-Running Man Area of Traditional Cultural Concern, in identifying its preference for the No Action Alternative.

ERP No. F–COE–H36110–NB Western Sarpy/Clear Creek Flood Reduction Study Including Environmental Restoration Component, Lower Platte River and Tributaries, Saunders and Sarpy Counties, NB.

Summary: EPA expressed its continuing objections to this levee project, as proposed, citing two significant environmental issues: (1) Project need and alternatives; and (2) economic analysis.

ERP No. F–SFW–K99029–CA San Joaquin County Multi-Species Habitat Conservation and Open Space Plan, Issuance of Incidental Take Permit, San Joaquin County, CA.

Summary: EPA expressed continued concern with the proposed SJMSCP's compliance with EPA's CWA Section 404(b)(1) guidelines. The Record of Decision (ROD) should state that CWA Section 404 coverage is not provided by the SJMSCP, describe Section 404(b)(1) requirements, and describe the measures that will be taken to ensure full compensation for temporal, spacial, and functional losses of open-space and multi-species habitat. EPA requested early notification and participation in the project's Regional General 404 Permit process.

ERP No. FS–FHW–A42026–NB US Highway 75 Roadway Improvement, Murray, Nebraska (Highway N–1) to Bellevue, Nebraska (Fairview Road), Updated Information concerning Project Changes and Changes to the Existing Environmental Setting, Funding, Cass and Sarpy Counties, NB.

Summary: EPA expressed no objections to the project as proposed.

Dated: January 16, 2001.

Joseph C. Montgomery,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 01–1688 Filed 1–18–01; 8:45 am]

BILLING CODE 6560–50–U

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–6614–7]

Environmental Impact Statements; Notice of Availability

Responsible Agency:

Office of Federal Activities, General Information (202) 564–7167 or *www.epa.gov/oeca/ofa*

Weekly receipt of Environmental Impact Statements

Filed January 8, 2001 Through January 12, 2001

Pursuant to 40 CFR 1506.9.

EIS No. 010008, Final EIS, AFS, ID, East Beaver and Miner's Creek Timber Sales and Prescribed Burning Project, Implementation, Caribou-Targhee National Forest, Dubois Ranger District, Clark County, ID, Due: February 20, 2001, Contact: John Councilman (208) 558–7301.

EIS No. 010009, Final EIS, AFS, WY, Squirrel Meadows—Grand Targhee Land Exchange Proposal, Implementation, Targhee National Forest, Teton County, WY, Due: February 20, 2001, Contact: Patty Bates (208) 354–2312.

EIS No. 010010, Final EIS, FHW, LA, North-South Expressway Const. I–220 in Shreveport, LA to the Arkansas State Line, Funding and COE Section 404 Permit Issuance, Caddo Parish, LA, Due: February 20, 2001, Contact: William C. Farr (225) 757–7615.

EIS No. 010011, Final EIS, FHW, NY, Miller Highway Project (P.I.N. 103.27), Relocation of Miller Highway between West 59th Street to West 72nd Streets, on the Upper West Side of Manhattan, Funding and COE Section 404 Permit, New York County, NY, Due: February 20, 2001, Contact: Harold Brown (518) 431–4127.

EIS No. 010012, Final EIS, FHW, NV, AZ, US 93 Hoover Dam Bypass Project, Construction of a New Bridge and Highway, Funding, Right-of-Way Easement, U.S. Coast Guard, NPDES and COE Section 404 Permits, Federal Lands—Lake Mead National Recreation Area and Hoover Dam Reservation, Clark County, NV and Mohave County, AZ, Due: February 20, 2001, Contact: Dave Zanetell (303) 716–2167.

EIS No. 010013, Draft EIS, AFS, AK, Threemile Timber Sale, Implementation, Petersburg Ranger District, Tongass National Forest, AK, Due: March 12, 2001, Contact: Everett Kissinger (907) 772–5860.

EIS No. 010014, Draft EIS, AFS, AK, Gravina Island Timber Sale, Implementation, Timber Harvest and Related Activities, Ketchikan-Misty Fiords Ranger District, Tongass National Forest, AK, Due: March 5, 2001, Contact: Susan Marthaller (907) 225–2148.

EIS No. 010015, Draft EIS, BLM, CO, NM, Programmatic EIS—Southern Ute Indian Reservation Oil and Gas Development, Implementation, San Juan Basin, LaPlata, Archuleta, Montezuma Counties, CO and Rio Arriba and San Juan Counties, NM, Due: March 20, 2001, Contact: Don Englishman (970) 385–1346.

EIS No. 010016, Final EIS, AFS, OR, Triangle Land Exchange Project, Between Clearwater Land Exchange Oregon (Clearwater) an Oregon Partnership, Implementation, Malheur, Umatilla and Wallowa-Whitman National Forests, Baker, Grant, Harney and Wallowa Counties, OR, Due: February 20, 2001, Contact: John Day (541) 575–3000.

EIS No. 010017, Final EIS, NPS, CA, NV, Legislative EIS—Timbisha Shoshone Tribal Homeland, To Establish a Permanent Tribal Land Base and Related Cooperative Activities, The Transfer of Federal Land and Acquisition of Private Land, Death Valley National Park, Saline Valley, CA and Lida Ranch near Lida, NV, Due: February 20, 2001, Contact: Joan DeGraff (760) 255–8830.

EIS No. 010018, Draft EIS, FHW, OK, I–40 Crosstown Expressway Transportation Improvements, From I–235/I–35 Interchange West to Meridan Avenue, Funding, Oklahoma City, OK, Due: March 15, 2001, Contact: Lubin Quinones (405) 605–6011.

Dated: January 16, 2001.

Joseph C. Montgomery,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 01–1689 Filed 1–18–01; 8:45 am]

BILLING CODE 6560–50–U

ENVIRONMENTAL PROTECTION AGENCY

[OPP–42077A; FRL–6747–2]

Delaware State Plan for Certification of Applicators of Restricted Use Pesticides; Notice of Approval

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of approval.

SUMMARY: In the **Federal Register** of May 26, 2000 (65 FR 34178) (FRL–6488–6), EPA issued a notice of intent to approve an amended Delaware Plan for the certification of applicators of restricted use pesticides. In this notice EPA solicited comments from the public on the proposed action to approve the amended Delaware Plan. The amended Certification Plan Delaware submitted to EPA contained several statutory, regulatory, and programmatic changes to its current Certification Plan. The proposed amendments establish new requirements for the certification and recertification of pesticide applicators, requires training for registration of non-certified employees, adopts EPA's requirements for direct supervision, adds new commercial subcategories, and establishes the payment of fees for commercial applicators, issuance of business licenses, and dealer permits.

No comments were received and EPA hereby approves the amended Delaware Plan.

ADDRESSES: The amended Delaware Certification Plan can be reviewed at the locations listed under Unit I.B. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Magda Rodriguez-Hunt, Pesticides/Asbestos Programs and Enforcement Branch (3WC32), Environmental Protection Agency, Region III, 1650 Arch St., Philadelphia, PA 19103; telephone number: 215–814–2128; fax number: 215–814–3113; e-mail address: rodriguez-hunt.magda.@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. This action may, however, be of interest to those involved in agriculture and anyone involved with the distribution and application of pesticides for agricultural purposes. Others involved with pesticides in a non-agricultural setting may also be affected. In addition, it may be of interest to others, such as, those persons who are or may be required to conduct testing of chemical substances under the Federal Food, Drug, and Cosmetic Act (FFDCA), or the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of the Amended State Plan, Other Related Documents, and Additional Information?

To obtain copies of the amended Delaware Certification Plan, other related documents, or additional information contact:

1. Magda Rodriguez-Hunt at the address listed under **FOR FURTHER INFORMATION CONTACT**.
2. Larry Towle, Delaware Department of Agriculture, Pesticides Compliance, 2320 Dupont Highway, Dover, DE 19901; telephone number: 302–739–4811; e-mail address: larry@smtp.dda.state.de.us.
3. John MacDonald, Field and External Affairs Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.; telephone number: 703–305–7370; e-mail address: macdonald.john@epa.gov.

II. What Action is the Agency Taking?

EPA is approving the amended Delaware Certification Plan. This approval is based upon the EPA review of the Delaware Plan and finding it in compliance with FIFRA and 40 CFR part 171. Further, there were no public comments submitted to the earlier **Federal Register** Notice soliciting comments. The amended Delaware Certification Plan is therefore approved.

List of Subjects

Environmental protection.

Dated: January 2, 2001,

Bradley Campbell,

Regional Administrator, Region III.

[FR Doc. 01–1350 Filed 1–18–01 8:45 am]

BILLING CODE 6560–50–S

FEDERAL RESERVE SYSTEM

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Board of Governors of the Federal Reserve System

TIME AND DATE: 11 a.m., Wednesday, January 24, 2001.

PLACE: Marriner S. Eccles Federal Reserve Board Building, 20th and C Streets, NW., Washington, DC 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.
2. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Lynn S. Fox, Assistant to the Board; 202–452–3204.

SUPPLEMENTARY INFORMATION: You may call 202–452–3206 beginning at approximately 5 p.m. two business days before the meeting for a recorded announcement of bank and bank holding company applications scheduled for the meeting; or you may contact the Board's Web site at http://www.federalreserve.gov for an electronic announcement that not only lists applications, but also indicates procedural and other information about the meeting.

Dated: January 17, 2001.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 01–1780 Filed 1–17–01; 11:13 am]

BILLING CODE 6210–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–1168]

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. 00–048N]

Relative Risk to Public Health from Foodborne Listeria Monocytogenes Among Selected Categories of Ready-to-Eat Foods; Draft Risk Assessment Document and Risk Management Action Plan; Availability

AGENCY: Food and Drug Administration, HHS, and Food Safety and Inspection Service, USDA.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), and the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA) are announcing the availability of two documents: A draft risk assessment on the relationship between foodborne *Listeria monocytogenes* and human health that considers 20 ready-to-eat food categories, and a risk management action plan based on the *L. monocytogenes* risk assessment. We are making these documents available, and we are seeking public comment of a technical nature on the draft risk assessment. The risk management action plan identifies immediate actions as well as short-term and long-term activities targeted to reduce *L. monocytogenes* associated illnesses. This plan is intended to respond to the President's directive to reduce *L. monocytogenes* associated illnesses by 50 percent by the year 2005. HHS and USDA invite comments on the risk management strategies reflected in the action plan. A public meeting to discuss the draft risk assessment and the risk management plan will be announced in a future issue of the **Federal Register**.

DATES: Comments on the draft risk assessment and the HHS/USDA risk management action plan must be submitted by March 20, 2001.

ADDRESSES: Printed copies of the draft risk assessment and the risk management action plan may be requested by faxing your name and mailing address with the names of the documents you are requesting by faxing your name and mailing address with the names of the documents you are requesting to the CFSAN Outreach and Information Center at 1–877–366–3322. The documents may be reviewed at the

FDA Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday, and at the FSIS Docket Clerk's Office between 8:30 a.m. and 4:30 p.m., Monday through Friday.

Submit written comments to the Dockets Management Branch (HFA–305), Docket No. 99N–1168, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Two copies of comments are to be submitted, except that individuals may submit one copy.

or

Submit one original and two copies of written comments to FSIS Docket Clerk, Docket No. 00–048N, U.S. Department of Agriculture, Food Safety and Inspection Service, Room 102, Cotton Annex, 300 12th St. SW., Washington, DC 20250–3700. All comments submitted in response to this notice will be available for public inspection in the Docket Clerk's Office between 8:30 a.m. and 4:30 p.m., Monday through Friday. For electronic access to these documents see section III of the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT:

For information concerning the draft risk assessment document: Sherri B. Dennis, Risk Assessment Coordinator, Center for Food Safety and Applied Nutrition (HFS–032), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–260–3984, FAX 202–260–9653, or e-mail: sdennis@cfsan.fda.gov.

For information concerning the risk management action plan: Kathy Gombas, Center for Food Safety and Applied Nutrition (HFS–615), Food and Drug Administration, 200 C St. SW., Washington, DC 20204; 202–205–4231; FAX 202–260–0136, e-mail: Kathy.Gombas@cfsan.fda.gov or Charles Edwards, Food Safety and Inspection Service, U.S. Department of Agriculture, rm. 405, Cotton Annex, 300 12th St. SW., Washington, DC 20250–3700; 202–205–0675; FAX 202–205–0080.

SUPPLEMENTARY INFORMATION:

I. Draft Risk Assessment

A. Background

The draft risk assessment was written by FDA's Center for Food Safety and Applied Nutrition (CFSAN) and USDA/FSIS, in consultation with the Centers for Disease Control and Prevention (CDC). These agencies began this comprehensive quantitative microbial risk assessment (QMRA) in 1999, and have held two public meetings to present the framework of the assessment, the assumptions, and the modeling procedures.

In the **Federal Register** of May 7, 1999 (64 FR 24661), FDA, in collaboration with USDA/FSIS, announced plans to conduct a risk assessment to determine the extent of consumer exposure to foodborne *L. monocytogenes*. In the **Federal Registers** of May 7, 1999 (64 FR 24663), and August 13, 1999 (64 FR 44225), the agencies announced public meetings to discuss issues related to the risk models under development. You may refer to these notices for further background information.

B. The Listeria monocytogenes QMRA

The goal of this QMRA is to provide FDA and USDA/FSIS with information that will assist the agencies with the review of current programs and the development of new programs relating to the regulation of *L. monocytogenes* contamination in foods to ensure that such programs protect the public health. QMRA is a structured and systematic process of collecting and evaluating data and information to establish the risks to human health from consumption of pathogenic microorganisms. The draft risk assessment evaluates the available data on food consumption, contamination of various foods within 20 ready-to-eat food product categories by *L. monocytogenes*, growth of the pathogen in such foods, and the infectious dose. The draft risk assessment follows the framework recommended by both the National Academy of Sciences and the Codex Alimentarius Commission. This structured framework involves the following steps:

(1) *Hazard identification*. The collection and critical review of data and information on *L. monocytogenes*.

(2) *Exposure assessment*. The determination of total exposure to *L. monocytogenes* from consumption of various foods using prevalence and food consumption data.

(3) *Hazard characterization/Dose-response*. The assessment of the potential for *L. monocytogenes* to cause illness in human populations using epidemiological investigations and data from animal studies.

(4) *Risk characterization*. The integration of the exposure and dose-response data into a complex model to estimate both the risk to the public health and the uncertainty associated with this estimate.

The risk assessment process also includes the identification of data gaps and the development of, and the reliance on, reasonable assumptions when data are unavailable.

As part of a peer evaluation of the draft risk assessment, FDA and USDA/FSIS are seeking comments that can be used to improve:

(1) The assumptions made,

(2) the modeling technique,

(3) the data used, and

(4) the transparency of the draft risk assessment document.

It is our intent to review and evaluate all public comments and make modifications to the assessment, as appropriate. As noted previously, the draft risk assessment is available electronically on websites listed in section III of the Supplementary Information section of this document and may be reviewed at the FDA's Dockets Management Branch and FSIS's Docket Clerk's Office (addresses above).

II. HHS/USDA Risk Management Action Plan

A. Background

On May 5, 2000, the President directed the Secretary of HHS and the Secretary of Agriculture to identify aggressive steps to reduce significantly the risk of illness and death from *L. monocytogenes* in ready-to-eat foods. The President called for action to reduce the number of *L. monocytogenes* illnesses by 50 percent by the year 2005—5 years ahead of the previously established Healthy People 2010 target.

The President directed the Secretary of HHS to develop an action plan identifying additional steps necessary to reduce *L. monocytogenes* contamination. He specifically directed that the HHS plan include consideration of control measures for at-risk foods, publication of guidance for processors, retailers, and food service facilities, and consideration of enhanced labeling to provide additional safeguards for consumers. The President also directed the Secretary of Agriculture to report back on the actions that would reduce significantly the risk of illness and death from *L. monocytogenes* in ready-to-eat foods. The President in particular directed the Secretary of Agriculture to ''complete proposed regulations that include any appropriate microbiological testing and other industry measures'' to prevent cross-contamination in the processing environment; ensure that the processing of ready-to-eat products meets appropriate standards; and ensure that such products are safe throughout their shelf-life. Taken together, these actions are designed to reduce *L. monocytogenes*-related illnesses by 50 percent by 2005.

B. The L. Monocytogenes Action Plan

The action plan outlines the actions HHS and USDA intend to undertake to

reduce *L. monocytogenes* illnesses from ready-to-eat foods. The plan focuses on those food categories identified in the draft risk assessment as either warranting additional measures to reduce *L. monocytogenes* contamination or warranting collection of additional data. Within HHS, FDA and CDC have the primary responsibility for implementation of this action plan. Within USDA, FSIS has the primary responsibility for implementation of this plan, working in concert with other USDA agencies through the Office of Food Safety.

The action plan contains the following eight action areas:

(1) Enhance consumer and health care provider information and education efforts;

(2) Develop and revise guidance for processors, retailers, and food service/institutional establishments that manufacture or prepare ready-to-eat foods;

(3) Develop and deliver training/technical assistance to the regulated industry and food safety regulatory employees;

(4) Review and redirect enforcement and regulatory strategies including microbial product sampling;

(5) Propose new regulations and revisions to existing regulations as needed;

(6) Enhance disease surveillance and outbreak response;

(7) Initiate projects with retail operations such as delicatessens and salad bars to pilot new *L. monocytogenes* control measures including employee practices; and

(8) Coordinate research activities to refine the risk assessment, enhance preventive controls, and support regulatory, enforcement, and educational activities.

As noted, the draft risk assessment will be available, along with other information, to assist HHS and USDA as they consider the specific means to implement the elements of the action plan.

III. Electronic Access

The draft risk assessment document and the risk management plan are available electronically as follows:

Draft Risk Assessment Document	www.cfsan.fda.gov www.fsis.usda.gov www.foodsafety.gov www.foodriskclearinghouse.umd.edu
The Risk Management Action Plan	www.cfsan.fda.gov www.foodsafety.gov www.fsis.usda.gov

Dated: January 11, 2001.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation, Food and Drug Administration, HHS.

Thomas J. Billy,

Administrator, Food Safety Inspection Service, USDA.

[FR Doc. 01–1439 Filed 1–18–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–1075]

Public Health Impact of Vibrio Parahaemolyticus in Raw Molluscan Shellfish; Draft Risk Assessment Document; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft risk assessment on the relationship between *Vibrio parahaemolyticus* in raw molluscan shellfish, specifically oysters, and human health. FDA began this quantitative microbial risk assessment (QMRA) in 1999, and the agency has held three public meetings on the framework of the assessment, the assumptions, and the modeling procedures. As part of the review process, the agency is making this draft risk assessment available and is seeking comments on the technical aspects of the draft risk assessment. A public meeting to discuss the draft risk assessment will be announced in a future issue of the **Federal Register**.

DATES: Submit written comments on the draft risk assessment by March 20, 2001.

ADDRESSES: The draft risk assessment is available electronically on the FDA Internet at www.foodsafety.gov/dms/fs-toc.html. Hard copies of the draft risk assessment will be available upon request; fax requests to 1–877–366–3322. The draft risk assessment may also be reviewed at the Dockets Management Branch (address below) between 9 a.m. and 4 p.m., Monday through Friday.

Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Two copies of comments are to be submitted, except that individuals may submit one copy. Comments must be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: *For specific technical information contact:* Marianne Miliotis, *Vibrio parahaemolyticus* Risk Assessment

Team Leader, Center for Food Safety and Applied Nutrition (HFS–327), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4824, FAX 202–205–4939, or e-mail: mmilioti@cfsan.fda.gov.

For general information contact: Sherri B. Dennis, Risk Assessment Coordinator, Center for Food Safety and Applied Nutrition (HFS–032), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–260–3984, FAX 202–260–9653, or e-mail: sdennis@cfsan.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 7, 1999 (64 FR 24664), FDA announced plans to conduct a risk assessment to determine the extent of exposure of consumers to *V. parahaemolyticus* in raw molluscan shellfish. On August 13, 1999 (64 FR 44226), FDA announced public meetings to discuss issues related to the risk models under development. You may refer to these notices for background.

II. The V. Parahaemolyticus QMRA

The goal of this QMRA is to provide FDA with information that will assist the agency with the review of current programs relating to the regulation of *V. parahaemolyticus* in raw molluscan shellfish to ensure that such programs protect the public health. QMRA is a structured and systematic process of collecting and evaluating data and information to determine the risks to human health from consumption of pathogenic microorganisms. This draft risk assessment evaluates factors that most influence the prevalence of *V. parahaemolyticus* in shellfish at harvest and after harvest handling practices. The draft risk assessment also evaluates preventive and intervention strategies, as well as the FDA and Interstate Shellfish Sanitation Conference guideline of up to 10,000 viable *V. parahaemolyticus* cells per gram of seafood. The draft risk assessment follows the framework recommended by both the National Academy of Sciences and the Codex Alimentarius Commission. This structured framework involves the following steps:

- *Hazard identification*. The collection and critical review of data and information on *V. parahaemolyticus*.
- *Exposure assessment*. The determination of the likelihood of ingesting pathogenic *V. parahaemolyticus* by eating raw molluscan shellfish harboring the organism and the amount of pathogenic *V. parahaemolyticus* present when consumed.
- *Hazard characterization/dose-response*. The relationship of the levels of *V. parahaemolyticus* ingested with the frequency and magnitude of illness using epidemiological investigations and clinical trials.
- *Risk characterization*. The integration of dose-response and exposure assessments into a complex model to estimate risk of illness and range of uncertainty associated with this estimate. The risk assessment process also involves the identification of data gaps and the development of reasonable assumptions if data are unavailable.

FDA began this QMRA in 1999. Recognizing the public health importance of this pathogen, the scientific knowledge and data currently available were rigorously evaluated to assure that this assessment will serve to facilitate several processes, including the formulation of effective guidance for the industry, regulators, and consumers and the evaluations of risk mitigation strategies.

As part of a peer evaluation of the draft risk assessment, FDA is seeking comments in the following areas: (1) The assumptions, (2) the modeling technique, (3) the data sets used, and (4) transparency of the document. FDA intends to review and evaluate all public comments and make modifications to the assessment, as appropriate.

As noted previously, the draft risk assessment is available electronically on FDA's website and may be reviewed in the agency's Dockets Management Branch.

Dated: December 18, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–1440 Filed 1–18–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4644–N–03]

Federal Property Suitable as Facilities To Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for possible use to assist the homeless.

EFFECTIVE DATE: January 19, 2001.

FOR FURTHER INFORMATION CONTACT: Clifford Taffet, Department of Housing and Urban Development, Room 7262, 451 Seventh Street SW, Washington, DC 20410; telephone (202) 708–1234; TTY number for the hearing- and speech-impaired (202) 708–2565, (these telephone numbers are not toll-free), or call the toll-free Title V information line at 1–800–927–7588.

SUPPLEMENTARY INFORMATION: In accordance with the December 12, 1988 court order in *National Coalition for the Homeless* v. *Veterans Administration*, No. 88–2503–OG (D.D.C.), HUD publishes a Notice, on a weekly basis, identifying unutilized, underutilized, excess and surplus Federal buildings and real property that HUD has reviewed for suitability for use to assist the homeless. Today's Notice is for the purpose of announcing that no additional properties have been determined suitable or unsuitable this week.

Dated: January 11, 2001.

John D. Garrity,

Director, Office of Special Needs Assistance Programs.

[FR Doc. 01–1398 Filed 1–18–01; 8:45 am]

BILLING CODE 4210–29–M

DEPARTMENT OF THE INTERIOR

Office of the Secretary; Notice of Deadline for Submitting Completed Applications To Begin Participation in the Tribal Self-Governance Program in Fiscal Year 2002 or Calendar Year 2002

AGENCY: Office of Self-Governance, Interior.

ACTION: Notice of application deadline.

SUMMARY: In this notice, the Office of Self-Governance (OSG) establishes a March 1, 2001, deadline for tribes/consortia to submit completed applications to begin participation in the tribal self-governance program in fiscal year 2002 or calendar year 2002.

DATES: Completed application packages must be received by the Director, Office of Self-Governance by March 1, 2001.

ADDRESSES: Application packages for inclusion in the applicant pool should be sent to the Director, Office of Self-Governance, U.S. Department of the Interior, Mail Stop 2548, 1849 C Street, NW., Washington DC 20240.

FOR FURTHER INFORMATION CONTACT: Dr. Kenneth D. Reinfeld, U.S. Department of the Interior, Office of Self-Governance, 1849 C Street NW., Mail Stop 2548, Washington DC 20240; Telephone 202–208–5734.

SUPPLEMENTARY INFORMATION: Under the Tribal Self-Governance Act of 1994 (Public Law 103–413), as amended by the Fiscal Year 1997 Omnibus Appropriations Bill (Public Law 104–208), the Director, Office of Self-Governance may select up to 50 additional participating tribes/consortia per year for the tribal self-governance program, and negotiate and enter into an annual written funding agreement with each participating tribe. The Act mandates that the Secretary submit copies of the funding agreements at least 90 days before the proposed effective date to the appropriate committees of the Congress and to each tribe that is served by the Bureau of Indian Affairs (BIA) agency that is serving the tribe that is a party to the funding agreement. Initial negotiations with a tribe/consortium located in a BIA region and/or agency which has not previously been involved with self-governance negotiations, will take approximately two months from start to finish. Agreements for an October 1 to September 30 fiscal year need to be signed and submitted by July 1. Agreements for a January 1 to December 31 fiscal year need to be signed and submitted by October 1.

Background

On December 15, 2000, a final rule was published in the **Federal Register** implementing Tribal Self-Governance, as authorized by Title IV of the Indian Self-Determination and Education Assistance Act. This rule has been negotiated among representatives of Self-Governance and non-Self-Governance Tribes and the U.S. Department of the Interior. Selection of additional tribes for participation in tribal self-governance is governed by subparts 1000.10 to 1000.31.

Purpose of Notice

The final rule established at 25 CFR subparts 1000.10 to 1000.31 will be used to govern the application and selection process for tribes/consortia to begin their participation in the tribal self-governance program in fiscal year 2002 and calendar year 2002. Applicants should be guided by the requirements in these subparts in preparing their applications. Copies of these subparts may be obtained from the information contact person identified in this notice.

Tribes/consortia wishing to be considered for participation in the tribal self-governance program in fiscal year 2002 or calendar year 2002 must respond to this notice, except for those which are (1) currently involved with negotiations with the Department; (2) one of the 77 tribal entities with signed agreements; or (3) one of the tribal entities already included in the applicant pool as of the date of this notice.

Dated: December 22, 2000.

Kevin Gover,

Assistant Secretary—Indian Affairs.

[FR Doc. 01–396 Filed 1–18–01; 8:45 am]

BILLING CODE 4310–02–P

INTERNATIONAL TRADE COMMISSION

Sunshine Act Meeting; Emergency Notice of Change of Time of Meeting

AGENCY HOLDING THE MEETING: United States International Trade Commission.

DATE AND TIME: January 18, 2001 at 11 a.m.

PLACE: Room 101, 500 E Street SW., Washington, DC 20436, Telephone: (202) 205–2000.

STATUS: Open to the public.

In accordance with 19 CFR § 201.35(d)(1), notice is hereby given that the Commission has determined to change the time of the meeting being held Thursday, January 18, 2001 from 2 p.m. to 11 a.m. Earlier notification of such change was not possible.

Issued: January 17, 2001.

By order of the Commission.

Donna R. Koehnke,

Secretary.

[FR Doc. 01–1815 Filed 1–17–01; 2:18 pm]

BILLING CODE 7020–02–M

DEPARTMENT OF LABOR

Employment Standards Administration, Wage and Hour Division

Minimum Wages for Federal and Federally Assisted Construction; General Wage Determination Decisions

General wage determination decisions of the Secretary of Labor are issued in accordance with applicable law and are based on the information obtained by the Department of Labor from its study of local wage conditions and date made available from other sources. They specify the basic hourly wage rates and fringe benefits which are determined to be prevailing for the described classes of laborers and mechanics employed on construction projects of a similar character and in the localities specified therein.

The determinations in these decisions of prevailing rates and fringe benefits have been made in accordance with 29 CFR Part 1, by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act of March 3, 1931, as amended (46 Stat. 1494, as amended, 40 U.S.C. 276a) and of other Federal statutes referred to in 29 CFR Part 1, Appendix, as well as such additional statutes as may from time to time be enacted containing provisions for the payment of wages determined to be prevailing by the Secretary of Labor in accordance with the Davis-Bacon Act. The prevailing rates and fringe benefits determined in these decisions shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged on contract work of the character and in the localities described therein.

Good cause is hereby found for not utilizing notice and public comment procedure thereon prior to the issuance of these determinations as prescribed in 5 U.S.C. 553 and not providing for delay in the effective date as prescribed in that section, because the necessity to issue current construction industry wage determinations frequently and in large volume causes procedures to be impractical and contrary to the public interest.

General wage determination decisions, and modifications and supersedes decisions thereto, contain no expiration dates and are effective from their date of notice in the **Federal Register**, or on the date written notice is received by the agency, whichever is earlier. These decisions are to be used in accordance with the provisions of 29 CFR Parts 1 and 5. Accordingly, the applicable decision, together with any modifications issued, must be made a part of every contract for performance of the described work within the geographic area indicated as required by an applicable Federal prevailing wage law and 29 CFR Part 5. The wage rates and fringe benefits, notice of which is published herein, and which are contained in the Government Printing Office (GPO) document entitled ''General Wage Determinations Issued Under The Davis-Bacon and Related Acts,'' shall be the minimum paid by contractors and subcontractors to laborers and mechanics.

Any person, organization, or governmental agency having an interest in the rates determined as prevailing is encouraged to submit wage rate and fringe benefit information for consideration by the Department. Further information and self-explanatory forms for the purpose of

submitting this data may be obtained by writing to the U.S. Department of Labor, Employment Standards Administration, Wage and Hour Division, Division of Wage Determinations, 200 Constitution Avenue, NW., Room S–3014, Washington, DC 20210.

Modifications to General Wage Determination Decisions

The number of decisions listed in the Government Printing Office document entitled ''General Wage Determinations Issued Under the Davis-Bacon and Related Acts'' being modified are listed by Volume and State. Dates of publication in the **Federal Register** are in parentheses following the decisions being modified.

Volume I

None

Volume II

None

Volume III

None

Volume IV

None

Volume V

None

Volume VI

None

Volume VII

None

General Wage Determination Publication

General wage determinations issued under the Davis-Bacon and Related Acts, including those noted above, may be found in the Government Printing Office (GPO) document entitled ''General Wage Determinations Issued Under The Davis-Bacon and Related Acts.'' This publication is available at each of the 50 Regional Government Depository Libraries and many of the 1,400 Government Depository Libraries across the country.

The general wage determinations issued under the Davis-Bacon and Related Acts are available electronically by subscription to the FedWorld Bulletin Board System of the National Technical Information Service (NTIS) of the U.S. Department of Commerce at 1–800–363–2068.

Hard-copy subscriptions may be purchased from: Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, (202) 512–1800.

When ordering hard-copy subscription(s), be sure to specify the State(s) of interest, since subscriptions may be ordered for any or all of the seven separate volumes, arranged by State. Subscriptions include an annual edition (issued in January or February) which includes all current general wage determinations for the States covered by each volume. Throughout the remainder of the year, regular weekly updates are distributed to subscribers.

Dated: Signed at Washington, DC this 11th Day of January 2001.

Carl J. Poleskey,

Chief, Branch of Construction Wage Determinations.

[FR Doc. 01–1444 Filed 1–18–01; 8:45 am]

BILLING CODE 4510–27–M

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meeting

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Pub. L. 94–409, that the Securities and Exchange Commission will hold the following meeting during the week of January 22, 2001.

A closed meeting will be held on Tuesday, January 23, 2001, at 10 a.m.

Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the closed meeting. Certain staff members who have an interest in the matters may also be present.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(4), (8), (9)(A) and (10) and 17 CFR 200.402(a)(4), (8), (9)(A) and (10), permit consideration of the scheduled matters at the closed meeting.

The subject matters of the closed meeting will be:

institution and settlement of injunctive actions; and

institution and settlement of administrative proceedings of an enforcement nature.

At times, changes in Commission priorities require alterations in the scheduling of meeting items. For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact:

The Office of the Secretary at (202) 942–7070.

Dated: January 16, 2001.

Jonathan G. Katz,

Secretary.

[FR Doc. 01–1701 Filed 1–16–01; 4:20 pm]

BILLING CODE 8010–01–M

SMALL BUSINESS ADMINISTRATION

Administrator's Line of Succession Designation, No. 1–A, Revision 23

This document replaces and supercedes ''Line of Succession Designation No. 1–A, Revision 22.''

Line of Succession Designation No. 1–A, Revision 23

Effective immediately, the Administrator's Line of Succession Designation is as follows:

(a) If I am absent from the office the Deputy Administrator will assume all functions and duties of the Administrator. In the event both I and the Deputy Administrator are absent from the office, I designate the officials in listed order below to serve as Acting Administrator with full authority to perform all acts which the Administrator is authorized to perform:

(1) Chief of Staff;

(2) General Counsel;

(3) Associate Deputy Administrator for Management and Administration;

(4) Associate Deputy Administrator for Capital Access;

(5) Associate Deputy Administrator for Government Contracting and Business Development;

(6) Associate Deputy Administrator for Entrepreneurial Development;

(7) Counselor to the Administrator;

(8) Chief Operating Officer;

(9) Deputy General Counsel;

(10) Chief Financial Officer.

(a) An individual serving in an acting capacity in any of the positions listed in paragraph (a)(1) through (10) is not also included in this Line of Succession. Instead, the next non-acting incumbent on the list shall serve as Acting Administrator.

(b) This designation shall remain in full force and effect until revoked or superceded in writing by the Administrator, or by the Deputy Administrator when serving as Acting Administrator.

(c) Serving as Acting Administrator has no effect on the officials listed in paragraph (a)(1) through (10), above, with respect to their full-time position's authorities, duties and responsibilities (except that such official cannot both recommend and approve an action).

Dated: January 5, 2001.

Aida Alvarez,

Administrator.

[FR Doc. 01–1584 Filed 1–18–01; 8:45 am]

BILLING CODE 8010–01–U

SOCIAL SECURITY ADMINISTRATION

Rate for Attorney Fee Assessment Beginning in 2001

AGENCY: Social Security Administration.

ACTION: Notice.

SUMMARY: The Social Security Administration is announcing that the attorney-fee assessment rate under section 206(d) of the Social Security Act, 42 U.S.C. 406(d), for 2001 is 6.3 percent.

FOR FURTHER INFORMATION CONTACT: John Watson, Social Security Administration, Office of the General Counsel, Phone: (410) 965–3137, email: *John.Watson@ssa.gov.*

SUPPLEMENTARY INFORMATION: Section 406 of Public Law No. 106–170, the Ticket to Work and Work Incentives Improvement Act of 1999, established an assessment for the services required to determine and certify payments to attorneys from the benefits due claimants under Title II of the Social Security Act. This provision is codified in section 206 of the Social Security Act (42 U.S.C. 406). The legislation set the assessment for the calendar year 2000 at 6.3 percent of the amount that would be required to be certified for direct payment to the attorney under either section 206(a)(4) or 206(b)(1) before the application of the assessment. For subsequent years, the legislation requires the Commissioner of Social Security to determine the percentage rate necessary to achieve full recovery of the costs of determining and certifying fees to attorneys, but not in excess of 6.3 percent.

The Commissioner of Social Security has determined, based on available data, that the current rate of 6.3 percent will continue. We based our decision to continue the 6.3 percent assessment rate on work sampling and management information data for performing these functions. We are continuing to review our data to determine if a change is appropriate subsequently.

Dated: January 16, 2001.

Yvette S. Jackson,

Deputy Commissioner for Finance, Assessment and Management.

[FR Doc. 01–1608 Filed 1–18–01; 8:45 am]

BILLING CODE 4191–02–U

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Generalized System of Preferences (GSP); Deadline for Submitting Public Comments on Modification of Duty-Free Treatment for Certain Products Imported From India.

AGENCY: Office of the United States Trade Representative (USTR).

ACTION: Notice of request for public comment

SUMMARY: This notice informs the public that the U.S. Government is considering whether to modify duty-free treatment accorded to certain imports from India under the U.S. Generalized System of Preferences (GSP). The review is being undertaken to determine whether India offers ''equitable and reasonable market access for U.S. goods and services.'' If the conclusion is negative, the U.S. government is prepared to take steps that would lead to withdrawal of existing benefits on some products imported from India. Some or all of the products listed in the Annex may be affected. This notice sets forth the deadline for submitting public comments. A decision on this matter is expected on or about April 1, 2001.

FOR FURTHER INFORMATION CONTACT: GSP Subcommittee, Office of the United States Trade Representative, 600 17th Street, NW., Room 518, Washington, DC 20508 (Tel. 202/395–6971). Public versions of all documents relating to this review are available for public inspection by appointment in the USTR public reading room between 9:30–12 a.m. and 1–4 p.m. (Tel. 202/395–6186).

SUPPLEMENTARY INFORMATION: The GSP program is authorized pursuant to Title V of the Trade Act of 1974, as amended (''the Trade Act'') (19 U.S.C. 2461 *et seq.*). The GSP program grants duty-free treatment to designated eligible articles that are imported from designated beneficiary developing countries. Once granted, GSP benefits may be withdrawn, suspended or limited by the President with respect to any article or with respect to any country. In determining whether to withdraw, suspend, or limit GSP benefits, the President must consider several factors, one of which is whether the country offers equitable and reasonable market access for U.S. goods and services (19 U.S.C. 2462(c)(4)). India is a beneficiary of the GSP program. In 1999, more than $1 billion in imports from India were granted duty-free treatment under the GSP program; through October 2000, more than $966 million in imports from India received duty-free treatment under GSP, an increase of over 13% over 1999.

On June 12, 1998, the American National Soda Ash Corporation (ANSAC) filed a petition in the 1998 GSP country review contending that the Government of India has failed to provide the United States equitable and reasonable access to India's soda ash market. ANSAC requested that India's benefits under the GSP program be withdrawn, suspended or limited. This petition was accepted for review and was the subject of public comment and hearings. The United States also raised these concerns with the Government of India over the course of two years without resolution. Accordingly, absent a substantial improvement in equitable and reasonable market access for U.S. goods and services in India, the TPSC may recommend that the President withdraw GSP benefits for India on some or all of the products identified in the Annex to this notice.

Opportunities for Public Comment and Inspection of Comments

The GSP Subcommittee of the TPSC invites comments in support of, or in opposition to, the withdrawal, suspension or limitation of duty-free treatment under the GSP program for certain products imported from India. The deadline for submissions is 5 p.m. on Friday, February 16, 2001.

Parties submitting comments must submit an original and 14 copies, in English, to the Chairman of the GSP Subcommittee, Trade Policy Staff Committee, 600 17th Street, NW., Room 518, Washington, DC 20508. Information and comments will be available for public inspection by appointment with the staff of the USTR public reading room, except for information submitted in confidence pursuant to 15 CFR 2007.7. If the document contains business confidential information, an original and 14 copies of a public version of the submission along with 15 copies of the confidential version must be also submitted. The business confidential version of the submission should be clearly marked ''business confidential'' at the top and bottom of each page of the document. A nonconfidential summary of the business confidential information must be included with the business confidential submission, along with a written explanation of why the business confidential material should be protected. The public version should also be clearly marked at the top and bottom of each and every page (either ''public version'' or ''nonconfidential''). Submissions should comply with 15

CFR part 2007, including sections 2007.0, and 2007.1.

Jon Rosenbaum,

Assistant U.S. Trade Representative for Trade and Development.

Annex

The products under consideration in this Annex encompass all articles that are classified under the specified numerical subheadings in the Harmonized Tariff Schedule of the United States listed below.

2008.19.15
2008.19.25
2008.19.90
2008.30.37
2008.30.48
2008.30.60
2008.30.95
2008.91.00
2008.99.15
2008.99.20
2008.99.28
2008.99.35
2008.99.40
2008.99.45
2008.99.50
2008.99.61
2008.99.63
2008.99.65
2008.99.80
2008.99.90
2511.10.50
3907.10.00
3907.20.00
3907.40.00
3907.50.00
3907.91.40
3907.91.50
3917.10.10
3917.10.90
3917.21.00
3917.22.00
3917.23.00
3917.29.00
3917.31.00
3917.32.60
3917.33.00
3917.39.00
3917.40.00
3926.10.00
3926.20.90
3926.30.10
3926.40.00
3926.90.10
3926.90.15
3926.90.20
3926.90.25
3926.90.30
3926.90.33
3926.90.35
3926.90.40
3926.90.45
3926.90.50
3926.90.56
3926.90.57
3926.90.60
3926.90.70
3926.90.75
3926.90.83
3926.90.87
3926.90.98
4104.31.20
4203.10.20
4203.30.00
4203.40.30
5903.10.10
5903.10.20
5903.20.20
5903.90.10
5903.90.20
6307.90.60
6307.90.85
6307.90.99
7113.11.10
7113.11.20
7113.19.10
7113.19.30
7113.20.10
7113.20.30
7113.20.50
7202.11.10
7202.19.10
7202.19.50
7202.41.00
7202.49.50
7202.80.00
7202.99.10
7307.11.00
7307.19.30
7307.21.10
7307.22.10
7307.22.50
7307.23.00
7307.29.00
7307.91.10
7307.92.30
7307.92.90
7307.93.60
7307.93.90
7307.99.10
7307.99.30
7307.99.50
7308.10.00
7308.20.00
7308.30.10
7308.30.50
7308.40.00
7318.12.00
7318.13.00
7318.15.60
7318.15.80
7318.19.00
7318.21.00
7318.24.00
7318.29.00
7320.10.30
7320.10.90
7320.20.10
7320.20.50
7320.90.50
7323.91.50
7323.93.00
7323.94.00
7323.99.30
7323.99.70
7323.99.90
7325.91.00
7325.99.50
7326.19.00
7326.20.00
7326.90.60
7326.90.85
7606.11.30
7606.11.60
7606.12.30
7606.12.60
7606.91.30
7606.91.60
7606.92.30
7606.92.60
7609.00.00
7615.11.00
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8205.59.80
8205.60.00
8205.70.00
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8207.90.45
8207.90.60
8207.90.75
8413.30.90
8413.91.10
8466.10.80
8466.20.10
8466.20.80
8466.30.10
8466.30.60
8466.30.80
8466.92.50
8466.93.30
8466.93.53
8466.93.75
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8501.62.00
8501.63.00
8501.64.00
8543.19.00
8543.20.00
8543.30.00
8543.40.00
8543.89.40
8543.89.60
8543.89.70
8543.89.80
8543.89.96
8543.90.15
8543.90.35
8543.90.68
8543.90.88
8544.11.00
8544.19.00
8544.20.00
8544.41.80
8544.49.80
8544.51.90
8544.59.20
8544.59.40
8544.60.20
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8544.60.60
8708.10.30
8708.10.60
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8708.29.50
8708.31.50
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8708.80.45

[FR Doc. 01–1645 Filed 1–16–01; 2:41 pm]

BILLING CODE 3190–01–U

Corrections

Federal Register
Vol. 66, No. 13
Friday, January 19, 2001

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 122 and 412

[FRL–6921–4]

RIN 2040–AD19

National Pollutant Discharge Elimination System Permit Regulation and Effluent Limitations Guidelines and Standards for Concentrated Animal Feeding Operations

Correction

In proposed rule document 01–1 beginning on page 2960 in the issue of Friday, January 12, 2001, make the following correction:

On page 2960, in the second column, in the **DATES** section, ''May 2, 2001'' should read ''May 14, 2001''.

[FR Doc. C1–1 Filed 1–18–01; 8:45 am]

BILLING CODE 1505–01–D

Federal Register

Friday,
January 19, 2001

Part II

Department of Labor

Mine Safety and Health Administration

30 CFR Part 72

Diesel Particulate Matter Exposure of Underground Coal Miners; Final Rule

30 CFR Part 57

Diesel Particulate Matter Exposure of Undergound Metal and Nonmetal Miners; Final Rule

DEPARTMENT OF LABOR

Mine Safety and Health Administration

30 CFR Part 72

RIN 1219–AA74

Diesel Particulate Matter Exposure of Underground Coal Miners

AGENCY: Mine Safety and Health Administration (MSHA), Labor.

ACTION: Final rule.

SUMMARY: This rule establishes new health standards for underground coal mines that use equipment powered by diesel engines.

This rule is designed to reduce the risks to underground coal miners of serious health hazards that are associated with exposure to high concentrations of diesel particulate matter (dpm). DPM is a very small particle in diesel exhaust. Underground miners are exposed to far higher concentrations of this fine particulate than any other group of workers. The best available evidence indicates that such high exposures put these miners at excess risk of a variety of adverse health effects, including lung cancer.

The final rule for underground coal mines would require that the dpm emissions from certain pieces of equipment be restricted to prescribed levels. Underground coal mine operators would also be required to train miners about the hazards of dpm exposure.

By separate notice, MSHA will publish a rule to reduce dpm exposures in underground coal mines.

DATES: The provisions of the final rule are effective March 20, 2001. However, § 72.500(b) will not apply until July 19, 2002; §72.501(b) will not apply until July 21, 2003; and, §72.501(c) will not apply until January 19, 2005.

FOR FURTHER INFORMATION CONTACT: David L. Meyer, Director, Office of Standards, Regulations, and Variances, MSHA, 4015 Wilson Boulevard, Arlington, VA 22203–1984. Mr. Meyer can be reached at dmeyer@msha.gov (Internet E-mail), 703–235–1910 (voice), or 703–235–5551 (fax). You may obtain copies of the final rule in alternative formats by calling this number. The alternative formats available are either a large print version of the final rule or the final rule in an electronic file on computer disk. The final rule also is available on the Internet at http://www.msha.gov/REGSINFO.HTM.

SUPPLEMENTARY INFORMATION:

I. Key Features of MSHA's Final Rule Limiting the Concentration of Diesel Particulate Matter (DPM) in Underground Coal Mines

(1) What are the requirements for permissible equipment?

Permissible equipment must not emit more than 2.5 grams per hour of dpm, as measured in a laboratory test. Any permissible equipment that is added to a mine's inventory underground more than 60 days after the date this rule is published will have to meet this standard upon introduction. This includes newly purchased equipment, used equipment, or a piece of equipment receiving a replacement engine with a different serial number than the engine it is replacing, including engines or equipment coming from one mine into another. It does not include a piece of equipment whose engine was previously part of the mine's inventory and rebuilt.

Within 18 months from the date the rule is issued, the entire permissible fleet must meet this standard.

The rule leaves the choice of controls used to achieve the emissions limit to operators. Operators may use any combination of controls (*e.g.,* cleaner engine, OCC, filter) to meet the emissions standard specified in this section.

As a practical matter, MSHA expects that to comply with this standard, most permissible equipment will be equipped with a paper filter. As explained in Part IV of this preamble, MSHA has verified that there are commercially available paper filters which will allow 99% of the existing 541 units in the permissible fleet to meet this requirement—including permissible units powered by the Deutz MWM 916, the Caterpillar 3304 and the Caterpillar 3306. Commercially available paper filters capable of bringing the emissions of these units into compliance include a model which can be installed directly on the exhaust coming from a water scrubber or on the exhaust coming from a heat exchanger, as well as the integrated DST® system. Other filters which use paper with the same performance characteristics will also be acceptable. Control devices whose dpm removal efficiency has not been demonstrated by laboratory testing on a diesel engine can be evaluated following the procedures in 30 CFR 72.503 of this part added by this rulemaking. Moreover, the rule provides that MSHA may rely upon the test results of other organizations who perform equivalent tests.

MSHA will publish on its web site a list of tested control devices and their performance. Compliance will be determined by reference to this data—there will be no in-mine testing.

The only engine which might not be able to meet these requirements for dpm emissions from permissible equipment with a paper filter is the Isuzu QD–100. MSHA's inventory indicates there are currently only two units of permissible equipment using this engine; however, these two units can comply at a derated power setting.

The engines currently approved for permissible use are generally high in particulate emissions. MSHA is committed to taking actions which will facilitate the approval for permissible use of the lower-emission engines which have become available in recent years. These actions could include waiving test fees, contracting for the performance of such tests, or on an interim basis permitting the use of an engine approved for nonpermissible use in a permissible package. MSHA will solicit input from the mining community, through a **Federal Register** notice as it considers how to proceed in this regard.

(2) What are the requirements for heavy-duty non-permissible equipment?

Non-permissible heavy duty equipment will ultimately not be permitted under the final rule to emit more than 2.5 grams per hour of dpm. For reasons of feasibility, this requirement will be implemented in phases.

Any heavy duty equipment added to a mine's inventory more than 60 days after the date of publication of this rule will have to comply with an interim emissions limit for that machine of 5.0 gr/hr. This includes newly purchased equipment, used equipment, or a piece of equipment receiving a replacement engine with a different serial number than the engine it is replacing, including engines or equipment coming from one mine into another. It does not include a piece of equipment whose engine was previously part of the mine's inventory and rebuilt.

All heavy duty equipment in the fleet must meet the interim standard of 5.0 grams per hour of dpm in 30 months.

Finally, another 18 months later (4 years in all), all nonpermissible heavy duty equipment in the fleet will have to meet the final standard of 2.5 grams per hour of dpm.

As with permissible equipment, the rule leaves the choice of controls used to achieve the emissions limit to operators. Any combination of controls (*e.g.,* cleaner engine, OCC, filter) can be used as long as compliance with the standard specified in this section is met.

As a practical matter, MSHA believes that most existing heavy duty equipment will utilize commercially available hot gas filters (*e.g.,* ceramic cell, wound fiber, sintered metal, etc.) to comply with the final limit. All the existing fleet can reach the interim limit with such a filter; some will not need one. MSHA determined that all but a few can reach the final limit with such a filter.

The rule provides that MSHA may rely upon the test results of organizations who perform filtration efficiency tests. In this regard, MSHA will accept the results of filter tests performed by VERT. VERT is an acronym for Verminderung der Emissionen von Realmaschinen in Tunnelbau, a consortium of several European agencies conducting diesel emission research in connection with major planned tunneling projects in Austria, Switzerland and Germany. VERT was established to advance hot gas filter technology due to concerns in Europe about dpm levels. This gave VERT the opportunity to acquire the necessary filter evaluation expertise. A wide range of commercially available hot gas filters have been tested by VERT and the filtration efficiency determined. The Secretary may also accept filter efficiency test results from other testing organizations that can demonstrate a high level of expertise in filter evaluation (see § 72.503(c) of the final rule).

Operators using the DST'' system with the catalytic convertor on heavy duty equipment, or the Jeffrey dry exhaust system, will also be deemed in compliance with the final rule, since test results conducted in the same manner as the requirement in the final rule demonstrate that those systems can reduce the emissions from all existing heavy duty engines to below the limit. Filtration devices whose filter efficiency has not been demonstrated by testing on a diesel engine can be evaluated following the procedures in 30 CFR 72.503 of this part added by this rulemaking.

MSHA will publish on its web site a list of tested control devices and their performance. Compliance will be determined by reference to this data—there will be no in-mine testing.

The standard may also be met through the use of newer, cleaner engines in some heavy duty equipment with low horsepower engines. There are already many engines approved for non-permissible use in underground coal mines that will enable heavy duty equipment to limit emissions, thus allowing the use of lower efficiency filters. MSHA is also considering approaches that would expedite the approval of additional engines based on evidence that such engines meet EPA standards which ensure the engines are at least as clean as required under MSHA approval standards.

(3) What are the requirements for generators and compressors?

The final rule provides that generators and compressors meet the same dpm emissions standards as heavy duty equipment. Thus, generators and compressors will ultimately not be permitted to emit more than 2.5 grams per hour of dpm. Generators and compressors introduced into the fleet of an underground coal mine more than 60 days after the final rule is published will have to meet an interim emissions limit of 5.0 g/hr. Generators and compressors in the existing fleet will have 30 months to meet the interim standard of 5.0 grams per hour of dpm. After an additional 18 months (4 years in all), all generators and compressors underground will have to meet the final standard of 2.5 grams per hour of dpm.

Although the proposed rule would not have covered generators and compressors, MSHA explicitly asked the mining community if there were types of light duty equipment that should, because of operating characteristics, be treated like heavy duty equipment. Generators and compressors generate more dpm emissions than other light-duty equipment based on their known duty cycle and type of work for which they are designed; indeed, they use engines whose horsepower often exceeds that in permissible equipment. Accordingly, MSHA has determined they should be covered by this rulemaking.

MSHA's inventory indicates that the 34 generators and 29 compressors constitute less than 3% of the underground light duty diesel fleet. The existing compressors are using engines which should meet the standard's interim and final requirements with a commercially available hot gas filter.

Generators and compressors will be able to utilize the same technologies as heavy duty machines to comply with this standard. This will include hot gas filters or paper filters, as appropriate. Smaller generators and compressors may utilize the clean engine technologies.

(4) What are the requirements for other nonpermissible equipment?

The final rule provides that any piece of nonpermissible light-duty equipment introduced into an underground coal mine more than 60 days after the date of publication of the rule must not emit more than 5.0 grams per hour of dpm. This includes newly purchased equipment, used equipment, or a piece of equipment receiving a replacement engine with a different serial number than the engine it is replacing, including engines or equipment coming from one mine into another, but it does not include a piece of equipment whose engine was previously part of the mine's inventory and rebuilt.

The final rule does not impose any new requirements on the existing nonpermissible light-duty fleet (except for generators and compressors as noted above).

While new light duty equipment would not have been covered by the proposed rule, MSHA explicitly asked the mining community if it would be feasible to cover such new light duty equipment, even if it were not feasible to set limits for all light duty equipment. MSHA has determined that it is feasible to require that newly introduced light duty equipment meet the same 5 gr/hr standard as new heavy duty equipment.

To facilitate compliance with this standard, light duty equipment which uses an engine meeting certain EPA standards listed in the MSHA rule will be deemed to automatically meet the MSHA dpm standard for newly introduced light-duty equipment. For example, any ''heavy duty highway engine'' produced after 1994 will be deemed to meet this dpm standard. The agency has determined that there are already MSHA approved engines available in a full range of horsepower sizes that can meet the EPA standards listed in this final rule.

In practice, what this rule does is simply ensure that very old engines with few, if any, emission controls are not added to a mine's current light duty fleet, thus accelerating the turnover to a newer generation of technology.

(5) Is there a summary of the applicable requirements and effective dates?

All of the emissions standards established by MSHA's final rule are summarized in Table I–1.

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Table I-1

Type of Equipment	Emissions Limit	When Applicable (from date final rule published)
Permissible		
newly introduced	2.5 grams per hour	60 days
existing fleet	2.5 grams per hour	18 months
Heavy duty nonpermissible		
newly introduced	5.0 grams per hour	60 days
existing fleet (interim)	5.0 grams per hour	30 months
existing fleet (final)	2.5 grams per hour	4 years
Generators and compressors	same as heavy duty	same as heavy duty
Other light duty nonpermissible		
newly introduced	5.0 grams per hour (or listed EPA standards)	60 days
entire fleet	no requirements	

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(6) What other requirements are contained in the final rule for underground coal mines?

Miners have to be trained annually in the risks of dpm exposure and in control methods being used at the mine. Also, certain information about diesel engines and aftertreatment devices has to be added to the mine ventilation plan. The paperwork requirements added by this rule are small—on average, less than 7 hours in the first year and 4 hours per year thereafter for a mine operator that uses diesel powered equipment. Furthermore, manufacturers of diesel powered equipment will incur burden hours only during the first year that the rule is in effect in order to amend existing MSHA approvals. During the first year that the rule is in effect the average manufacturer will incur 70 paperwork burden hours.

(7) Will the final rule eliminate any health risks to miners resulting from the use of diesel powered equipment underground?

Although the Agency expects that health risks will be substantially reduced by this rule, the best available evidence indicates that a significant risk of adverse health effects due to dpm exposures will remain after the rule is fully implemented.

MSHA considered establishing stricter standards for certain types of equipment, and covering more light duty equipment, but concluded that such actions would either be technologically or economically infeasible for the coal mining industry as a whole at this time. As MSHA takes actions to facilitate the introduction of newer and cleaner engines underground, and as control technologies continue to develop, additional reductions in dpm levels may become feasible for the industry as a whole. MSHA will continue to monitor developments in this area.

(8) What are the costs and benefits of the final rule?

Costs

Table I–2 summarizes the compliance costs to mine operators that use diesel powered equipment for each section of the rule; total compliance costs are about $7 million a year. Table I–3 summarizes the compliance costs to mine operators that use diesel powered equipment by mine size (*i.e.,* mines employing fewer than 20 workers, mines employing between 20 and 500 workers, and mines employing more than 500 workers). In addition, there is a total annualized cost to diesel equipment manufacturers of $30,030.

MSHA's full Regulatory Economic Analysis, (REA) from which Tables I–2 and I–3 are derived, provides considerable detail on the assumptions MSHA used in developing these cost estimates, and on the costs associated with the controls required for particular engines in the current fleet. For example, MSHA is estimating that for a Caterpillar 3304 PCNA in a heavy duty piece of equipment, an operator will have to spend about $4,500 a year to achieve compliance with the limits for that equipment (hot gas filter, cost annualized, plus annual costs of regeneration). Copies of MSHA's full (REA) analysis are in the record and are available to the mining community upon request.

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Table I-2:
Total Yearly Compliance Costs for Mine Operators

Requirement	Total Yearly Industry Cost
Section 72.500 (Permissible Equipment)	$ 4,468,965
Section 72.501 (Heavy Duty Equipment)	$ 2,278,970
Section 72.502 (Light Duty Equipment)	$ 121,391
Section 72.503 (Filter Maintenance Training)	$ 2,971
Section 72.510 (Miner Health Training)	$ 196,209
Section 75.520 (Diesel Equipment Inventory)	$ 2,327
TOTAL	$ 7,070,833

Table I-3:
Total Cost By Mine Size Class

	Number of Employees		
	< 20	20 to 500	> 500
Compliance Costs	$7,411	$6,087,732	$975,690

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Benefits

Benefits of the rule include reductions in lung cancer. In the long run, as the mining population turns over, MSHA estimates that a minimum of 1.8 lung cancer deaths will be avoided per year.[1]

Benefits of the rule will also include reductions in the risk of death from cardiovascular, cardiopulmonary, or respiratory causes and in sensory irritation and respiratory symptoms. MSHA does not believe that the available data can support reliable or precise quantitative estimates of these benefits. Nevertheless, the expected reductions in the risk of death from cardiovascular, cardiopulmonary, or respiratory causes appear to be significant, and the expected reductions in sensory irritation and respiratory symptoms appear to be rather large.

(9) What actions has MSHA taken, and what additional actions does it plan to take, to facilitate compliance with this rule?

This rule is a continuation of efforts by MSHA to help the mining community deal with the use of diesel engines in mining. The diesel equipment rule, now in effect, has itself contributed to the reduction of diesel exhaust emissions through the use of low sulfur diesel fuel, the requirement that all engines underground be approved, and improved maintenance. In one case, testimony was presented by a mine operator that timely engine maintenance, triggered by the weekly undiluted exhaust emissions test required by the new regulation, has greatly reduced carbon monoxide emissions from diesel equipment. These properly tuned engines will generate less particulate. MSHA has devoted workshops specifically to dpm control, issued a Toolbox of control methods to assist the mining community in this regard, and developed a computerized Estimator to help individual mines evaluate the impact of alternative approaches of controlling dpm emissions. The agency has verified the efficiency of the current generation of paper filters, and has sponsored work on the measurement of dpm in ambient mine atmospheres.

This final rule includes certain provisions to facilitate compliance—*e.g.,* authorizing MSHA to rely on the testing requirements of organizations like VERT, and permitting compliance with certain EPA requirements to be deemed as compliance with the requirements in this rule for newly introduced light duty equipment. The agency is, as described above, planning to take action in consultation with the mining community to facilitate the approval, and in particular the approval for permissible use, of a newer, cleaner generation of diesel engines. The agency will be preparing a compliance guide for this rule, and posting a variety of useful information on its web site. If necessary, additional workshops may be scheduled. In addition, MSHA is ready to provide special technical assistance to those who are planning to bring new engines or equipment underground in the next few months.

(10) Are surface mines addressed in this rule?

Surface areas of underground mines, and surface mines, are not covered by this rule. In certain situations the concentrations of dpm at surface mines may be a cause for concern: *e.g.,* production areas where miners work in the open air in close proximity to loader-haulers and trucks powered by older, out-of-tune diesel engines, shops, or other confined spaces where diesel engines are running. The Agency believes, however, that these problems are currently limited and readily controlled through education and technical assistance. The Agency would like to emphasize, however, that surface miners are entitled to the same level of protection as other miners; and the Agency's risk assessment indicates that even short-term exposures to concentrations of dpm like those observed may result in serious health problems. Accordingly, in addition to providing education and technical assistance to surface mines, the Agency will also continue to evaluate the hazards of diesel particulate exposure at surface mines and will take any necessary action, including regulatory action if warranted, to help the mining community minimize any hazards.

II. Background Information

This part provides the context for this preamble. The nine topics covered are:

(1) The role of diesel-powered equipment in underground coal mining in the United States;

(2) The composition of diesel exhaust and diesel particulate matter (dpm);

(3) The difficulties in measuring ambient dpm in underground coal mines;

(4) Limiting the public's exposure to diesel and other fine particulates—ambient air quality standards;

(5) The impact on emissions of MSHA approval standards and environmental tailpipe standards;

(6) Methods for controlling dpm emissions in underground coal mines;

(7) Existing standards for underground coal mines that limit miner exposure to diesel emissions;

(8) Information on how certain states are restricting occupational exposure to diesel particulate matter; and

(9) A history of this rulemaking.

Material on these subjects which was available to MSHA at the time of the proposed rulemaking was included in Part II of the preamble that accompanied the proposed rule (63 FR 17501 *et seq.*). This version has been updated to reflect the record, to discuss certain issues relevant to underground coal mines in more detail, and reorganized as appropriate.

(1) The Role of Diesel-Powered Equipment in Underground Coal Mining in the United States

Diesel engines, first developed about a century ago, now power a full range of mining equipment. However at this time, less than 20% of underground coal mines (fewer than 150 underground coal mines) utilize this technology. Equipment powered by other sources (electrical power delivered by cable or trolley, and battery power) continues to predominate in this mining sector. Moreover, unlike in other mining sectors, most of the current diesel fleet in underground coal mines consists of light-duty support vehicles, and only limited numbers of the equipment used in digging or hauling coal is powered by diesel engines.

Many in the mining industry believe that diesel-powered equipment has productivity and safety advantages over equipment powered by other sources. Others cite evidence to the contrary, and several key underground coal mining states continue to ban or significantly restrict the use of diesel-powered equipment in underground coal mines. The use of diesel engines to power equipment in underground coal mining is increasing and appears likely to continue to do so absent significant improvement in other power technologies.

Historical Overview of Diesel Power Use in Mining. As discussed in the notice of proposed rulemaking, the diesel engine was developed in 1892 by the German engineer Rudolph Diesel. It was originally intended to burn coal dust with high thermodynamic efficiency. Later, the diesel engine was modified to burn middle distillate petroleum (diesel fuel). In diesel engines, liquid fuel droplets are injected

[1] This lower bound figure could significantly underestimate the magnitude of the health benefits. For example, the estimate based on the mean value of all the studies examined is 13 lung cancer deaths avoided per year.

into a prechamber or directly into the cylinder of the engine. Due to compression of air in the cylinder the temperature rises high enough in the cylinder to ignite the fuel.

The first diesel engines were not suited for many tasks because they were too large and heavy (weighing 450 lbs. per horsepower). It was not until the 1920's that an efficient lightweight diesel power unit was developed. Since diesel engines were built ruggedly and had few operational failures, they were used in the military, railway, farm, construction, trucking, and busing industries. The U.S. mining industry was slow to begin using these engines. Thus, when in 1935 the former U.S. Bureau of Mines published a comprehensive overview on metal mine ventilation (McElroy, 1935), it did not mention ventilation requirements for diesel-powered equipment. By contrast, the European mining community began using these engines in significant numbers, and various reports on the subject were published during the 1930's. According to a 1936 summary of these reports (Rice, 1936), the diesel engine had been introduced into German mines by 1927. By 1936, diesel engines were used extensively in coal mines in Germany, France, Belgium and Great Britain. Diesel engines were also used in potash, iron and other mines in Europe. Their primary use was in locomotives for hauling material.

It was not until 1939 that the first diesel engine was used in the United States mining industry, when a diesel haulage truck was used in a limestone mine in Pennsylvania, and not until 1946 was a diesel engine used in coal mines. Today, however, diesel engines are used to power a wide variety of equipment in all sectors of U.S. mining. Production equipment includes vehicles such as haultrucks and shuttle cars, load-haul-dump units, face drills, and explosives trucks. Diesel engines are also used in support equipment including generators and air compressors, ambulances, crane trucks, ditch diggers, foam machines, forklifts, graders, locomotives, longwall component carriers, lube units, mine sealant machines, personnel carriers, hydraulic power units, rock dusting machines, roof drills, tractors, utility trucks, water spray units, and welders.

Current Patterns of Diesel Power Use in Underground Coal Mining. The underground coal mining sector is not as reliant upon diesel power as are other mining sectors. While nearly all underground metal and nonmetal mines, and nearly all surface mines, use diesel-powered equipment, less than 20% of underground coal mines use it. Table II–1 provides further information on the current inventory.

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Table II-1. Diesel Equipment in Underground Coal Mines

Mine size	# Mines	# Mines w/Diesel	# Engines
Small[a]	382	7	20
Large	528	138	3,101
All	910	145	3,121

Notes on Table II-1:
(a) A "small" mine is one with less than 20 miners.

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The great majority of the diesel engines used in underground coal mines are used to power support equipment, rather than production equipment. This is in sharp contrast to other sectors. For example, in underground metal and nonmetal mines, of the approximate 4,100 pieces of diesel equipment normally in use at the time of MSHA's proposal, nearly half of the units were estimated to be used for loading and hauling. By contrast, of the approximately 3,000 pieces of diesel equipment in use in underground coal mines, MSHA estimates that fewer than 10% are used for coal loading and haulage. Moreover, because of space constraints and other operating conditions in underground coal mines, virtually all coal loading and hauling equipment has engines less than 200 horsepower; by contrast, virtually all such equipment in metal and nonmetal mines has engines greater than 200 horsepower and ranging to more than 750 horsepower or greater. As a result, the average horsepower of diesel engines powering equipment in underground coal mines is much less than the average engine in underground metal and nonmetal mines and all surface mines. This is significant because, other things being equal, lower horsepower engines are going to produce less dpm emissions by mass than higher horsepower engines.

The engines in underground coal mines can be divided into three categories recognized under existing MSHA regulations: ''permissible'', ''heavy-duty nonpermissible'', and ''light-duty nonpermissible.'' In this final dpm rule, MSHA is establishing different requirements for each of these categories. Accordingly, some background on this categorization is needed.

Use of Diesel Engines in Permissible Equipment. Under existing regulations, equipment, whether powered by diesel engines or electricity, that is used in areas of the mine where methane gas is likely to be present in dangerous concentrations must be MSHA-approved ''permissible'' equipment.

Permissible diesel powered equipment for use in coal mines is provided with special equipment to prevent the ignition of methane. This special equipment includes flame arresters and special treatment of flanges and joints. Since diesel engines normally have very hot surface temperatures and hot exhaust gas that can constitute an ignition source, permissible diesels must be provided with a means to maintain the temperatures of surfaces and the exhaust gas below 302°F.

MSHA regulations are very specific in defining those areas of the mine where permissible equipment is required. Generally, permissible equipment is required where the coal mining is actually being performed, because the mining process typically liberates methane. These areas are commonly referred to as ''inby'' areas. In some cases, however, permissible equipment is required to be used in other areas of the mine. For example, only permissible diesel-powered equipment may be used in return aircourses. The permissible equipment provides an additional level of fire protection because of the strict temperature controls on the equipment surface and exhaust. This increased protection is required because of the potential for the accumulation of dangerous levels of methane in these aircourses.

MSHA's January 2000 inventory indicates that of the 3,121 diesel powered pieces of equipment in underground coal mines, 528 units are permissible pieces. The emissions generated by permissible equipment make a significant contribution to dpm concentrations in the mines where they are functioning. This is because the equipment has large engines, works hard and continuously in locations generally far from ventilation sources, and in close quarters with miners.

Moreover, the engines which have to date been approved for permissible use are among those which emit the highest levels of dpm (in grams/hour): the Caterpillar 3304, Caterpillar 3306 (available in two horsepower sizes), the Deutz D916–6, and the Isuzu QD–100. The Deutz D916–6 is still used in underground coal mines, however, it is no longer in production. MSHA recently approved the Caterpillar 3306PCTA permissible, the first approved turbocharged engine.

Diesel engines in the horsepower ratings required to power permissible equipment are now available in new low emissions technology engines. However, none of them has been approved for use on permissible equipment because no applications for MSHA approval have been received. This situation may reflect a lack of adequate incentives for engine and equipment manufacturers to incur the development costs to meet MSHA permissibility requirements or to pay the fees required for approval.

MSHA is developing programs that would facilitate the availability of engines that utilize the latest technologies to reduce gaseous and particulate emissions for use in permissible equipment. Current engine designs that utilize low emissions technologies are currently approved by MSHA in nonpermissible form.

One of the programs that MSHA is considering would follow the precedent established in the recently published diesel equipment rule. To facilitate compliance with this dpm rule, MSHA is considering funding the additional emissions testing needed to gain permissibility approval, previously approved, non-permissible engines that utilize low emissions technology engines, or waiving the normal fees that the Agency charges for the administrative and technical evaluation portion of the approval process.

Alternatively, MSHA may relax, as an interim measure, the requirement that engine approvals be issued only to engine manufacturers. Under this program an equipment manufacturer could utilize an engine, approved by MSHA as nonpermissible, in a permissible power package. MSHA would ensure that the additional emissions tests required for permissible engines are conducted as part of the power package approval process. Provisions of the two programs could be combined.

While the availability of cleaner engines would help reduce the dpm emissions from the permissible fleet, there are aftertreatment filters available for such equipment that are both highly efficient and relatively low cost. As discussed in more detail in section 6 of this part, because the exhaust temperature of these permissible pieces of equipment must be cooled for safety reasons, aftertreatment devices whose filtration media consists of paper can be directly installed on this equipment. Paper filters exposed to uncooled exhaust pose a fire and ignition hazard.

Use of Diesel Engines in Nonpermissible Equipment. In those areas of an underground coal mine where methane concentrations can be limited through the control of ventilation air, permissible equipment is not required. Generally, this is the case in areas away from the face, often referred to as ''outby'' areas. Most equipment operating in underground coal mines is ''nonpermissible'' equipment.

Nonpermissible equipment is divided into several categories for purposes of the diesel equipment rules that currently apply in underground coal mines (30 CFR part 75). In pertinent part, those rules provide:

§ 75.1908 Nonpermissible diesel-powered equipment; categories

(a) Heavy-duty diesel-powered equipment includes—

(1) Equipment that cuts or moves rock or coal;

(2) Equipment that performs drilling or bolting functions;

(3) Equipment that moves longwall components;

(4) Self-propelled diesel fuel transportation units and self-propelled lube units; or

(5) Machines used to transport portable diesel fuel transportation units or portable lube units.

(b) Light-duty diesel-powered equipment is any diesel-powered equipment that does not meet the criteria of paragraph (a) * * *

(c) * * *.

(d) Diesel-powered ambulances and fire fighting equipment are a special category of equipment that may be used underground only in accordance with the mine fire fighting and evacuation plan * * *.

MSHA's inventory indicates that of the 3,121 diesel powered pieces of equipment, 497 are heavy duty nonpermissible pieces, 66 are generators and air compressors, and 2,030—that is, about two-thirds of the total underground coal diesel fleet at present—are other light duty nonpermissible pieces.

The rationale for the division of nonpermissible dieselized equipment into these classes requires some background here because in this rulemaking on dpm, MSHA proposed making a significant distinction between the requirements applicable to each class.

The division resulted from MSHA's 1996 regulation establishing safety rules for the use of dieselized equipment in underground coal mines (the general history and purpose of which are summarized in section 9 of this Part). As discussed in the preamble to the final diesel safety rule (61 FR 55459–61), the purpose of the categorization was to take the diversity of nonpermissible equipment into account in establishing regulatory requirements relevant to safety. The final categorization scheme for nonpermissible equipment developed over the course of time in response to public comments to the proposed rule.

Equipment falling within the heavy duty category is typically used for extended periods during a shift on a continuous, rather than an intermittent,

basis. Heavy duty equipment also moves heavy loads or performs considerable work. Accordingly, to ensure such equipment could operate in a safe manner, the safety rule required that each piece of heavy duty equipment:

> * * * has to be equipped with an automatic fire suppression system addressing the additional fire risks resulting from the way this equipment is used. Heavy-duty equipment also produces greater levels of gaseous contaminants, and under the final rule is therefore subject to weekly undiluted exhaust emissions tests * * * and is included in the air quantity calculation of ventilation of diesel-powered equipment * * *. (61 FR 55461)

It is important to note that there are other types of underground coal mining equipment which, although they have operating characteristics much like heavy duty equipment, were not designated as such under the diesel equipment rule. That is because such equipment (*e.g.,* generators and compressors) is considered as portable equipment and special requirements were established in that rule to address the hazards presented by that equipment.

Ambulances and fire-fighting equipment which use diesel engines have operating characteristics like light-duty equipment, but under the diesel equipment rule are considered a special category of equipment that does not have to meet the requirements of that rule. The equipment in this category must only be used in emergencies or fire drills and in compliance with fire fighting and evaluation plan requirements. Consequently, such equipment is not required to have an approved engine or power package or comply with the design and performance requirements of §§ 75.1909 and 75.1910 (61 FR 55461).

Under the diesel equipment rule, heavy-duty equipment may be used to perform light-duty work; but equipment that is classified as light-duty may not be used, even intermittently, to perform the functions listed in paragraphs (a)(1) through (a)(5) of 30 CFR 75.1908 because it is not required to have the automatic fire suppression system that MSHA determined was necessary for such kinds of work. (Id.) As noted in the preamble, two machines of the same model could fall into different equipment categories depending on how they are used. Although of the same design, they do not present the same risk of fire because of the way in which they are used, nor do they produce the same quantities of exhaust contaminants:

> ''* * * machines that are operated for extended periods of time under heavy load generate more contaminants than machines that are not.'' (Id.)

It was for this reason—the rate of contaminant generation—that in proposing a rule to limit the concentration of dpm in underground coal mines, MSHA proposed making a distinction between heavy-duty equipment and light-duty equipment. MSHA proposed requiring heavy-duty nonpermissible equipment and permissible equipment to be equipped with filters capable of removing 95% of the dpm emitted by the engines in those pieces of equipment. The proposal did not include any controls for the dpm emitted from light-duty equipment nor for ambulances and fire-fighting equipment. As noted in section 9 of this part, the Agency asked the mining community to comment on the Agency's assumptions and consider some options in this regard. The record on this matter and MSHA's final decision are discussed in Part IV.

Whether categorized as heavy-duty or light-duty, the engine exhaust from nonpermissible equipment is not required to be cooled for safety reasons like exhaust from permissible equipment. Accordingly, this means that paper-type filters cannot be added directly to nonpermissible equipment without first adding a water scrubber or heat exchanger; otherwise, the paper would burn. As a result, control devices that are designed to filter hot exhaust gases (*e.g.,* ceramic filters) provide a cost effective alternative for dpm control with nonpermissible equipment.

Does Diesel Power Have Advantages Over Alternative Sources of Power for Equipment Used in Underground Coal Mines? As pointed out by a commenter, a number of power sources for mining equipment have been tried in the mining industry only to be rejected for various reasons (*e.g.,* gasoline engines, cables, and compressed air). Today, this commenter continued, there are three general ways of powering mining equipment: electric power (delivered by electric trailing cables or by trolley wires), on-board battery power, and diesel. Table II–2 reproduces a list provided by this commenter as to his view of some of the ''advantages and challenges'' of these power sources; MSHA is reproducing this list as a convenient summary, but does not necessarily agree or disagree with each specific entry.

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Table II-2
One Commenter's Comparison of Power Sources

Power Type	Electric w/trailing cable	Electric w/trolley wire	Battery	Diesel
Necessary infra-structure	electric power centers must be available at all areas where this type of electric trailing cable equipment is used	trolley wires and rails must be available at all areas where electric trolley wire equipment is used	battery charging stations must be available within the operating range of all battery powered equipment	refueling stations must be available within the operating reach of all diesel powered equipment
Availability of power source	the machine must be within reach and tethered to the electric power center	the machine must be connected to the energized electric trolley wire	the machine must be within reach of the charging station once the battery is depleted, usually at least once a shift	the vehicle is driven to a refueling station or a refueling vehicle is driven to the vehicle - refueling is typically performed every 1-3 shifts
Mobility	the range is limited by the reach of the trailing capable and is usually less than 500 feet	limited to areas with energized trolley wires	good as long as the battery is charged, weak when the battery charge is low	excellent and unlimited mobility in all properly ventilated areas of the mine
Operating time between service	uninterrupted until the trailing cable extent has been reached	uninterrupted as long as operating within reach of the trolley wire	may be less than a shift - multiple batteries are normally needed	at least one full shift, often several shifts
Safety concerns	electrocution hazard from damaged energized cables, back injuries from lifting and moving heavy cables	electrocution hazard from contact with energized trolley wires, open sparks	fire hazard during recharging the batteries; battery acid spills, hydrogen release	fuel spills, health concerns, acid exhaust emissions
Conclusions	prone to back injuries and electrocution risk	hazardous and prone to electrocution risk	prone to fire risk	requires emission controls

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Some in the mining industry strongly favor the use of diesel engines to power equipment in underground coal mines. A representative of a company with four underground coal mines testified that it has 200 pieces operated by diesel power, and is continuing to add more. Another commenter stated that diesel is the power source of choice for moving personnel and supplies in large underground mines where coal is moved by conveyor belt.

A number of commenters asserted that diesel-powered equipment has productivity and safety advantages over electrically-powered and battery-powered equipment.

One commenter argued that diesel reduces the risks associated with the use of electrical equipment by eliminating the need for trolley wires, trolley poles and trailing cables that cause injuries, accidents and fatalities—shocks, electrocutions, burns, fires, tripping or being struck by trolley poles, and also reduce the number of material handling injuries. This commenter also argued that unlike electrical power, diesel use does not restrict mining plans or the mining cycle because operations are not hampered by cable length or time consuming power moves, provide greater flexibility in underground travel routes, and make equipment moves from one area of a mine to another more efficient. This commenter further claimed that compared to battery-powered mining equipment (which arguably provides the same flexibility), diesels can haul coal more efficiently over longer distance, provide more power, and eliminate time-consuming battery change-out time.

Another commenter noted the increased potential for fatalities and injuries in underground coal mines when trolley wires are present, and further that trolley wires restrict ventilation in one entry.

Another commenter noted the difficulties of evacuating miners in the event of emergencies over the large distances in some underground mines using sources of power that were more prone to failure than diesel.

Another commenter asserted that all of the 18 employees who had died since 1972 as a result of exposed overhead direct current trolley lines could have lived if diesel power had been in use, and pointed to examples of fires initiated by trolley wires with associated loss of productivity. This commenter also noted that battery powered equipment has been known to cause injuries, and explosions both from its production of hydrogen gas and from sparks igniting methane in the mine atmosphere.

Commenters also note that many asserted safety risks associated with the use of diesel powered equipment in underground coal mines have now been addressed as a result of MSHA's safety rules.

Other commenters, however, pointed out that there are a number of the nation's most productive underground coal mines (including both those using longwall and those using room and pillar mining techniques) which do not use this technology. These commenters challenged industry claims that diesel power is necessary for business to survive. Some also noted that miners are trained to protect themselves better from safety hazards that accompany the use of electrical power, like tripping on cables and electrical hazards, but are not able to protect themselves from health hazards they cannot see. In this regard, the hearing transcripts are replete with reminders by underground coal miners of their concern about what they are breathing in light of the tragic experience with black lung disease.

As indicated by MSHA in the preamble to the proposed rule (63 FR 17503), not many studies done recently address the contentions that diesel power provides safety and/or productivity advantages, and the studies which have been reviewed by MSHA do not clearly support this hypothesis.

Outlook for Use of Diesel Engines To Power Equipment in Underground Coal Mines

The use of diesel engines to power equipment in underground coal mining is increasing. In fact, since this rulemaking was proposed, MSHA's inventory has recorded an increase of about 5% in the number of diesel-powered pieces of equipment at the roughly 145 coal mines using diesel power underground. This trend appears likely to continue, absent significant improvement in other power technologies.

Several key underground coal mining states—Ohio, Pennsylvania and West Virginia—continue to ban or significantly restrict the use of diesel-powered equipment in underground coal mines (as discussed in section 8 of this Part). There are 339 underground coal mines in these states. If the current restrictions in these States were relaxed, in accordance with the expressed interest of industry groups toward this end, many of these underground coal mines are likely to begin using diesel to power some equipment.

Full implementation of MSHA's recent rules for the safe use of diesel-powered equipment in underground coal mines (discussed in section 7 of this part), is also likely to lead to increased diesel use because they resolve certain safety concerns that discouraged the mining community from using such equipment more widely. Another factor suggesting that the use of diesel power will expand is that both miners and mine operators are concerned about the future of their industry.

On the other hand, operators as well as miners have acknowledged that potential health hazards associated with the use of diesel power must be addressed if its use is to become widespread. Although the Agency expects that health risks will be substantially reduced by this rule, the best available evidence indicates that a significant risk of adverse health effects due to dpm exposures will remain after the rule is fully implemented. As explained in Part V of this preamble, however, MSHA has concluded that the underground coal mining sector as a whole cannot feasibly reduce dpm concentrations further at this time. Nevertheless, the efforts by US and overseas environmental regulators to restrict dpm and other diesel emissions into the environment, discussed in sections 4, 5 and 6 of this Part, are leading to technological improvements in engines, fuel and filters that will help reduce this risk.

Currently, diesel power faces only a limited number of competitive power sources. It is unclear how quickly new ways to generate energy to run mobile vehicles will be available for use in underground mining activities. New hybrid electric automobiles have been introduced this year by two manufacturers (Honda and Toyota); these vehicles combine traditional internal combustion power sources (in this case gasoline) with electric storage and generating devices that can take over during part of the operating period. By reducing the time the vehicle is directly powered by combustion, such vehicles reduce emissions. Further developments in electric storage devices (batteries), and chemical systems that generate electricity (fuel cells) are being encouraged by government-private sector partnerships. For further information on recent developments, see the Department of Energy alternative fuels web site at http://www.afdc.doe.gov/altfuels.html., and ''The Future of Fuel Cells'' in the July 1999 issue of *Scientific American.* Until such new technologies mature, and are reviewed for safe use underground, MSHA assumes that the mining community's interest in the use underground of diesel-power as an

alternative to direct electric power is likely to continue.

(2) The Composition of Diesel Exhaust and Diesel Particulate Matter (DPM)

The emissions from diesel engines are actually a complex mixture of compounds, containing gaseous and particulate fractions. The specific composition of the diesel exhaust in a mine will vary with the type of engines used and how they are used. Factors such as type of fuel, load cycle, engine maintenance, tuning, and exhaust treatment will affect the composition of both the gaseous and particulate fractions of the exhaust. This complexity is compounded by the multitude of environmental settings in which diesel-powered equipment is operated. Nevertheless, there are a few basic facts about diesel emissions that are of general applicability.

The gaseous constituents of diesel exhaust include oxides of carbon, nitrogen and sulfur, alkanes and alkenes (*e.g.,* butadiene), aldehydes (*e.g.,* formaldehyde), monocyclic aromatics (*e.g.,* benzene, toluene), and polycyclic aromatic hydrocarbons (*e.g.,* phenanthrene, fluoranthene). The oxides of nitrogen (NO_X) merit particular mention because in the atmosphere they can precipitate onto particulate matter. Thus, reducing the emissions of NO_X is a way that engine manufacturers can control particulate production indirectly. (See section 5 of this part).

The particulate components of the diesel exhaust gas include the so-called diesel soot and solid aerosols such as ash particulates, metallic abrasion particles, sulfates and silicates. Most of these particulates are in the invisible sub-micron range of 100nm.

The main particulate fraction of diesel exhaust is made up of very small individual particles. These particles have a solid core consisting mainly of elemental carbon. They also have a very surface-rich morphology. This extensive surface absorbs many other toxic substances, that are transported with the particulates, and can penetrate deep into the lungs. More than 1,800 different organic compounds have been identified as absorbed onto the elemental carbon core. A portion of this hydrocarbon material results from incomplete combustion of fuel; however, most is derived from engine lubrication. In addition, the diesel particles contain a fraction of non-organic adsorbed materials. Figure II–1 illustrates the composition of dpm.

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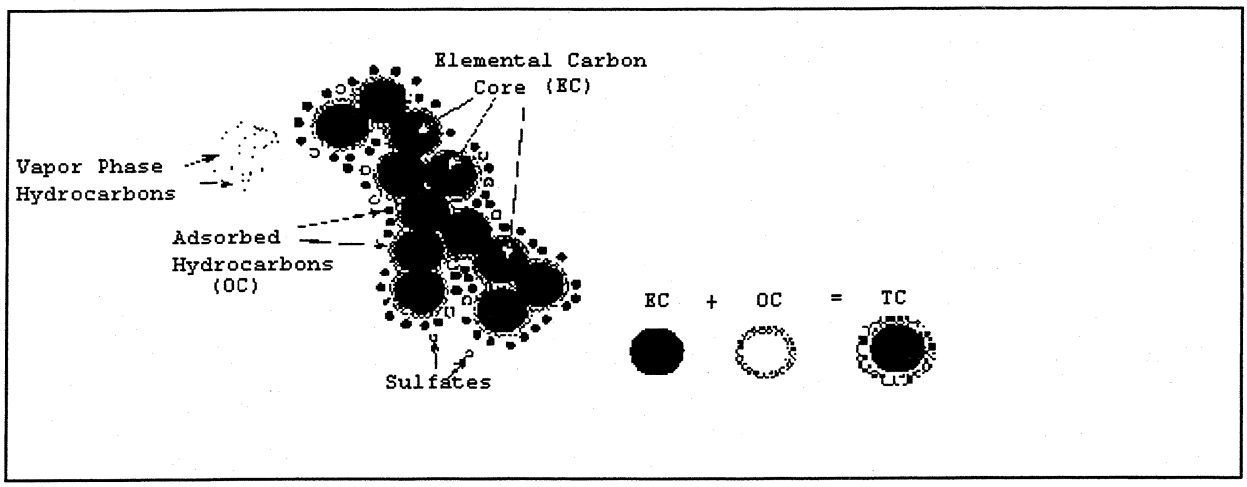
Figure II-1
DPM components



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Diesel particles released to the atmosphere can be in the form of individual particles or chain aggregates (Vuk, Jones, and Johnson, 1976). In underground coal mines, more than 90% of these particles and chain aggregates are submicrometer in size—i.e., less than 1 micrometer (1 micron) in diameter. Dust generated by mining and crushing of material—*e.g.,* silica dust, coal dust, rock dust—is generally not submicrometer in size. Figure II–2 shows a typical size distribution of the particles found in the environment of a mine using equipment powered by diesel engines (Cantrell and Rubow, 1992). The vertical axis represents relative dpm concentration, and the horizontal axis the particle diameter.

As can be seen, the distribution is bimodal, with dpm generally less than 1 μm in size, and dust generated by the mining process greater than 1 μm.

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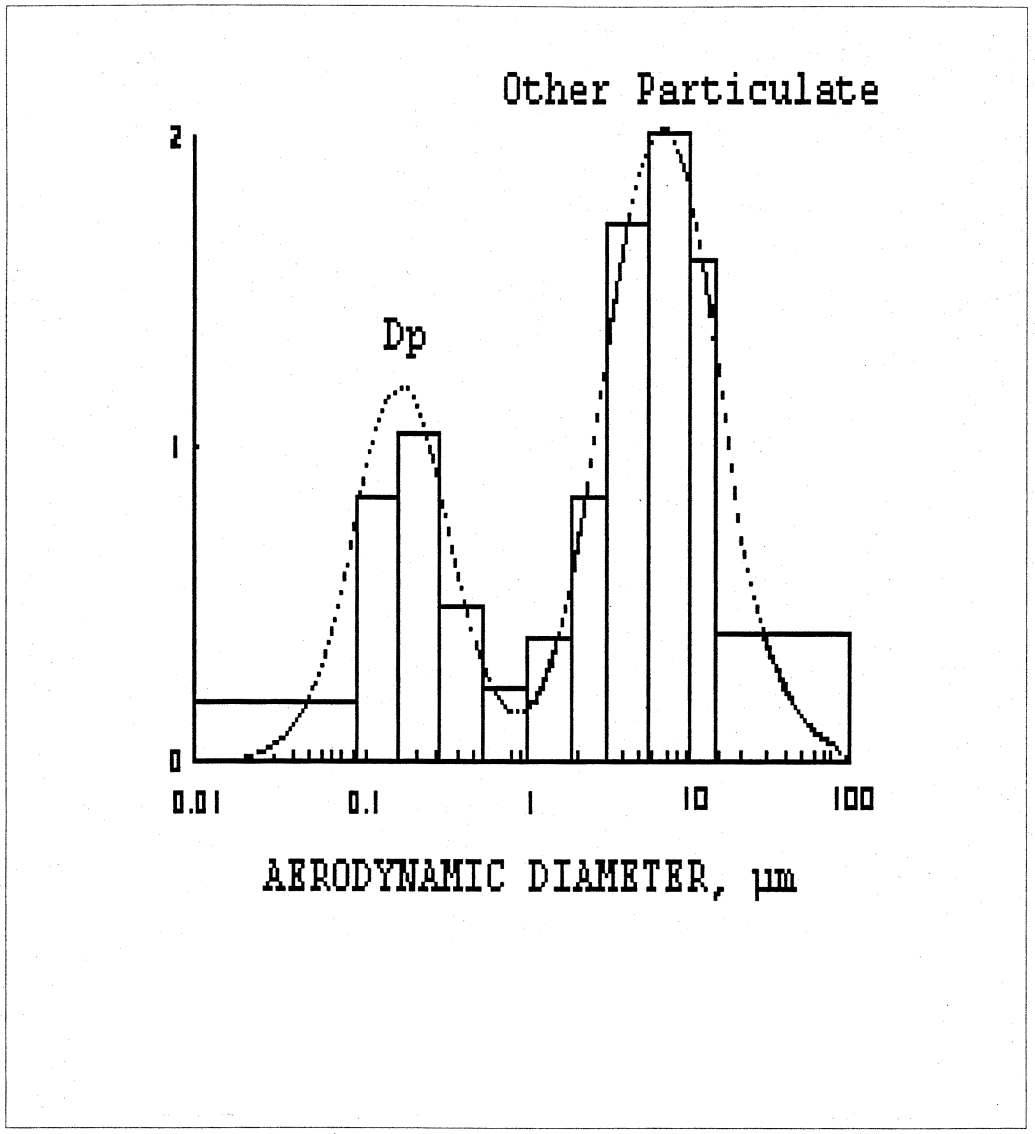
Figure II-2 -Typical distribution of dpm relative to distribution of other mining particulates.



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As shown on Figure II–3 diesel particulates have a bimodal size distribution which includes small nuclei mode particles and larger accumulation mode particles. As further shown, most of diesel particle mass is contained in the accumulation mode but most of the particle number can be found in the nuclei mode.

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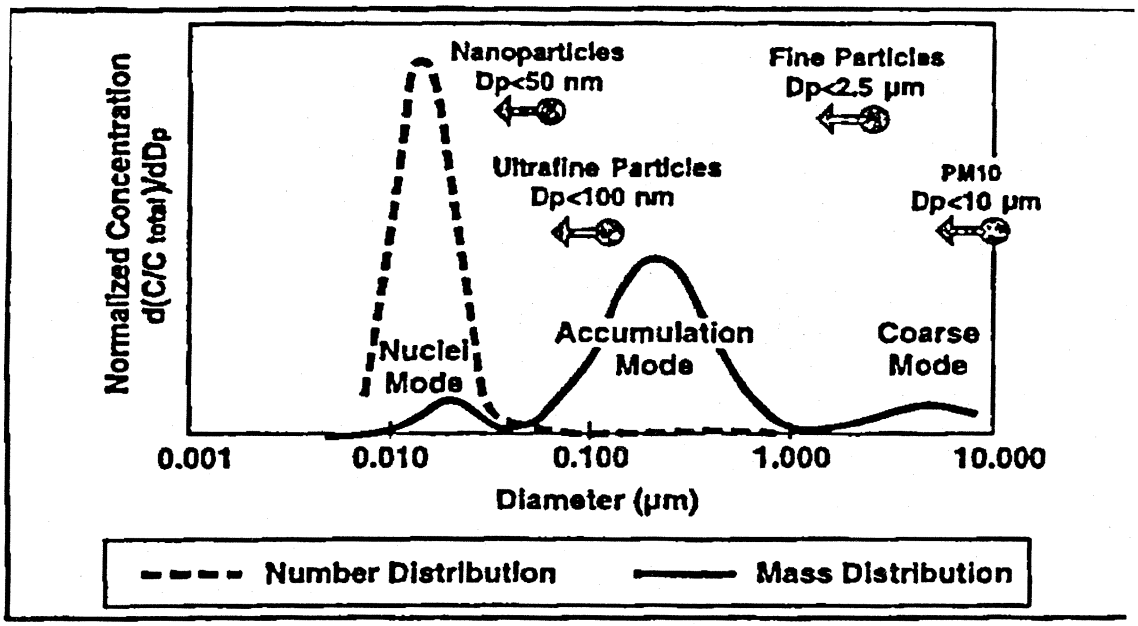
Figure II-3



Diesel particulate size distribution.

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The particles in the nuclei mode, also know as nanoparticles, are being investigated for their health hazard relevance. Interest in these particles has been sparked by the finding that newer ''low polluting'' engines emit higher numbers of small particles than the old engine technology engines. Although the exact composition of diesel nanoparticles is not known, it is thought that they may be composed of condensates (hydrocarbons, water, sulfuric acid). The amount of these condensates and the number of nanoparticles depends very significantly on the particulate sampling conditions, such as dilution ratios, which were applied during the measurement.

Both the maximum particle concentration and the position of the nuclei and accumulation mode peaks, however, depend on which representation is chosen. In mass distributions, the majority of the particulates (*i.e.*, the particulate mass) is found in the accumulation mode. The nuclei mode, depending on the engine technology and particle sampling technique, may be as low as a few percent, sometimes even less than 1%. A different picture is presented when the number distribution representation is used. Generally, the number of particles in the nuclei mode contributes to more than 50% of the total particle count. However, sometimes the nuclei mode particles represent as much as 99% of the total particulate number. The topic of dpm, with particular reference to very tiny particles known as nanoparticles, is discussed further in section 5 of this Part.

(3) The Difficulties of Measuring Ambient DPM in Underground Coal Mines.

As it indicated in its notice of proposed rulemaking to limit the concentrations of dpm in underground coal mines (63 FR 17498, 17500), MSHA decided not to propose a rule to require the measurement of ambient dpm levels in underground coal mines in order to determine compliance. The Agency observed that while there are a number of methods which can measure ambient dpm at high concentrations in underground coal mines with reasonable accuracy. When the purpose is exposure assessment, MSHA does not believe any of these methods provide the accuracy that would be required to measure ambient dpm levels in underground coal mines at lower concentrations.

In particular, MSHA expressed concern about potential difficulties in using the available methods to distinguish between dpm and submicron coal mine dust (63 FR 17506–17507). While the use of an available impactor device can prevent larger particles from entering the sampler (*e.g.,* carbonates), albeit at the expense of eliminating the larger fraction of dpm as well, there are limits on the extent to which it can help MSHA distinguish how much of the fine particulate reaching the sampler is coal dust and how much is dpm. To make the distinction analytically, NIOSH method 5040 would have to be adjusted so that only the elemental carbon is determined. However, as MSHA noted, there are no established relationships between the concentration of elemental carbon and total dpm under various operating conditions. The organic carbon component of dpm can vary with engine type and duty cycle; hence, the amount of whole dpm present for a measured amount of elemental carbon may vary. Accordingly, MSHA concluded that it was ''not confident that there is a measurement method for dpm that will provide accurate, consistent and verifiable results at lower concentration levels in underground coal mines'' (63 FR 17500).

Since there has been no disagreement with MSHA's initial conclusion about the current availability of an accurate, consistent and verifiable method of measuring dpm concentration levels in underground coal mines, the final rule is not dependent on ambient air measurements. MSHA has proposed using such a method for underground metal and nonmetal mines, and the validity of the measurement was the subject of much comment; accordingly, a more complete discussion of this topic will be found in the preamble of the final rule for underground metal and nonmetal mines.

(4) Limiting the Public's Exposure to Diesel and Other Fine Particulates—Ambient Air Quality Standards

Pursuant to the Clean Air Act, the Federal Environmental Protection Agency (EPA) is responsible for setting air pollution standards to protect the public from toxic air contaminants. These include standards to limit exposure to particulate matter. The pressures to comply with these limits have an impact upon the mining industry, which emits various types of particulate matter into the environment during mining operations, and a special impact on the coal mining industry whose product is used extensively in emission-generating power facilities. But those standards hold interest for the mining community in other ways as well, for underlying some of them is a large body of evidence on the harmful effects of airborne particulate matter on human health. Increasingly, that evidence has pointed toward the risks of the smallest particulates—including the particles generated by diesel engines.

This section provides an overview of EPA's rulemaking efforts to limit the ambient air concentration of particulate matter, including its recent particular focus on diesel and other fine particulates. Additional and up-to-date information about the most current rulemaking in this regard is available on an EPA's Web site, http://www.epa.gov/ttn/oarpg/naaqsfin/.

EPA is also engaged in other work of interest to the mining community. Together with some state environmental agencies, EPA has actually established limits on the amount of particulate matter that can be emitted by diesel engines. This topic is discussed in the next section of this Part (section 5). Environmental regulations also establish the maximum sulfur content permitted in diesel fuel used in highway vehicles, and such sulfur content can be an important factor in dpm generation. This topic is discussed in section 6 of this Part. In addition, EPA and some state environmental agencies have also been exploring whether diesel particulate matter is a carcinogen or a toxic material at the concentrations in which it appears in the ambient atmosphere; discussion of these studies can be found in Part III of this preamble.

Background. Air quality standards involve a two-step process: Standard setting by EPA, and implementation by each State.

Under the law, EPA is specifically responsible for reviewing the scientific literature concerning air pollutants, and establishing and revising National Ambient Air Quality Standards (NAAQS) to minimize the risks to health and the environment associated with such pollutants. This review is to be conducted every five years. Feasibility of compliance by pollution sources is not supposed to be a factor in establishing NAAQS. Rather, EPA is required to set the level that provides ''an adequate margin of safety'' in protecting the health of the public.

Implementation of each national standard is the responsibility of the states. Each must develop a state implementation plan that ensures air quality in the state consistent with the ambient air quality standard. Thus, each state has a great deal of flexibility in targeting particular modes of emission (*e.g.,* mobile or stationary, specific industry or all, public sources of emissions vs. private-sector sources), and in what requirements to impose on polluters. However, EPA must approve the state plans pursuant to criteria it establishes, and then take measurements of pollution to determine whether all counties within the state are meeting each ambient air quality standard. An area not meeting an NAAQS is known as a ''nonattainment area''.

Total Suspended Particulates (TSP). Particulate matter originates from all types of stationary, mobile and natural sources, and can also be created from the transformation of a variety of gaseous emissions from such sources. In the context of a global atmosphere, all these particles mix together, and both people and the environment are exposed to a ''particulate soup,'' the chemical and physical properties of which vary greatly with time, region, meteorology, and source category.

The first ambient air quality standards dealing with particulate matter did not distinguish among these particles. Rather, the EPA established a single NAAQS for ''total suspended particulates'', known as ''TSP.'' Under this approach, the states could come into compliance with the ambient air requirement by controlling any type or size of TSP. As long as the total TSP was under the NAAQS—which was established based on the science available in the 1970s—the state met the requirement.

Particulates Less than 10 Microns in Diameter (PM_{10}). When the EPA completed a new review of the scientific evidence in the mid-eighties, its conclusions led it to revise the particulate NAAQS to focus more narrowly on those particulates less than 10 microns in diameter, or PM_{10}. The standard issued in 1987 contained two components: an annual average PM_{10} limit of 50 μg/m³, and a 24-hour PM_{10} limit of 150 μg/m³. This new standard required the states to reevaluate their situations and, if they had areas that exceeded the new PM_{10} limit, to refocus their compliance plans on reducing the levels of particulates smaller than 10 microns in size. Sources of PM_{10} include power plants, iron and steel production, chemical and wood products manufacturing, wind-blown and roadway fugitive dust, secondary aerosols and many natural sources.

Some state implementation plans required surface mines to take actions to help the state meet the PM_{10} standard. In particular, some surface mines in Western states were required to control the coarser particles—*e.g.,* by spraying water on roadways to limit dust. The mining industry has objected to such controls, arguing that the coarser particles do not adversely impact health, and has sought to have them excluded from the EPA ambient air standards (Shea, 1995; comments of Newmont Gold Company, March 11, 1997, EPA docket number A–95–54, IV–D–2346).

Particulate Less than 2.5 Microns in Diameter ($PM_{2.5}$). The next EPA scientific review was completed in 1996. A proposed rule was published in November of 1996, and, after public hearings and review by the Office of Management and Budget, a final rule was promulgated on July 18, 1997 (62 FR 38651).

The new rule further modifies the standard for particulate matter. Under the new rule, the existing national ambient air quality standard for PM_{10} remains basically the same—an annual average limit of 50 μg/m³ (with some adjustment as to how this is measured for compliance purposes), and a 24-hour ceiling of 150 μg/m³. In addition, however, the new rule would establish a NAAQS for ''fine particulate matter'' that is less than 2.5 microns in size. The $PM_{2.5}$ annual limit was set at 15 μg/m³, with a 24-hour ceiling of 65 μg/m³.

The basis for the $PM_{2.5}$ NAAQS was a large body of scientific data indicating that particles in this size range are responsible for the most serious health effects associated with particulate matter. The evidence was thoroughly reviewed by a number of scientific panels through an extended process. The proposed rule resulted in considerable public attention, and hearings by Congress, in which the scientific evidence was further discussed. Moreover, challenges to the EPA's determination that this size category warranted rulemaking were rejected by a three-judge panel of the DC Circuit Court. (*ATA* v. *EPA*, 175 F.3d 1027, D.C. Circuit 1999).

A majority of the DC Circuit Court, however, agreed with challenges to the EPA's determination to keep the existing requirements on PM_{10} as a surrogate for the coarser particulates in this category (those particulates between 2.5 and 10 microns in diameter); instead, the Court ordered EPA to develop a new standard for this size category.

Implications for the Mining Community. As noted earlier in this part, diesel particulate matter is mostly less than 1.0 micron in size. It is, therefore, a fine particulate; in some regions of the country, diesel particulate generated by highway and off-road vehicles constitutes a significant portion of the ambient fine particulate (June 16, 1997, PM–2.5 Composition and Sources, Office of Air Quality Planning and Standards, EPA). As noted in Part III of this preamble, some of the scientific studies of health risk from fine particulates used to support the EPA rulemaking were conducted in areas where the major fine particulate was from diesel emissions. Accordingly, MSHA has concluded that it must consider the body of evidence of human health risk from environmental exposure to fine particulates in assessing the risk of harm to miners of occupational exposure to diesel particulate, and did so in its risk assessment (see part III of this preamble). Comments on the appropriateness of this conclusion by MSHA, are reviewed in Part III.

(5) *The impact on emissions of MSHA approval standards and environmental tailpipe standards.*

MSHA requires that the gaseous emissions from all diesel engines used in underground coal mines meet certain minimum standards of cleanliness; only engines which meet those standards are ''approved'' for use in underground coal mines. The 1996 diesel equipment safety rule required that all engines in the underground mining fleet be approved engines. Thus, these rules set a ceiling for various types of diesel gas emissions. But diesel engines do not have to meet a dpm emissions standard to be ''approved'' for underground use.

Engine emissions of dpm are however, restricted by Federal environmental regulations, supplemented in some cases by State restrictions. Over time, these regulations have required, and are continuing to require, that new diesel engines meet tighter and tighter standards on dpm emissions. As these cleaner engines replace or supplement older engines in underground coal mines, they can lead to a significant reduction in the amount of dpm emitted by the underground fleet.

This section reviews developments in this area. Although this subject was discussed in the preamble of the proposed dpm rule (63 FR 17507), this review here updates the relevant information.

MSHA Approval Requirements for Engines Used in Underground Coal Mines. MSHA requires that all diesel engines used in underground coal mines be ''approved'' by MSHA for such use, and be maintained by operators in approved condition. Among other things, approval of an engine by MSHA ensures that engines exceeding certain pollutant standards are not used in underground coal mines. MSHA sets the standards for such approval, establishes the testing criteria for the approval process, and administers the tests. The costs to obtain approval of an engine are usually borne by the engine manufacturer or equipment manufacturer.

MSHA's 1996 diesel equipment rule (discussed in more detail in section 7 of this Part) made significant changes to diesel engine requirements for underground coal mines. The new rule required the entire underground coal fleet to convert to approved engines no later than November 1999. Accordingly, by the time this rule to limiting dpm exposure goes into effect, all diesel engines in underground coal mines are expected to be approved engines.

The new rule also required that during the approval process the agency determine the particulate index (PI) for the engine. The particulate index (or PI), calculated under the provisions of 30 CFR 7.89, indicates the air quantity necessary to dilute the diesel particulate in the engine exhaust to 1 milligram of diesel particulate matter per cubic meter of air.

Unlike the ventilation rate set for each engine, the PI does not appear on the engine's approval plate (61 FR 55421). Furthermore, the particulate index of an engine is not, under the diesel equipment rule, used to determine whether or not the engine can be used in an underground coal mine.

At the time the diesel equipment rule was issued, MSHA explicitly deferred the question of whether to require engines used in mining environments to meet a specific PI (61 FR 55420–21, 55437). While the matter was discussed during the diesel equipment rulemaking, the approach taken in the final rule was to adopt the multi-level aproach recommended by the Diesel Advisory Committee. This multi-level approach included the requirement to use clean fuel, low emission engines, equipment design, maintenance, and ventilation, all of which are included in the final rule. The requirement for determining the particulate index was included in the diesel equipment rule in order to provide information to the mining community in purchasing equipment—so that mine operators can compare the particulate levels generated by different engines. Mine operators and equipment manufacturers, can use the information along with consideration of the type of machine the engines would power and the area of the mine in which it would be used to make decisions concerning the engine's contribution of diesel particulate to the mine's total respirable dust. Equipment manufacturers can use the particulate index to design and install exhaust after-treatments (61 FR 55421). So that the PI for any engine is known to the mining community, MSHA reports the index in the approval letter, posts the PI and ventilating air requirement for all approved engines on its website, and publishes the index containing its lists of approved engines.

In the proposed dpm rule, MSHA indicated that given that the equipment rule was recently promulgated, it did not yet have enough information to determine the feasibility of a requirement that certain engines meet a specific PI in order to be used underground (63 FR 17564). MSHA received comments on this subject during the hearings and thereafter; the Agency's response to these comments is included in Part IV of this preamble.

Authority for Environmental Engine Emission Standards. The Clean Air Act authorizes the federal Environmental Protection Agency (EPA) to establish nationwide standards for mobile sources of air pollution, including those powered by diesel engines (often referred to in environmental regulations as ''compression ignition'' or ''CI'' engines). These standards are designed to reduce the amount of certain harmful atmospheric pollutants emanating from mobile sources: the mass of particulate matter, nitrogen oxides (which as previously noted, can result in the generation of particulates in the atmosphere), hydrocarbons and carbon monoxide.

California has its own engine emission standards. New engines destined for use in California must meet these standards. The standards are issued and administered by the California Air Resources Board (CARB). In many cases, the California standards are the same as the national standards; as noted herein, the EPA and CARB have worked on certain agreements with the industry toward that end. In other

situations, the California standards may be more stringent than federal standards.

Regulatory responsibility for implementation of the Clean Air Act is vested in the Office of Transportation and Air Quality (formerly the Office of Mobile Sources), part of the Office of Air and Radiation of the EPA. Some of the discussion which follows was derived from materials which can be accessed from the agency's home page on the World Wide Web at (http://www.epa.gov/omswww/omshome.htm). Information about the California standards may be found at the CARB home page at (http://www.arb.ca.gov/homepage.htm).

Diesel engines are generally divided into three broad categories for purposes of engine emissions standards, in accordance with the primary use for which the type of engine is designed: (1) Light duty vehicles and light duty trucks (*i.e.,* trucks under 8500 lbs GVWR, which include pick-up trucks and SUVs. EPA has also established a class of ''medium duty passenger vehicles'' which include passenger vehicles over 8500 lbs. These vehicles, mostly large SUVs, are treated like light-duty trucks for the purposes of emission standards; (2) heavy duty highway engines (*i.e.,* those designed primarily to power trucks) greater than 8500 lbs GVWR) which range from the largest pick-up trucks to over the road trucks); and (3) nonroad vehicles (*i.e.,* those engines designed primarily to power small equipment, construction equipment, locomotives, farm equipment and other non-highway uses).

The terms ''heavy duty'' and ''light duty'' are used differently by EPA and MSHA. The category of an engine for purposes of environmental regulations is not the same as the category of mining equipment in which it is used. The engine categories used by EPA have been established with reference to normal transportation uses. But as explained in section 1 of this Part, MSHA has established a classification system for underground coal mining equipment based on how that equipment is used in mining. This system includes ''permissible'' equipment (required where explosive methane gas may be present in significant quantities) and two categories of ''nonpermissible'' equipment known as ''heavy duty nonpermissible'' and ''light duty nonpermissible''. Accordingly, ''heavy duty'' engines might be used in ''light duty'' nonpermissible equipment.

The exact emission standards which a new diesel engine must meet varies with engine category and the date of manufacture. Through a series of regulatory actions, EPA has developed a detailed implementation schedule for each of the three engine categories. The schedule generally forces technology while taking into account certain technological realities.

Detailed information about each of the three engine categories is provided below; a summary table of particulate matter emission limits is included at the end of the discussion.

EPA Emission Standards for Light-Duty Vehicles and Light Duty Trucks. Although vehicle engines in these categories are not currently approved for use in underground coal mines, it might be sought in the future. Accordingly, some information about the applicable environmental regulations is provided here.[2]

Current light-duty vehicles generally comply with the Tier 1 and National LEV emission standards. Particulate-matter emission limits are found in 40 CFR part 86. In 1999, EPA issued new Tier 2 standards that will be applicable to light-duty cars and trucks beginning in 2004. With respect to pm, the new rules phase in tighter emissions limits to parts of production runs for various subcategories of these engines over several years; by 2009, all light duty trucks must limit pm emissions to a maximum of 0.02 g/mi (40 CFR 86.1811–04(c)). Engine manufacturers may, of course, produce complying engines before the various dates required.

EPA Emissions Standards for Heavy-Duty Highway Engines. In 1988, a standard limiting particulate matter emitted from the heavy duty highway diesel engines went into effect, limiting dpm emissions to 0.6 g/bhp-hr. The Clean Air Act Amendments of 1990 and associated regulations provided for phasing in even tighter controls on NO_X and particulate matter through 1998. Thus, engines had to meet ever tighter standards for NO_X in model years 1990, 1991 and 1998; and tighter standards for PM in 1991 (0.25 g/bhp-hr) and 1994 (0.10 g/bhp-hr). The latter remains the standard for PM from these engines for current production runs (40 CFR 86.094–11(a)(1)(iv)(B)). Since any heavy duty highway engine manufactured since 1994 must meet this standard, there is a supply of engines available today which meet this standard. These engines are used in commercial mining pickup trucks.

New standards for this category of engines are gradually being put into place. On October 21, 1997, EPA issued a new rule for certain gaseous emissions from heavy duty highway engines that will take effect for engine model years starting in 2004 (62 FR 54693). The rule establishes a combined requirement for NO_X and Non-methane Hydrocarbon (NMHC). The combined standard is set at 2.5 g/bhp-hr, which includes a cap of 0.5g/bhp-hr for NMHC. EPA promulgated a rulemaking on December 22, 2000 (65 FR 80776) to adopt the next phase of new standards for these engines. EPA is taking an integrated approach to: (a) Reduce the content of sulfur in diesel fuel; and thereafter, (b) require heavy-duty highway engines to meet tighter emission standards, including standards for PM. The purpose of the diesel fuel component of the rulemaking is to make it technologically feasible for engine manufacturers and emissions control device makers to produce engines in which dpm emissions are limited to desired levels in this and other engine categories. The EPA's rule will reduce pm emissions from new heavy-duty engines to 0.01 g/bhp-hr, a reduction from the current 0.1 g/bhp-hr. MSHA assumes it will be some time before there is a significant supply of engines that can meet this standard, and the fuel supply to make that possible.

EPA Emissions Standards for Nonroad Engines. Nonroad engines are those designed primarily to power small portable equipment such as compressors and generators, large construction equipment such as haul trucks, loaders and graders, locomotives and other miscellaneous equipment with non-highway uses. Engines of this type are used most frequently in the underground coal mines to power equipment.

Nonroad diesel engines were not subjected to emission controls as early as other diesel engines. The 1990 Clean Air Act Amendments specifically directed EPA to study the contribution of nonroad engines to air pollution, and regulate them if warranted (Section 213 of the Clean Air Act). In 1991, EPA released a study that documented higher than expected emission levels across a broad spectrum of nonroad engines and equipment (EPA Fact Sheet, EPA420–F–96–009, 1996). In response, EPA initiated several regulatory programs. One of these set Tier 1 emission standards for larger land-based nonroad engines (other than for rail use). Limits were established for engine emissions of

[2] The discussion focuses on the particulate matter requirements for light duty trucks, although the current pm requirement for all light duty vehicles is the same. The EPA regulations for these categories apply to the unit, rather than just to the engine itself; for heavy-duty highway engines and nonroad engines, the regulations attach to the engines.

hydrocarbons, carbon monoxide, NO_X, and dpm. The limits were phased in over model years from 1996 to 2000. With respect to particulate matter, the rules required that starting in model year 1996, nonroad engines from 175 to 750 hp meet a limit on pm emissions of 0.4 g/bhp-hr, and that starting in model year 2000, nonroad engines over 750 hp meet the same limit.

Particulate matter standards for locomotive engines were set subsequently (63 FR 18978, April, 1998). The standards are different for line-haul duty-cycle engine and switch duty-cycle engines. For model years from 2000 to 2004, the standards limit pm emissions to 0.45 g/bhp-hr and 0.54 g/bhp-hr respectively; after model year 2005, the limits drop to 0.20 g/bhp-hr and 0.24 g/bhp-hr respectively.

In October 1998, EPA established additional standards for nonroad engines (63 FR 56968). Among these are gaseous and particulate matter limits adopted for the first time (Tier 1 limits) for nonroad engines under 50 hp. Tier 2 emissions standards for engines between 50 and 175 hp include pm standards for the first time. Further, they establish Tier II particulate matter limits for all other land-based nonroad engines (other than locomotives which previously had Tier II standards). Some of the non-particulate emissions limits set by the 1998 rule are subject to a technology review in 2001 to ensure that the required levels are feasible; EPA has indicated that in the context of that review, it intends to consider further limits for particulate matter. Because of the phase-in of these Tier II pm standards, and the fact that some manufacturers will produce engines meeting the standard before the requirements go into effect, there are or soon will be some Tier II pm engines in some sizes available, but it is likely to be a few years before a full size range of Tier II pm nonroad engines is available.

Table II–3 provides a full list of the EPA required particulate matter limitations on nonroad diesel engines for tier 1 and 2. For example, a nonroad engine of 175 hp produced in 2001 must meet a standard of 0.4 g/hp-hr; a similar engine produced in 2003 or thereafter must meet a standard of 0.15 g/hp-hr.

TABLE II–3.—EPA NONROAD ENGINE PM REQUIREMENTS

kW range	Tier	Year first applicable	PM limit (g/kW-hr)
kW<8	1	2000	1.00
	2	2005	0.80
8≤kW<19	1	2000	0.80
19≤kW<37	1	1999	0.80
	2	2004	0.60
37≤kW<75	1	1998	.....
	2	2004	0.40
75≤kW<130	1	1997	.....
	2	2003	0.30
130≤kW<225	1	1996	0.54
	2	2003	0.20
225≤kW<450	1	1996	0.54
	2	2001	0.20
450≤kW<560	1	1996	0.54
	2	2002	0.20
kW>560	1	2000	0.54
	2	2006	0.20

The Impact of MSHA and EPA Engine Emission Standards on the Underground Coal Mining Fleet. In the mining industry, engines and equipment are often purchased in used condition, and frequently rebuilt. Thus, many of the diesel engines in an underground coal mine's fleet today may only meet older environmental emission standards, or no environmental standards at all. Although the environmental tailpipe requirements on dpm are already bringing about a reduction in the overall contribution of dpm to the general atmosphere, the beneficial effects of the EPA regulations on mining atmospheres will be slower absent incentive or regulatory actions that accelerate the turnover of mining fleets to engines that emit less dpm. Moreover, while the requirement that all underground coal mine engines be ''MSHA approved'' is leading to a less polluting fleet than would otherwise be the case, there are many approved engines that do emit significant levels of pollution, and in particular dpm. As noted in the discussion of MSHA's approval requirements, the Agency is taking internal actions to ensure that these requirements do not inadvertently slow the introduction of cleaner engine technology.

It should be noted that in theory, underground mines can still purchase certain types of new engines that do not have to meet EPA standards. For example, the current rules on nonroad diesel engines state that they do not apply to engines intended to be used in underground coal and metal and nonmetal mines (40 CFR 89.1(b)). Moreover, it is not uncommon for engine manufacturers to take a model submitted for EPA testing and adjust the horsepower or other features for use in a mining application. In recent years, however, engine manufacturers have significantly cut back on such adjustments because the mining community is not a major market. Accordingly, MSHA believes that most of the diesel engines that will be available for underground mines in the future will meet the applicable EPA standard. In addition, many of the recently approved engines by MSHA currently meet the tier II nonroad pm standards.

The Question of Nanoparticles. Comments received from several commenters on the proposed rule for diesel particulate matter exposure of underground coal miners raised questions relative to ''nanoparticles;'' i.e., particles found in the exhaust of diesel engines that are less than 50 nanometers (nm) in diameter.

One commenter was concerned about recent indications that nanoparticles may pose more of a health risk than the larger particles that are emitted from a diesel engine. This commenter submitted information demonstrating

that nanoparticles emitted from the engine could be removed effectively from the exhaust using aftertreatment devices such as ceramic traps.

Another commenter was concerned that MSHA's proposed rule for underground coal mines is based on removing 95% of the particulate by mass. He believed that this reduction in mass was attributed to those particles greater than 0.1μm but less than 1μm and did not address the recent scientific hypothesis that it may be the very small nanopaticles that are responsible for adverse health effects. Based on the recent scientific information on the potential health effects resulting from exposure to nanoparticles, this commenter did not believe that potential the risk of cancer would be reduced if exposure levels to nanoparticles increased. He indicated that studies suggest that the increase in nanoparticles will exceed 6 times their current levels.

Current environmental emission standards established by EPA and CARB, and the particulate index calculated by MSHA, focus on the total mass of diesel particulate matter emitted by an engine—for example, the number of grams per some unit of measure (i.e. grams/brake-horsepower). Thus, the technology under development by the engine industry to meet the standards accordingly focuses on reducing the mass of dpm emitted from the engine. There is some evidence, however, that some aspects of this new technology, particularly fuel injection, is resulting in an increase in the number of nanoparticles emitted from the engine.

Figure II–3, repeated here from section 2 of this Part, illustrates this situation (Majewski, W. Addy, Diesel Progress, June, 1998).

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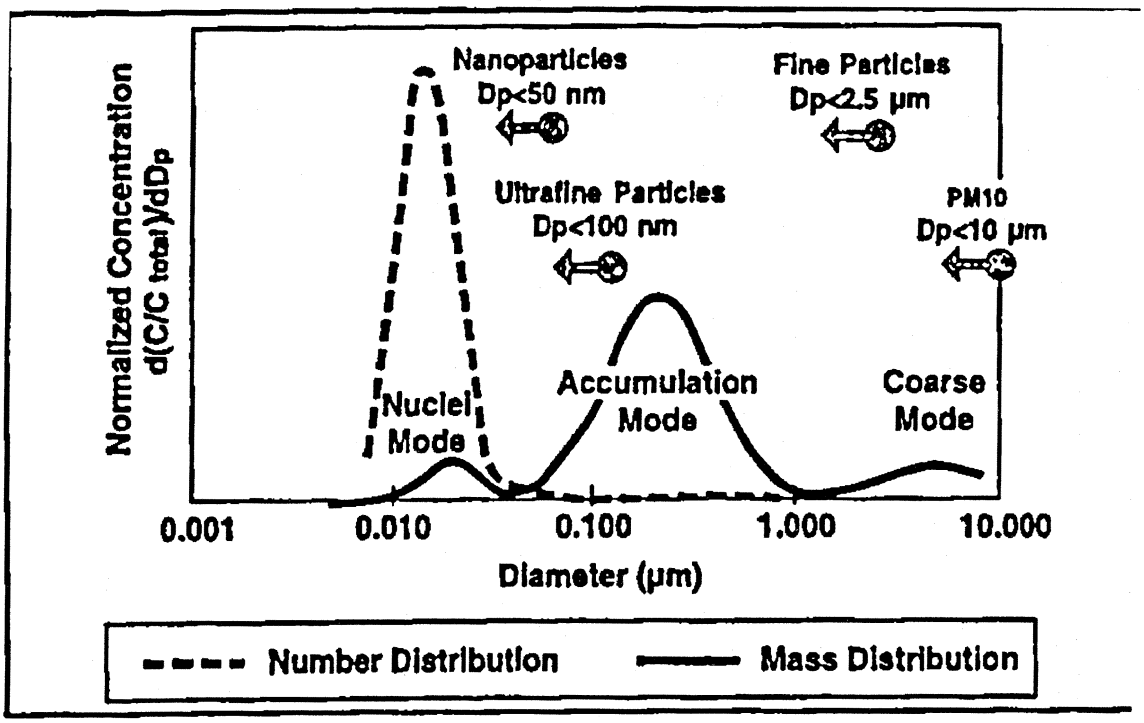
Figure II-3



Diesel particulate size distribution.

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The formation of particulates starts with particle nucleation followed by subsequent agglomeration of the nuclei particles into an accumulation mode. Thus, as illustrated in Figure II–3, the majority of the mass of dpm is found in the accumulation mode, where the particles are generally between 0.1 and 1 micron in diameter. However, when considering the number of particles emitted from the engine, more than half and sometimes almost all of the particles (by number) are in the nuclei mode.

A number of studies have demonstrated that the size of the particles emitted from the newer low emission diesel engines, has shifted toward the generation of nuclei mode particles. One study (cited by Majewski) compared a 1991 engine to its 1988 counterpart. The total PM mass in the newer engine was reduced by about 80%; but the new engine generated thousands of times more particles than the older engine (3000 times as much at 75 percent load and about 14,000 times as much at 25 percent load). One hypothesis offered for this phenomenon is that the cleaner engines produce less soot particles on which particulates can condense and accumulate, and hence they remain in nuclei mode. The accumulation particles act as a ''sponge'' for the condensation and/or adsorption of volatile materials. In the absence of that sponge, gas species which are to become liquid or solid will nucleate to form large numbers of small particles (see diesel.net technology guide). Mayer, while pointing out that nanoparticle production was a problem with older engines as well, concurs that the technology used to clean up pollution in newer engines is not having any positive impact on nanoparticle production. While there is scientific evidence that the newer engines, designed to reduce the mass of pollutants emitted from the diesel engine, emit more particles in the nuclei mode, quantifying the magnitude of these particles has been difficult. This is because as dpm is released into the

atmosphere the diesel particulate undergoes very complex changes. In addition, current sampling procedures produce artificial particulates, which otherwise would not exist under atmospheric conditions. Experimental work conducted at West Virginia University (Bukarski) indicate that nanoparticles are not generated during the combustion process, but rather during other physical and chemical processes which the exhaust undergoes in aftertreatment systems.

While current medical research findings indicate that small particulates, particularly those below 2μm in diameter, may be more harmful to human health than the larger ones, much more medical research and diesel emission studies are needed to fully characterize diesel nanoparticles emissions and their influence on human health. If nanoparticles are found to have an adverse health impact by virtue of size or number, it could require significant adjustments in environmental engine emission regulation and technology. It could also have implications for the type of controls utilized, with some asserting that aftertreatment filters are the only effective way to limit the emission of nanoparticles and others asserting that aftertreatment filters can increase the number of nanoparticles.

As discussed in Part III, the available evidence on the risks for dpm exposure do not currently include enough data to draw conclusions about the risks of exposure to significant numbers of very small particles. Research on nanoparticles and their health effects is currently a topic of investigation. As there have been few measurements of the number of particles emitted (as opposed to mass), it will be very difficult for epidemiologists to extrapolate information in this regard.

Based on the comments received and a review of the literature currently available on the nanoparticle issue, MSHA believes that promulgation of the final rules for underground coal and metal and nonmetal mines is necessary to protect miners. The nanoparticle issues discussed above will not be answered for some time because of the extensive research required to address the questions raised. MSHA's rules will require the application of exhaust aftertreatment devices on nearly all of the most polluting engines. The application of these measures will reduce the number of nanoparticles as well as the mass of the larger particles to which a miner will be exposed—miners wanted aftertreatment on all machines for this purpose.

(6) Other Methods for Controlling DPM in Underground Coal Mines

As discussed in the last section, the introduction of new engines underground will play a significant role in reducing the concentration of dpm in underground coal mines. There are, however, other approaches to reducing dpm concentrations in underground coal mines. Among these are: use of aftertreatment devices to eliminate particulates emitted by an engine; altering fuel composition to minimize engine particulate emission; use of maintenance practices and diagnostic systems to ensure that fuel, engine and aftertreatment technologies work as intended to minimize emissions; enhancing ventilation to reduce particulate concentrations in a work area; enclosing workers in cabs or other filtered areas to protect them from exposure; and use of work and fleet practices that reduce miner exposures to emissions.

As noted in section 9 of this Part, information about these approaches was solicited from the mining community in a series of workshops in 1995, and highlights were published by MSHA as an appendix to the proposed rule on dpm ''Practical Ways to Control Exposure to Diesel Exhaust in Mining—a Toolbox.'' During the hearings and in written comments on this rulemaking, these control methods were discussed.

This section provides updated information on two methods for controlling dpm emissions: aftertreatment devices and diesel fuel content. There was considerable comment on aftertreatment devices because MSHA's proposed rule would have required that certain equipment be equipped with high-efficiency particulate filters; the efficiency of such devices remains an important issue in determining the technological and economic feasibility of the final rule. Moreover, some commenters strongly favored the use of oxidation catalytic converters, a type of aftertreatment device used to reduce gaseous emission but which can also lessen dpm levels. Accordingly, information about them is reviewed here. With respect to diesel fuel composition, a recent rulemaking initiative by EPA, and actions taken by other countries in this regard, are discussed here because of their implications for the mining community.

Emissions aftertreatment devices. One of the most discussed approaches to controlling dpm emissions involves the use of devices placed on the end of the tailpipe to physically trap diesel particulate emissions and thus limit their discharge into the mine atmosphere. These aftertreatment devices are often referred to as ''particle traps'' or ''soot traps,'' but the term filter is also used. The two primary categories of particulate traps are those composed of ceramic materials (and thus capable of handling uncooled exhaust), and those composed of paper materials (which require the exhaust to first be cooled). Typically, the latter are designed for conventional permissible equipment which have water scrubbers installed which cool the exhaust. However, another alternative that is now used in coal mines is ''dry system technology'' which cools the diesel exhaust with a heat exchanger and then uses a paper filter. In addition, ''oxidation catalytic converters,'' devices used to limit the emission of diesel gases, and ''water scrubbers,'' devices used to cool the emission of diesel gases, are discussed here as well, because they also can have effect on limiting particle emission.

Water Scrubbers. Water scrubbers are devices added to the exhaust system of diesel equipment. Water scrubbers are essentially metal boxes containing water through which the diesel exhaust gas passes. The exhaust gas is cooled, generally to below 170 degrees F. A small fraction of the unburned hydrocarbons is condensed and remains in the water with some of the dpm. Tests conducted by the former Bureau of Mines and others indicate that no more than 20 to 30 percent of the dpm is removed. However, MSHA has no definitive evidence on the amount of dpm reduction that can be achieved with a particular water scrubber. The water scrubber does not remove the carbon monoxide, the oxides of nitrogen, or other gaseous emission that remains a gas at room temperature, so their effectiveness as aftertreatment devices is limited.

The water scrubber serves as an effective spark and flame arrester and as a means to cool the exhaust gas. Consequently, it is used in most of the permissible diesel equipment in mining as part of the safety components needed to gain MSHA approval.

The water scrubber has several operating characteristics which keep it from being a candidate for an aftertreatment device on nonpermissible equipment. The space required on the vehicle to store sufficient water for an 8 hour shift is not available on some equipment. Furthermore, the exhaust contains a great deal of water vapor which condenses under some mining conditions creating a fog which can adversely effect visibility. Also, operation of the equipment on slopes can cause the water level in the scrubber

to change resulting in water blowing out the exhaust pipe. Control devices can be placed within the scrubber to maintain the appropriate water level. Because these devices are in contact with the water through which the exhaust gas has passed, they need frequent maintenance to insure that they are operating properly and have not been corroded by the acidic water created by the exhaust gas. The water scrubber must be flushed frequently to remove the acidic water and the dpm and other exhaust residue which forms a sludge that adversely effects the operation of the unit. These problems, coupled with the relatively low dpm removal efficiency, have prevented widespread use of water scrubbers as a primary dpm control device on nonpermissible equipment.

Oxidation Catalytic Converters (OCCs). Oxidation catalytic converters (OCCs) were among the first devices added to diesel engines in mines to reduce the concentration of harmful gaseous emissions discharged into the mine environment. OCCs began to be used in underground mines in the 1960's to control carbon monoxide, hydrocarbons and odor (Haney, Saseen, Waytulonis, 1997). Their use has been widespread. It has been estimated that more than 10,000 OCCs have been put into the mining industry over the last several years (McKinnon, dpm Workshop, Beckley, WV, 1995).

Several of the harmful emissions in diesel exhaust are produced as a result of incomplete combustion of the diesel fuel in the combustion chamber of the engine. These include carbon monoxide and unburned hydrocarbons including harmful aldehydes. Catalytic converters, when operating properly, remove significant percentages of the carbon monoxide and unburned hydrocarbons. Higher operating temperatures, achieved by hotter exhaust gas, improve the conversion efficiency.

Oxidation catalytic converters operate, in effect, by continuing the combustion process outside the combustion chamber. This is accomplished by utilizing the oxygen in the exhaust gas to oxidize the contaminants. A very small amount of material with catalytic properties, usually platinum or a combination of the noble metals, is deposited on the surfaces of the catalytic converter over which the exhaust gas passes. This catalyst allows the chemical oxidation reaction to occur at a lower temperature than would normally be required.

For the catalytic converter to work effectively, the exhaust gas temperature must be above 370 degrees Fahrenheit for carbon monoxide and 500 degrees Fahrenheit for hydrocarbons. Most converters are installed as close to the exhaust manifold as possible to minimize the heat loss from the exhaust gas through the walls of the exhaust pipe. Insulating the segment of the exhaust pipe between the exhaust manifold and the catalytic converter extends the portion of the vehicle duty cycle in which the converter works effectively.

The earliest catalytic converters for mining use consisted of alumina pellets coated with the catalytic material and enclosed in a container. The exhaust gas flowed through the pellet bed where the exhaust gas came into contact with the catalyst. Designs have evolved, and now the most common design is a metallic substrate, formed to resemble a honeycomb, housed in a metal shell. The catalyst is deposited on the surfaces of the honeycomb. The exhaust gas flows through the honeycomb and comes into contact with the catalyst.

Soon after catalytic converters were introduced, it became apparent that there was a problem due to the sulfur found in diesel fuels in use at that time. Most diesel fuels in the United States contained anywhere from 0.25 to 0.50 percent sulfur or more on a mass basis. In the combustion chamber, this sulfur was converted to SO_2, SO_3, or SO_4 in various concentrations, depending on the engine operating conditions. In general, most of the sulfur was converted to gaseous SO_2. When exhaust containing the gaseous sulfur dioxide passed through the catalytic converter, a large proportion of it was converted to solid sulphates which are in fact, diesel particulate. Sulfates can ''poison'' the catalyst, severely reducing its life.

Recently, as described elsewhere in this preamble, the EPA required that diesel fuel used for over the road trucks contain no more than 500 ppm (0.05 percent) sulfur. This action made low sulfur fuel available throughout the United States. MSHA, in its recently promulgated regulations for the use of diesel powered equipment in underground coal mines required that this low sulfur fuel be used. When the low sulfur fuel is burned in an engine and passed through a converter with a moderately active catalyst, only small amounts of SO_2 and additional sulfate based particulate are created. However, when a very active catalyst is used, to lower the operating temperature of the converter or to enhance the CO removal efficiency, even the low sulfur fuel has sufficient sulfur present to create an SO_2 and sulfate based particulate problem. Consequently, as discussed later in this section, the EPA has notified the public of its intentions to promulgate regulations that would limit the sulfur content of future diesel fuel to 15 ppm (0.0015 percent) for on-highway use in 2006.

The particulate removal capabilities of some OCCs are significant in gravimetric terms. In 1995, the EPA implemented standards requiring older buses in urban areas to reduce the dpm emissions from rebuilt bus engines (40 CFR 85.1403). Aftertreatment manufacturers developed catalytic converter systems capable of reducing dpm by 20%. Such systems are available for larger diesel engines common in the underground metal and nonmetal sector. However, as has been pointed out by Mayer, the portion of particulate mass that seems to be impacted by OCCs is the soluble component, and this is a smaller percentage of particulate mass in utility vehicle engines than in automotive engines. Moreover, some measurements indicate that more than 40% of NO is converted to more toxic NO_2, and that particulate mass actually increases using an OCC at full load due to the formation of sulfates. In summation, Mayer concluded that the OCCs do not reduce the combustion particulates, produce sulfate particulates, or have unfavorable gaseous phase reactions increasing toxicity, and that the positive effects are irrelevant for construction site diesel engines. He concludes that the negative effects outweigh the benefits (Mayer).

The Phase 1 interim data report of the Diesel Emission Control-Sulfur Effects (DECSE) Program (a joint government-industry program established to explore lower sulfur content that is discussed in more detail later in this section) similarly indicates that testing of OCCs under certain operating conditions can increase dpm emissions due to an increase in the sulfate fraction. (DECSE Program Summary, Dec. 1999) Another commenter also notes that oxidation catalytic activity can increase sulfates under certain operating temperatures, and that oxidation is a part of aftertreatment systems approaches like the DST® and some ceramic traps. But this commenter asserts that the sulfate production occurs at an operating mode that is seldom seen in real operation.

Other commenters during the rulemaking strongly supported the use of OCCs to reduce particulate and other diesel emissions. They argue that the OCCs result in significant reductions in dpm and in dpm generating gases. One commenter noted that with a clean engine, an OCC might well reduce particulates enough to meet any requirements established by MSHA.

However, another commenter noted that OCCs and ceramic traps can fail when used at higher altitude mines due to the lower oxygen content in the exhaust system. Another commenter asserted that OCCs are not effective at low temperature, although they are improving. Accordingly, this commenter indicated that OCCs have an impact only on light duty equipment when the equipment is working, not when it is idling, and are virtually useless on permissible equipment because of the low exhaust temperatures achieved through cooling. Despite a specific request from MSHA at the rulemaking hearings, no data were provided by OCC advocates to demonstrate that they can perform well at the lower temperatures normally found in light duty equipment.

Hot gas particulate traps. Throughout this preamble, MSHA is referring to the particulate traps (filters) that can be used in the undiluted hot exhaust stream from the diesel engine as hot gas filter. Hot gas filter refers to the current commercially available particulate filters such as ceramic cell, woven fiber filter, sintered metal filter, etc.

Following publication of EPA rules in 1985 limiting diesel particulate emissions from heavy duty diesel engines, development of aftertreatment devices capable of more significant reductions in particulate levels began to be developed for Comerica applications.

The wall flow type ceramic honeycomb diesel particulate filter system was initially the most promising approach (SAE, SP–735, 1988). This consisted of a ceramic substrate encased in a shock-and vibration-absorbing material covered with a protective metal shell. The ceramic substrate is arranged in the shape of a honeycomb with the openings parallel to the centerline. The ends of the openings of the honeycomb cells are plugged alternately. When the exhaust gas flows through the particulate trap, it is forced by the plugged end to flow through the ceramic wall to the adjacent passage and then out into the mine atmosphere. The ceramic material is engineered with pores in the ceramic material sufficiently large to allow the gas to pass through without placing excessive back pressure on the engine, but small enough to trap the particulate on the wall of the ceramic material. Consequently, these units are called wall flow traps.

Work with ceramic filters in the last few years has led to the development of the ceramic fiber wound filter cartridge (SAE, SP–1073, 1995). The ceramic fiber has been reported by the manufacturer to have dpm reduction efficiencies up to 80 percent. This system has been used on vehicles to comply with German requirements that exhaust from all diesel engines used in confined areas be filtered. Other manufacturers have made the wall flow type ceramic honeycomb dpm filter system commercially available to meet the German standard. One commenter noted that a total exhaust, wall-flow, ceramic filter developed in Canada in collaboration with a US firm has been successfully demonstrated underground with a reduction of between 60% and 90% of particulate matter.

The development of these devices has proceeded in response to international and national efforts to regulate dpm emissions. However, due to the extensive work performed by the engine manufacturers on new technological designs of the diesel engine's combustion system, and the use of low sulfur fuel, particulate traps were found to be unnecessary for compliance with the EPA standards of the time for vehicle engines.

These devices proved to be quite effective in removing particulate, achieving particulate removal efficiencies of greater than 90 percent.

It was quickly recognized that this technology, while not immediately required for most vehicles, might be useful in mining applications. The former Bureau of Mines investigated the use of catalyzed diesel particulate filters in underground mines in the United States (BOM, RI–9478, 1993). The study demonstrated that filters could work, but that there were problems associated with their use on individual unit installations, and the Bureau made recommendations for installation of ceramic filters on mining vehicles.

Canadian mines also began to experiment with ceramic traps in the 1980's with similar results (BOM, IC 9324, 1992). Work in Canada today continues under the auspices of the Diesel Emission Evaluation Program (DEEP), established by the Canadian Centre for Mineral and Energy Technology in 1996 (DEEP Plenary Proceedings, November 1996). The goals of DEEP are to: (1) evaluate aerosol sampling and analytical methods for dpm; and (2) evaluate the in-mine performance and costs of various diesel exhaust control strategies.

Reservations regarding their usefulness and practicality remain. One commenter stated at one of the MSHA workshops in 1995, ''while ceramic filters give good results early in their life cycle, they have a relatively short life, are very expensive and unreliable.'' Another commenter reported unsuccessful experiments with ceramic filters in 1991 due to their inability to regenerate at low temperatures, lack of reliability, high cost of purchase and installation, and short life. Another reported that ceramics would not work at higher altitudes because of lower oxygen content in the exhaust system. Another commenter pointed out that elevated operating temperatures in certain engine modes can result in sulfates adding as much as 50% to total particulate mass, and asserted that ceramic traps alone were unable to offset this effect on their own.

In response to the proposed rule, MSHA received information and claims about the current efficiency of such technologies. One commenter, representing those who manufacture emissions controls, and referring to technologies other than low temperature paper filters—such as higher temperature disposable paper filters, ceramic monolith diesel particulate filters, wound ceramic fiber filters, and metal fiber filters—asserted that there were technologies which could achieve in excess of 95% filtration efficiency under ''many operating conditions.'' Another commenter submitted copies of information provided to that commenter by individual manufacturers of emission control systems, many of which made similar claims. Another commenter, however, questioned manufacturer claims, asserting big differences had been observed between such claims an independent 8-mode tests.

It appears that two groups in particular have been doing some research comparing the efficiency of recent ceramic models: the University of West Virginia, as part of that State's efforts to develop rules on the use of diesel-powered equipment underground; and VERT (Verminderung der Emissionen von Realmaschinen in Tunnelbau), a consortium of several European agencies conducting research in connection with major planned tunneling projects in Austria, Switzerland and Germany to protect occupational health and subsequent legislation in each of the three countries restricting diesel emissions in tunneling (in both cases, background on the regulatory efforts of the jurisdictions involved is discussed in section 8 of this part).

The legislature of the State of West Virginia enacted the West Virginia Diesel Act, which created the West Virginia Diesel Commission and set forth an administrative vehicle to allow and regulate the use of diesel equipment in underground coal mines in that state. West Virginia University was appropriated funds to test diesel exhaust controls, as well as an array of

diesel particulate filters. The University was asked to provide technical support and data necessary for the Commission to make decisions on standards for emission controls.

The University provided data on four different engines and an assortment of configurations of available control devices, both hot gas filters and the DST® system (a system which, first cools the exhaust, then runs it through a paper filter). The range of collection efficiencies reported for the ceramic filters and oxidation catalysts combined fell between 65% and 78%. The highest collection efficiency obtained using the ISO 8 mode test cycle (test cycle described in rule) was 81% on the DST® system. The University reported problems with this system that would account for the lower than expected efficiency for a paper filter type system. A commenter who spoke for the Commission at MSHA's public hearing expressed serious reservations of the 95% collection efficiency of MSHA's proposed rule and believed it was not achievable with technology based on the University's current work. The WV Commission also provided MSHA a detailed proposal for setting a laboratory diesel particulate standard of 0.5 milligram per cubic meter. As discussed in part IV, this is similar to the Pennsylvania standard, but without a strict filter efficiency value, and as further discussed in part IV, MSHA's approach in this final rule is similar.

VERT's studies of particulate traps are detailed in two articles published in 1999 which have been widely disseminated to the diesel community here through www.DieselNet.com (Mayer et al., March 1999, and Mayer, April 1999). The March article focuses on the efficiency of the traps; the April article compares the efficiency of other approaches (OCCs, fuel reformulation, engine modifications to reduce ultra-fine particulates) with that of the traps. Here we focus only on the information about particulate traps.

The authors of the March article report that 29 particulate trap systems were tested using various ceramic, metal and fiber filter media and several regeneration systems. The authors of the March article summarize their conclusions as follows:

> The results of the 4-year investigations of construction site engines on test rigs and in the field are clear: particulate trap technology is the only acceptable choice among all available measures. Traps proved to be an extremely efficient method to curtail the finest particles. Several systems demonstrated a filtration rate of more than 99% for ultra-fine particulates. Specific development may further improve the filtration rate.
>
> A two-year field test, with subsequent trap inspection, confirmed the results pertaining to filtration characteristics of ultra-fine particles. No curtailment of the ultra-fine particles is obtained with any of the following: reformulated fuel, new lubricants, oxidation catalytic converters, and optimization of the engine combustion.
>
> Particulate traps represent the best available technology (BAT). Traps must therefore be employed to curtail the particulate emissions that the law demands are minimized. This technology was implemented in occupational health programs in Germany, Switzerland and Austria.

On the bench tests, it appears that the traps reduce the overall particulate matter by between 70 and 80%, with better results for solid ultrafine particulates; under hot gas conditions, it appears the non-solid components of particulate matter cannot be dependably retained by these traps. Consistent with this finding, it was found that polycyclic aromatic hydrocarbons (PAHs) decreased proportionately to the gravimetric decrease of carbon mass. The tests also explored the impact of additives on trap efficiency, and the impact of back pressure.

The field tests confirmed that the traps were easy to mount and retained their reliability over time, although regeneration using an external power source was required when low exhaust temperatures failed to do this automatically. Electronic monitoring of back pressure was recommended. In general, the tests confirmed that a whole series of trap systems have a high filtration rate and stable long time properties and are capable of performing under difficult construction site conditions. Again, the field tests indicated a very high reduction (97–99%) by particulate count, but a lower rate of reduction in terms of mass.

Subsequently, VERT has evaluated additional commerically available filter systems. A list of recently evaluated hot gas filters are shown in Table II–4. The filtration efficiency, expressed on a gravimetric basis is shown in the column headed ''PMAG—without additive''. The filtration efficiencies determined by VERT for these 6 filter systems range from 80.7% to 94.5%. The average efficiency of these filters is 87%. MSHA will be updating the list of VERT's evaluated systems as they become available.

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Table II-4
Efficiency of Diesel Particulate Traps VERT-Certification Test
Average 4 operation points, ISO 8187

Trap	Date	PMAG		PZAG		ECAG	
		without Additive	with Additive	without Additive	with Additive	without Additive	with Additive
3M	VERT-Certification Test Part 1 (new)	80.7	-	98.6	99.6	-	-
Oberland		90.5	-	98.4	99.4	-	-
JMC		94.5	-	99.3	-	-	-
IBIDEN		87.2	-	99.9	-	-	-
Corning		84.9	-	99.5	99.8	-	-
HJS/CRT		83.8	-	99.4	-	98.2	-
SHW(LIB1)	After VERT Field Test Part 3 (after 2000 hrs)	3.2	22.2	96.3	97.1	-	93.1
SHW(CAT1)		77.5	87.6	97.8	98.8	97.2	96.5
BUCK(LIB2)		76.5	81.0	95.4	97.8	94.0	95.5
BUCK(CAT3)		64.2	76.2	91.0	96.8	(87.0) [2]	95.3
ECS(LIB3)		12.4	43.0	99.9	99.9	99.3	99.0
DEUTZ(LIB4) [1]		(70.5)	(76.1)	(86.6)	(91.6)	(84.2)	
UNIKAT(CAT4)		54.7	76.2	99.0	99.6	98.1	98.4
AVERAGE		66.4		98.3		97.2	

[1] Small melting damage
[2] Uncertain data
[3] Coulometry is optional for VERT certification test

PMAG: Efficiency according to Total Particulate Mass PM
PZAG: Efficiency according to Integrated Particulate Count (20 - 300 nm) PZ
ECAG: Efficiency according to Elementary Carbon EC (2 state Coulometry)

$$PMAG = \frac{PM_{before\ trap} - PM_{after\ trapF}}{PM_{before\ trapF}} = \frac{PM_{Ref} - PM_{after\ trap}}{PM_{Ref}} \ (X\ 100\%)$$

$$PZAG = \frac{PZ_{before\ trap} - PZ_{after\ trap}}{PZ_{before\ trap}} = \frac{PZ_{Ref} - PZ_{after\ trap}}{PZ_{Ref}} \ (X\ 100\%)$$

$$\text{Penetration} = 1 - \text{Efficiency} = = \frac{PZ_{after\ PF}}{PZ_{Ref}} \ (X\ 100\%)$$

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Some commenters asserted that the VERT work was for relatively small engines and not for large engines, *i.e.* 600–700 hp, and hence could not be relied upon to demonstrate the availability of filters of such high efficiencies for the larger equipment used in some underground mines. MSHA believes this comment is misplaced. The efficiency of a filter is attributable to the design of the filter and not the size of the engine. VERT is documenting filter efficiencies of commercially available filters. It is customary in the industry, however, for the filter manufacturer to size the filter to fit the size of the engine. The mine operator must work with the filter manufacturer to verify that the filter needed will work for the intended machine. MSHA believes that this is no different for other types of options installed on machines for underground mining use.

More information about the results of the VERT tests on specific filters, and how MSHA intends to use this information to aid the mining industry in complying with the requirements of the standards for heavy duty equipment, generators and compressors, are discussed in Part IV of this preamble.

The accumulated dpm must be removed from particulate traps periodically. This is usually done by burning off the accumulated particulate in a controlled manner, called regeneration. If the diesel equipment on which the trap is installed has a duty cycle which creates an exhaust gas temperature greater than about 650 degrees Fahrenheit for more than 25 percent of the operating time, the unit will be self cleaning. That is, the hot exhaust gas will burn off the particulate as it accumulates. Unfortunately, only hard working equipment, such as load, haul, dump and haulage equipment usually satisfies the exhaust gas temperature and duration requirements to self regenerate.

Techniques are available to lower the temperature needed to initiate the regeneration. One technique under development is to use a fuel additive. A comparatively small amount of a chemical is added to the diesel fuel and burns along with the fuel in the combustion chamber. The additive is reported to lower the required regeneration temperature significantly. The additive combustion products are retained as a residue in the particulate trap. The trap must be removed from the equipment periodically to flush the residue. Another technique used to lower the regeneration temperature is to apply a catalyst to the surfaces of the trap material. The action of the catalyst is similar to that of the fuel additive. The catalyst also lowers the concentration of some gaseous emissions in the same manner as the oxidation catalytic converter described earlier.

A very active catalyst applied to the particulate trap surfaces and a very active catalyst in a catalytic converter installed upstream of the trap can create a situation in which the trap performs less efficiently than expected. Burning low sulfur diesel fuel, containing less than 500 ppm sulfur, will result in the creation of significant quantities of sulfates in the exhaust gas. These sulfates will still be in the gaseous state when they reach the ceramic trap and will pass through the trap. These sulfates will condense later forming diesel particulate. Special care must be taken in the selection of the catalyst formulation to ensure that sulfate formation is avoided. This problem does not occur in systems designed with a catalytic converter upstream of a water scrubber. The gaseous phase sulfates will condense when contacting the water in the scrubber and will not be discharged into the mine atmosphere. Thus far, no permissible diesel packages have been approved which incorporate a catalytic converter upstream of the water scrubber. One research project conducted by the former Bureau of Mines which attempted this arrangement was unsuccessful. In attempting to maintain a surface temperature less than the 300 degrees Fahrenheit (required for permissibility purposes) the exhaust gas was be cooled to the point that the catalytic converter did not reach the necessary operating temperature. It would appear that a means to isolate the catalytic converter from the exhaust gas water jacket is necessary for the arrangement to function as intended.

If the machine on which the particulate trap is installed does not work hard enough to regenerate the trap with the hot exhaust gas and the option to use a fuel additive or catalyzed trap is not appropriate, the trap can still be regenerated while installed on the machine. Systems are available whereby air is heated by an externally applied heat source and caused to flow through the particle trap when the engine is stopped. The heat can be supplied by an electrical resistance element installed in front of the trap. The heat can also be supplied by a burner installed into the exhaust pipe in front of the trap. The burner is fueled by an auxiliary fuel line. The fuel is ignited creating large quantities of hot gas. With both systems, an air line is also connected to the exhaust pipe to create a flow of hot gases through the particulate trap. Both systems utilize operator panels to control the regeneration process.

Equipment owners may choose to remove the particle trap from the machine to perform the regeneration. Particle traps are available with quick release devices. The trap is then placed on a specially designed device that creates a controlled flow of heated air that is passed through the filter burning off the accumulated particulate.

The selection of the most appropriate means to regenerate the trap is dependent on the equipment type, the equipment duty cycle, and the equipment utilization practices at the mine.

A program under the Canadian DEEP project is field testing dpm filter systems in a New Brunswick Mine. Investigators are testing four filter systems on trucks and scoops. The initial feedback from Canada is very favorable concerning the performance of filters. Operators are very positive and are requesting the vehicles equipped with the filters because of the noticeable improvement in air quality and an absence of smoke even under transient load conditions. One system undergoing testing utilizes an electrical heating element installed in the filter system to provide the heated air for regeneration of the filter. This heating element requires connection of the filter to an external electrical source at the end of the shift. Initial tests have been successful.

VERT has also published information on the extent of dpm filter usage in Europe as evidence that the filter technology has attained wide spread acceptance. MSHA believes this information is relevant to coal and metal/nonmetal mining because the tunneling equipment on which these filters are installed is similar to metal/nonmetal equipment and can be applied to heavy duty equipment in coal mining operations. VERT stated that over 4,500 filter systems have been deployed in England, Scandinavia, and Germany. Deutz Corporation has deployed 400 systems (Deutz's design) with full flow burners for regeneration of filters installed on engines between 50–600kw. The Oberland-Mangold company has approximately 1,000 systems in the field. They have accumulated an average of 8,400 operating hours in forklift trucks, 10,600 operating hours in construction site engines, and 19,200 operating hours in stationary equipment. The Unikat company has introduced in Switzerland over 250 traps since 1989 and 3,000 worldwide with some operating more than 20,000 hours. In German industry,

approximately 1,500 traps in forklifts are installed annually.

Paper filters. In 1990, the former Bureau of Mines conducted a project to develop a means to reduce the amount of dpm emitted from permissible diesel powered equipment using technologies that were available commercially and that could be applied to existing equipment. The project was conducted with the cooperation of an equipment manufacturer, a mine operator, and MSHA. In light of the fact that all permissible diesel powered equipment, at that time, utilized water scrubbers to meet the MSHA approval requirements, the physical characteristics of the exhaust from that type of equipment were the basis for the selection of candidate technologies. The technology selected for development was the pleated media filter or paper filter as it came to be called. The filter selected was an intake air cleaner normally used for over the road trucks. That filter was acceptable for use with permissible diesel equipment because the temperature of the exhaust gas from the water scrubber was less than 170 degrees F, well below the ignition point of the filter material. Recognizing that under some operating modes, water would be discharged along with the exhaust, a water trap was installed in the exhaust stream before it passed through the filter. After MSHA conducted a thorough permissibility evaluation of the modified system, this filter was installed on a permissible diesel coal haulage vehicle and a series of in-mine trials were conducted. It was determined, by in mine ambient gravimetric sampling, that the particulate filter reduced dpm emissions by 95 percent compared with the same machine without the filter. The test results showed that the filters would last between one and two shifts, depending on how hard the equipment worked. (BOM, IC 9324).

Following the successful completion of the former Bureau of Mines mine trial, several equipment manufacturers applied for and received MSHA approval to offer the paper filter kits as options on a number of permissible diesel machines. These filter kits were installed on other machines at the mine where the original tests were conducted, and later, on machines at other mines.

Despite the initial reports on the high efficiency of paper filters, during the hearings and in the comments on this rulemaking a number of commenters questioned whether, in practice, paper filters could achieve efficiencies on the order of 95% when used on existing permissible equipment. In order to determine whether it could verify those concerns, MSHA contracted with the Southwest Research Institute to verify the ability of such a paper filter to reduce the dpm generated by a typical engine used in permissible equipment. The results of this verification investigation are reviewed in Part IV of this preamble. They confirmed that commercially available paper filters are capable of achieving very high efficiencies.

Another commenter noted that the volatile fraction of particulate is not trapped by hot gas filters, but rather passes through the filter in gaseous form. The volatile fraction consists of, among other components, gaseous forms of sulfur compounds, lube oil and the high boiling point fraction of unburned fuel. These components condense in the mine atmosphere as diesel particulate. The commenter asserted that the process of volatilization is reduced in the water cooled exhaust, but it is present nevertheless.

MSHA recognizes that the volatile fraction of dpm passes through hot gas filters. This volatile fraction later condenses in the mine atmosphere and is collected on particulate samplers. This is not the case with hot gas filters that utilize a catalytic converter. The volatile fraction is oxidized in the catalytic converter and the gases produced do not condense as particulate. Paper filters are typically used with water scrubbers or heat exchangers, both of which condense the volatile fraction into dpm before the exhaust gas reaches the paper filter. This allows the paper filter to trap the condensed volatile fraction.

Dry systems technology. The recently developed means of achieving permissibility with diesel powered equipment in the United States is the dry exhaust conditioning system or dry system. This system combines several of the concepts described above as well as new, innovative approaches. The system also solves some of the problems encountered with older technologies.

The dry system in its most basic form consists of a heat exchanger to cool the exhaust gas, a mechanical flame arrestor to prevent the discharge of any flame from within the engine into the mine atmosphere, and a spark arrestor to prevent sparks from being discharged. The surfaces of these components and the piping connecting them are maintained below the 300 degrees F required by MSHA approval requirements. A filter, of the type normally used as an intake air filter element, is installed in the exhaust system as the spark arrestor. In terms of controlling dpm emissions, the most significant feature of the system is the use of this air filter element as a particulate filter. The filter media has an allowable operating temperature rating greater than the 300 degree F exhaust gas temperature allowed by MSHA approval regulations. These filters are reported to last up to sixteen hours, depending on how hard the machine operates.

The dry system can operate on any grade without the problems encountered by water scrubbers. Furthermore, there is no problem with fog created by operation of the water scrubber. Dry systems have been installed and are operating successfully on diesel haulage equipment, longwall component carriers, longwall component extraction equipment, and in nonpermissible form, on locomotives. However, as pointed out by commenters, requiring the use of a dry system on all mining equipment would be expensive, cumbersome, and in many cases would require considerable engineering measures that might render them infeasible.

Although the dry systems were originally designed for permissible equipment applications, they can also be used directly on outby equipment (whose emissions are not already cooled), or to replace water scrubbers used to cool most permissible equipment with a system that includes additional aftertreatment.

Two manufacturers have received approval for diesel power packages that are configured as described above; Paas Technologies, (under various corporate designations including Minecraft and a registered trade name, Dry Systems Technology, or DST ®) and Jeffrey Mining Equipment Company (currently Long-Airdox-Jeffrey).

The design of the dry system manufactured by DST ® includes a catalytic converter. However, with respect to the basic Paas Technologies system, without a catalytic converter, the initial reported laboratory reductions in dpm were dramatic: up to 98%.

During the hearings, however, there were many questions about the applicability of the early results to MSHA's proposed requirement that emissions of certain equipment be reduced 95% by mass. It was indicated by a commenter that the original Paas Technology dry system tests with a paper filter were performed at West Virginia University used high sulfur fuel which is currently prohibited in underground coal mines. The commenter stated that the University tested different fuels containing varying sulfur contents and the results indicated a fluctuation in overall dpm emission results. The commenter stated the

difference in dpm collection efficiency by the filter was on the order of 12 to 15%. Another commenter stated the difference in dpm reduction using a 0.37 percent fuel sulfur and a 0.04 percent fuel sulfur was about 22 percent. This commenter further stated that other published papers from Europe report the same dpm reductions with varying fuel sulfur levels, approximately 15 to 20 percent reduction.

As was stated ealier, Paas Technologies has further developed its system by the adding a catalytic converter in the exhaust before the particulate paper filter. Paas Technologies have developed a technique whereby the catalytic converter is mounted so that the exhaust gas temperature remains high enough for the converter to operate effectively while complying with the MSHA surface temperature requirement. In addition to removing most of the carbon monoxide, the catalytic converter removes most of the unburned hydrocarbons before they are cooled and condensed. This feature extends the operating life of the filter. Any sulfate formed in the catalytic converter or in the engine combustion process condenses to a solid form as the exhaust gas passes through the heat exchanger and is collected in the particulate filter.

Paas Technologies submitted a detailed set of test results on a 94hp MWM D–916–6 test engine equipped with a Model M38 DST® Management System, which included the catalytic converter, for the rulemaking record. These tests were conducted by Southwest Research Institute using an 8-mode test, with ASTM No. 2–D diesel fuel. Both the test cycle and test fuel (low sulfur) conformed with the test procedure detailed in the proposed rule and in this final rule. In idle mode, the dpm emissions were reduced about 90%; in mode 5, the dpm emissions were down 99%; on average of the 8 modes, the dpm emissions were reduced by 97%.

The Jeffrey system, which does not utilize a catalytic converter, was the subject of the MSHA verification initiative, noted in part IV. The verification was conducted in such a way as to test filter efficiency separately from whole system, with the low sulfur fuel required for coal mine use and without a catalytic converter. The verification confirmed that the paper filter has a dpm removal efficiency greater than 95 percent.

This data submitted to the rulemaking record demonstrates that paper filters used on dry systems can achieve a filtration efficiency that allows equipment to meet the 2.5 gm/hr standard with low sulfur diesel fuel both with and without a catalytic converter in the system.

Reformulated fuels. It has long been known that sulfur content can have a big effect on dpm emissions. In the diesel equipment rule, MSHA requires that fuel used in underground coal mines have less than 0.05% (500 ppm) sulfur. EPA regulations requiring that such low-sulfur fuel (less than 500 ppm) be used in highway engines, in order to limit air pollution, have in practice ensured that this is the type of diesel fuel available to mine operators, and they currently use this type of fuel for all engines.

EPA has proposed a rule which would require further reductions in the sulfur content of highway diesel fuel. Such an action was taken for gasoline fuel on December 21, 1999.

On May 13, 1999 (64 FR 26142) EPA published an Advance Notice of Proposed Rulemaking (ANPRM) relative to changes for diesel fuel. In explaining why it was initiating this action, EPA noted that diesel engines ''contribute greatly'' to a number of serious air pollution problems, and that diesel emissions account for a large portion of the country's particulate matter and nitrogen oxides-a key precursor to ozone. EPA noted that while these emissions come mostly from heavy-duty truck and nonroad engines, they expected the contribution to dpm emissions from light-duty equipment to grow due to manufacturers' plans to greatly increase the sale of light duty trucks. These vehicles are now subject to Tier 2 emission standards, whether powered by gasoline or diesel fuel. Such standards may be difficult to meet without advanced catalyst technologies that in turn are likely to require sulfur reductions in the fuel.

Moreover, planned Tier 3 standards for nonroad vehicles would require similar action (64 FR 26143). (For more information on the EPA planned engine standards, see section 5 of this Part). The EPA noted that the European Union has adopted new specifications for diesel fuel that would limit it to 50 ppm by 2005, (an interim limit of 350 ppm by this year), that the entire diesel fuel supply in the United Kingdom should soon be at 50 ppm, and that Japan and other nations were working toward the same goal (64 FR 26148).

In the ANPRM, EPA specifically noted that while continuously regenerating ceramic filters have shown considerable promise for limiting dpm emissions even at fairly low exhaust temperatures, the systems were fairly intolerant of fuel sulfur. Accordingly, the agency hopes to gather information on whether or not low sulfur fuel was needed for effective PM control (64 FR 26150). EPA's proposed rule was published in May 2000 and EPA issued final regulations addressing emissions standards (December 2000) for new model year 2007 heavy-duty diesel engines and the low-sulfur fuel rule. The regulations require ultra-low sulfur fuel be phased in during 2006–2009.

A joint government-industry partnership is also investigating the relationship between varying levels of sulfur content and emissions reduction performance on various control technologies, including particulate filters and oxidation catalytic convertors. This program is supported by the Department of Energy's Office of Heavy Vehicles Technologies, two national laboratories, the Engine Manufacturers Association, and the Manufacturers of Emission Controls Association. It is known as the Diesel Emission Control-Sulfur Effects (DECSE) Program; more information is available from its web site, http://www.ott.doe.gov/decse.

MSHA expects that once such cleaner fuel is required for transportation use, it will in practice become the fuel used in mining as well—directly reducing engine particulate emissions, increasing the efficiency of aftertreatment devices, and eventually through the introduction of new generation of cleaner equipment. Mayer states that reducing sulfur content, decreasing aromatic components and increasing the Cetane index of diesel fuel can generally result in a 5% to 15% reduction in total particulate emissions.

Several commenters in this rulemaking suggested other fuel formulations which could have a beneficial effect on dpm emissions. One commenter encouraged the use of FRF, Fire Resistant Fuel, which has various safety features as well as lower NO_X and PM, and noted it is under study for use by the military.

Another commenter noted the development of a catalytic ignition system that permits the engines to operate on alternative fuels which greatly reduce harmful emissions. For example, using a water-methanol mix, the commenter noted dramatic reductions in harmful emissions of NO_X, CO and HC over a gasoline, spark ignition engine. This commenter also noted that the ignition system could operate on a diesel engine, but provided no information about emissions reductions by its use.

Meyer reports the results of a test by VERT of a special synthetic fuel containing neither sulfur nor bound nitrogen nor aromatics, with a very high

Cetane index. The fuel performed very well, but produced only abut 10% fewer particulates than low sulfur diesel fuel, nor did it show any improvement in diminishing nonparticulate emissions.

Cabs. Even though cabs are not the type of control device that is attached to the exhaust of the diesel engine to reduce emissions, cabs can protect miners from environmental exposures to dpm. Both cabs and control booths are discussed in the context of reducing miners exposures to dpm.

A cab is an enclosure around the operator installed on a piece of mobile equipment. It can provide the same type of protection as a booth at a crusher station as found in some surface operations. While cabs are not available for all mining equipment, they are available for much of the larger equipment that also has application in the construction industry.

To be effective, a cab should be tightly sealed with windows and doors closed. Rubber seals around doors and windows should be in good condition. Door and window latches must operate properly. In addition to being well sealed, the cab should have an air filtration and pressurizing system. Air intake should be located away from engine exhaust. The airflow should provide one air change per minute for the cab and should pressurize the cab to 0.20 inches of water. While these are not absolute requirements, they do provide a guideline of how a cab should be designed. If a cab does not have an air filtration and pressurizing system, the diesel particulate concentration inside the cab will be similar to the diesel particulate concentration outside the cab.

MSHA has evaluated the efficiency of cab filters for diesel particulate reduction. Several different types of filter media have been tested in underground mines. These include standard filter paper and high efficiency filter paper. Filter papers can reduce diesel particulate exposures by 60 percent to 90 percent. When changing filter media, it is necessary to make sure that the airflow into the cab is not reduced and that the airflow through an air conditioning system is not reduced.

Although the installation of a cab does not relieve the mine operator from the responsibility of complying with the equipment dpm limits, cabs provide assistance in complying with noise and respirable dust regulations. Cabs protect the equipment operator protection from dpm, respirable dust and noise exposures.

(7) Existing Standards for Underground Coal Mines That Assist in Limiting Miner Exposure to Diesel Emissions

MSHA already has in place various requirements that indirectly help to control miner exposure to diesel emissions in underground mines—including exposure to diesel particulate. The first such requirements were developed in the 1940's; the most recent went into full effect only in November, 1999. It is important to understand these requirements because they form the base upon which this new rule is overlaid.

Early developments. In 1944, part 31 established procedures for limiting the gaseous emissions from diesel powered equipment and establishing the recommended dilution air quantity for mine locomotives that use diesel fuel. In 1949, part 32 established procedures for testing of mobile diesel-powered equipment for non-coal mines. In 1961, part 36 was added to provide requirements for the use of diesel equipment in gassy noncoal mines, in which engines must be temperature controlled to prevent explosive hazards. These rules were drafted in response to research conducted by the former Bureau of Mines.

Continued research by the former Bureau of Mines in the 1950s and 1960s led to refinements of its ventilation recommendations, particularly when multiple engines are in use. An airflow of 100 to 250 cfm/bhp for engines that have a properly adjusted fuel to air ratio was recommended (Holtz, 1960). An additive ventilation requirement was recommended for operation of multiple diesel units, which could be relaxed based on the mine operating procedures. This approach was subsequently refined to become a 100–75–50 percent guideline (MSHA Policy Memorandum 81–19MM, 1981). Under this guideline, when multiple pieces of diesel equipment are operated, the required airflow on a split of air would be the sum of: (a) 100 percent of the approval plate quantity for the vehicle with the highest approval plate air quantity requirement; (b) 75 percent of the approval plate air quantity requirement of the vehicle with the next highest approval plate air quantity requirement; and (c) 50 percent of the approval plate airflow for each additional piece of diesel equipment.

Limitations on Diesel Gasses. MSHA has limits on some of the gasses produced in diesel exhaust. These are listed in Table II–5, for both coal mines and metal/nonmetal mines, together with information about the recommendations in this regard of other organizations. As indicated in the table, MSHA requires mine operators to comply with gas specific threshold limit values (TLV®s) recommended by the American Conference of Governmental Industrial Hygienists (ACGIH) in 1972 (for coal mines) and in 1973 (for metal and nonmetal mines).

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TABLE II-5
GASEOUS EXPOSURE LIMITS (PPM)

Pollutant	Range of Limits Recommended		MSHA Limits	
			$Coal_A$	M/NM_B
HCHO	0.016_C	0.3_D	2	2
CO	25_D	50	50	50
CO_2	$5,000_C$	5,000	5,000	5,000
NO	$25_{C,D,E}$	25	25	25
NO_2	1_F	3_D	5	5
SO_2	$2_{C,D}$	5_E	2	5

Table Notes:
A) ACGIH, 1972
B) ACGIH, 1973
C) NIOSH recommended exposure limit (REL), based on a 10-hour, time-weighted average
D) ACGIH, 1996
E) OSHA permissible exposure limit (PEL)
F) NIOSH recommends only a 1-ppm, 15-minutes, short-term exposure limit (STEL)

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To change an MSHA exposure limit, regulatory action is required because the rule does not provide for their automatic updating. In 1989, MSHA proposed changing some of these gas limits in the context of a proposed rule on air quality standards (54 FR 35760). Following opportunity for comment and hearings, a portion of that proposed air quality rule (concerning control of drill dust and blasting) was promulgated. As a result of a recent legal action, MSHA's efforts to revise the specific limits for those gases emitted by diesel engines have been placed under the continued supervision of a federal court of appeals. This action is discussed in more detail in section 9 of this Part.

Diesel Equipment Rule for Underground Coal Mines. On October 25, 1996, MSHA promulgated standards for the ''Approval, Exhaust Gas Monitoring, and Safety Requirements for the Use of Diesel-Powered Equipment in Underground Coal Mines'' (61 FR 55412). The history of this ''diesel equipment rule'' (sometimes referred to here as the ''diesel safety rule'' to help distinguish it from this rulemaking which is oriented toward health) is set forth as part of the history of this rulemaking (see section 9 of this part).

The diesel equipment rule focuses on the safe use of diesels in underground coal mines. Integrated requirements are established for the safe storage, handling, and transport of diesel fuel underground, training of mine personnel, minimum ventilating air quantities for diesel powered equipment, monitoring of gaseous diesel exhaust emissions, maintenance requirements, incorporation of fire suppression systems, and design features for nonpermissible machines.

Certain requirements were included in the diesel equipment rule that are directly related to reducing diesel emissions. For example, the diesel equipment rule requires that the emissions of permissible and heavy duty equipment be tested weekly. The tests are conducted using instrumentation and the tests are conducted with the engines operated at a loaded condition which is representative of actual operation. The results are monitored and recorded. Higher than normal emissions readings indicate that the engines and equipment are not being maintained in approved condition. Although some of these requirements help reduce dpm emissions, they were not included in the rule for that specific purpose.

Lower-emission engines. The diesel equipment rule requires that virtually all diesel-powered engines used in underground coal mines be approved by MSHA; see 30 CFR part 7, (approval requirements), part 36 (permissible machines defined), and part 75 (use of such equipment in underground coal mines). The approval requirements, among other things, require clean-burning engines in diesel-powered equipment (61 FR 55417). In promulgating the final rule, MSHA recognized that clean-burning engines are ''critically important'' to reducing toxic gasses to levels that can be controlled through ventilation. To achieve the objective of clean-burning engines, the rule sets performance standards which must be met by virtually all diesel-powered equipment in underground coal mines.

As noted in section 5 of this part, the technical requirements for approved diesel engines focus on limiting the amount of various gases that an engine can emit, including undiluted exhaust limits for carbon monoxide and oxides of nitrogen (61 FR 55419). The limits for these gasses are derived from existing 30 CFR part 36.

The diesel equipment rule also provides that the particulate matter emitted by approved engines be determined during the testing required to gain approval. The particulate index (or PI), calculated under the provisions of 30 CFR 7.89, indicates what air quantity is necessary to dilute the diesel particulate in the engine exhaust to 1 milligram of diesel particulate matter per cubic meter of air. The purpose of the PI requirement is discussed in more detail in section 5 of this part.

Gas Monitoring. The diesel equipment rule also addresses the monitoring and control of gaseous diesel exhaust emissions (30 CFR part 70; 61 FR 55413). In this regard, the rule requires that mine operators take samples of carbon monoxide and nitrogen dioxide as part of existing onshift workplace examinations (61 FR 55413, 55430–55431). Samples exceeding an action level of 50 percent of the threshold limits set forth in 30 CFR 75.322 trigger corrective action by the mine operator (30 CFR part 70, 61 FR 55413).

Engine Maintenance. The diesel equipment rule requires that diesel-powered equipment be maintained in safe and approved condition (30 CFR 75.1914; 61 FR 55414). As explained in the preamble, maintenance requirements were included because of MSHA's recognition that inadequate equipment maintenance can, among other things, result in increased levels of harmful gaseous and particulate components from diesel exhaust (61 FR 55413–55414).

The rule also requires the weekly examination of diesel-powered equipment (30 CFR 75.1914(g)). To determine if more extensive maintenance is required, the rule further requires a weekly check of the gaseous CO emission levels on permissible and heavy duty outby machines. The CO check requires that the engine be operated at a repeatable loaded condition and the CO measured. The carbon monoxide concentration in the exhaust provides a good indication of engine condition. If the CO measurement increases to a higher concentration than what was normally measured during the past weekly checks, then a maintenance person would know that a problem has developed that requires further investigation.

In addition, operators are required to establish programs to ensure that those performing maintenance on diesel equipment are qualified (61 FR 55414).

Fuel. The diesel equipment rule also requires that underground coal mine operators use diesel fuel with a sulfur content of 0.05% (500 ppm) or less (30 CFR 75.1910(a); 61 FR 55413). Some types of exhaust aftertreatment technology designed to lower hazardous diesel emissions work more effectively when the sulfur content of the fuel is low. More effective aftertreatment devices will result in reduced hydrocarbons, carbon monoxide, and particulate levels. Low sulfur fuel also greatly reduces the sulfate production from the catalytic converters currently in use in underground coal mines thereby decreasing exhaust particulate. To further reduce miners' exposure to diesel exhaust, the final rule prohibits operators from unnecessarily idling diesel-powered equipment (30 CFR 75.1916(d).

Ventilation. The diesel equipment rule requires that as part of the approval process, ventilating air quantities necessary to maintain the gaseous emissions of diesel engines within existing required ambient limits be set. The ventilating air quantities are required to appear on the engine's approval plate. The rule also requires generally that mine operators maintain the approval plate quantity minimum airflow in areas of underground coal mines where diesel-powered equipment is operated. The engine's approval plate air quantity is also used to determine the minimum air quantity in areas where multiple units of diesel powered equipment are being operated. The minimum ventilating air quantity where multiple units of diesel powered equipment are operated on working sections and in areas where mechanized mining equipment is being installed or removed, must be the sum of 100 percent of the approval plate quantities of all of the equipment. As stated in the preamble of the diesel equipment rule, MSHA believes that effective mine ventilation is a key component in the control of miners' exposure to gasses and particulate emissions generated by diesel equipment.

Impact of the diesel equipment rule on dpm. The diesel equipment rule is helping the mining community use diesel-powered equipment more safely in underground coal mines. Moreover, the diesel equipment rule has many features which reduce the emission and concentration of harmful diesel emissions in underground coal mines—including the particulate component of these emissions.

During the public hearings on the equipment rule, miners complained about the high concentrations of diesel emissions at the section loading point and in the areas of the mine where longwall equipment is being installed or removed. Accordingly, MSHA established, in that rule, provisions which would address miners' concerns.

The equipment rule required that the approval plate ventilation quantity be provided at the section loading point. The loading point is also identified as a location where regular air quality samples are required to be taken. Corrective action is required if the samples of CO and NO_2 exceeded more than one half the allowable concentration limit of these gases.

Longwall equipment installations and removals are handled in a similar manner. The diesel emissions from all of the equipment in the area of the mine where the longwall move is being made are required to be considered in establishing the amount of ventilation air to be provided. A specific location where that quantity is to be measured is established. Additionally, the same air quality sampling program required for section loading points is required for areas of the mine where the longwall move is to take place.

Permissible haulage vehicles contribute the largest quantities of emissions at the section loading point. Longwall moves are typically carried out by permissible and heavy duty equipment such as shield carriers, mules, and locomotives which produce large quantities of diesel emissions. Emissions from these vehicles are reduced by the use of approved engines, low sulfur fuel, the loaded repeatable engine condition testing, regular maintenance by trained personnel and the ventilation and sampling provisions of the diesel equipment rule.

Because the effective dates for provisions of the diesel equipment regulations are staggered, the full impact of the new rules was not known at the time the dpm hearings were held. MSHA expects that the concentrations of diesel emissions at the section loading point and during longwall moves will be reduced as these provisions are fully implemented.

In developing the diesel equipment rule, however, MSHA did not explicitly consider the risks to miners of a working lifetime of dpm exposure at very high levels, nor the actions that could be taken to specifically reduce dpm exposure levels in underground coal mines. It was understood that the agency would be taking a separate look

at the health risks of dpm exposure. (61 FR 55420).

(8) Information on How Certain States Are Restricting Occupational Exposure to DPM

As noted earlier in this part, the Federal government has long been involved in efforts to restrict diesel particulate emissions into the environment—both through ambient air quality standards, and through restrictions on diesel engine emissions. While MSHA's actions to limit the concentration of dpm in underground mines are the first effort by the Federal government to deal with the special risks faced by workers exposed to diesel exhaust on the job, several states have already taken actions in this regard with respect to underground coal mines.

This section reviews some of these actions, as they were the subject of considerable discussion and comment during this rulemaking.

Pennsylvania. As indicated in section 1, Pennsylvania essentially had a ban on the use of diesel-powered equipment in underground coal mines for many years. As noted by one commenter, diesel engines were permitted provided the request was approved by the Secretary of the Department of Environmental Protection but no request was ever approved.

In 1995, one company in the State submitted a plan for approval and started negotiations with its local union representatives. This led to statewide discussions and the adoption of a new law in the State that permits the use of diesel-powered equipment in deep coal mines under certain circumstances specified in the law (Act 182). As further noted by this commenter, the drafters of the law completed their work before the issuance of MSHA's new regulation on the safe use of diesel-powered equipment in underground coal mines. The Pennsylvania law, unlike MSHA's diesel equipment rule, specifically addresses diesel particulate. The State did not set a limit on the exposure of miners to dpm, nor did it establish a limit on the concentration of dpm in deep coal mines. Rather, it approached the issue by imposing controls that will limit dpm emissions at the source.

First, all diesel engines used in underground deep coal mines in Pennsylvania must be MSHA-approved engines with an ''exhaust emissions control and conditioning system'' that meets certain tests. (Article II–A, Section 203–A, Exhaust Emission Controls). Among these are dpm emissions from each engine no greater than ''an average concentration of 0.12 mg/m^3 diluted by fifty percent of the MSHA approval plate ventilation for that diesel engine.'' In addition, any exhaust emissions control and conditioning system must include a ''Diesel Particulate Matter (DPM) filter capable of an average of ninety-five percent or greater reduction of dpm emissions.'' It also requires the use of an oxidation catalytic converter. Thus, the Pennsylvania statute requires the use of low-emitting engines, and then the use of aftertreatment devices that significantly reduce the particulates emitted from these engines.

The Pennsylvania law also has a number of other requirements for the safe use of diesel-powered equipment in the particularly hazardous environments of underground coal mines. Many of these parallel the requirements in MSHA's diesel equipment rule. Like MSHA's requirements, they too can result in reducing miner exposure to diesel particulate—*e.g.,* regular maintenance of diesel engines by qualified personnel and equipment operator examinations. The requirements in the Pennsylvania law take into account the need to maintain the aftertreatment devices required to control diesel particulate.

While both mine operators and labor supported this approach, it remains controversial. During the hearings on this rulemaking, one commenter indicated that at the time the standards were established, it would have taken a 95% filter to reduce dpm from certain equipment to the 0.12 mg/m^3 emissions standard because 0.25 sulfur fuel was being utilized. This test reported by the commenter was completed prior to MSHA promulgating the diesel equipment rule that required the use of .05% sulfur fuel. Another commenter pointed out that as operators in the state began considering the use of newer, less polluting engines, achieving an efficiency of 95% reduction of the emissions from any such engines would become even more difficult. There was some disagreement among the commenters as to whether existing technology would permit operators to meet the 0.12 mg/m^3 emission standard in many situations.

One commenter described the difficulty in efforts to get a small outby unit approved under the current Pennsylvania law. Accordingly, the industry has indicated that it would seek additional changes in the Pennsylvania diesel law. Commenters representing miners indicated that they were also involved in these discussions.

West Virginia. Until 1997, West Virginia law banned the use of diesel-powered equipment in underground coal mines. In that year, the State created the joint labor-management West Virginia Diesel Equipment Commission (Commission) and charged it with developing regulations to permit and govern diesel engine use in underground coal mines. As explained by several commenters, the Commission, in collaboration with West Virginia University (WVU), developed a protocol for testing diesel engine exhaust controls, and the legislature appropriated more than $150,000 for WVU to test diesel exhaust controls and an array of diesel particulate filters.

There were a number of comments received by MSHA on the test protocols and results. These are discussed in appropriate parts in this preamble. One commenter noted that various manufacturers of products have been very interested in how their products compare to those of other manufacturers tested by the WVU. Another asserted that mine operators had been slowing the scheduling of tests by WVA.

Pursuant to the West Virginia law establishing the Commission, the Commission was given only a limited time to determine the applicable rules for the use of diesel engines underground, or the matter was required to be referred to an arbitrator for resolution. One commenter during the hearings noted that the Commission had not been able to reach resolution and that indeed arbitration was the next step. Other commenters described the proposal of the industry members of the Commission—0.5mg/m^3 for all equipment, as configured, before approval is granted. In this regard, the industry members of the West Virginia Commission said:

> ''We urge you to accelerate the finalization of * * * these proposed rules. We believe that will aid our cause, as well as the other states that currently don't use diesel.'' (Id.)

Virginia. According to one commenter, diesel engine use in underground mining was legalized in Virginia in the mid-1980s. It was originally used on some heavy production equipment, but the haze it created was so thick it led to a drop in production. Thereafter, most diesel equipment has been used outby (805 pieces). The current state regulations consist of requiring that MSHA approved engines be used, and that the ''most up-to-date, approved, available diesel engine exhaust aftertreatment package'' be utilized. There are no distinctions between types of equipment. The commenter noted that more hearings were planned soon. Under a directive from the governor of Virginia, the state is reviewing its

regulations and making recommendations for revisions to sections of its law on diesels.

Ohio. The record of this rulemaking contains little specific information on the restrictions on the underground use of diesel-powered equipment in Ohio. MSHA understands, however, that in practice it is not used. According to a communication with the Division of Mines and Reclamation of the Ohio Division of Natural Resources, this outcome stems from a law enacted on October 29, 1995, now codified as section 1567.35 of Ohio Revised Code Title 15, which imposes strict safety restrictions on the use of various fuels underground.

(9) History of this Rulemaking

As discussed throughout this part, the Federal government has worked closely with the mining community to ascertain whether and how diesel-powered equipment might be used safety and healthfully in this industry. As the evidence began to grow that exposure to diesel exhaust might be harmful to miners, particularly in underground mines, formal agency actions were initiated to investigate this possibility and to determine what, if any, actions might be appropriate. These actions, including a number of non-regulatory initiatives taken by MSHA, are summarized here in chronological sequence.

Activities Prior to Proposed Rulemaking on DPM. In 1984, the National Institute for Occupational Safety and Health (NIOSH) established a standing Mine Health Research Advisory Committee to advise it on matters involving or related to mine health research. In turn, that standing body established the Mine Health Research Advisory Committee Diesel Subgroup to determine if:

> * * * there is a scientific basis for developing a recommendation on the use of diesel equipment in underground mining operations and defining the limits of current knowledge, and recommending areas of research for NIOSH, if any, taking into account other investigators' ongoing and planned research. (49 FR 37174).

In 1985, MSHA established an Interagency Task Group with NIOSH and the former Bureau of Mines (BOM) to assess the health and safety implications of the use of diesel-powered equipment in underground coal mines.

In April 1986, in part as a result of the recommendation of the Task Group, MSHA began drafting proposed regulations on the approval and use of diesel-powered equipment in underground coal mines. Also in 1986, the Mine Health Research Advisory Committee Diesel Subgroup (which, as noted above, was created by a standing NIOSH committee) summarized the evidence available at that time as follows:

> It is our opinion that although there are some data suggesting a small excess risk of adverse health effects associated with exposure to diesel exhaust, these data are not compelling enough to exclude diesels from underground mines. In cases where diesel equipment is used in mines, controls should be employed to minimize exposure to diesel exhaust.

On October 6, 1987, pursuant to section 102(c) of the Mine Act, 30 U.S.C. 812(c), which authorizes MSHA to appoint such advisory committees as it deems appropriate, the agency appointed an advisory committee ''to provide advice on the complex issues concerning the use of diesel-powered equipment in underground coal mines.'' (52 FR 37381). MSHA appointed nine members to this committee, officially known as The Mine Safety and Health Administration Advisory Committee on Standards and Regulations for Diesel-Powered Equipment in Underground Coal Mines (hereafter the MSHA Diesel Advisory Committee). As required by section 101(a)(1) of the Mine Act, MSHA provided the MSHA Diesel Advisory Committee with draft regulations on the approval and use of diesel-powered equipment in underground coal mines. The draft regulations did not include standards setting specific limitations on diesel particulate, nor had MSHA at that time determined that such standards would be promulgated.

In July 1988, the MSHA Diesel Advisory Committee completed its work with the issuance of a report entitled ''Report of the Mine Safety and Health Administration Advisory Committee on Standards and Regulations for Diesel-Powered Equipment in Underground Coal Mines.'' It also recommended that MSHA promulgate standards governing the approval and use of diesel-powered equipment in underground coal mines. The MSHA Diesel Advisory Committee recommended that MSHA promulgate standards limiting underground coal miners' exposure to diesel exhaust.

With respect to diesel particulate, the MSHA Diesel Advisory Committee recommended that MSHA ''set in motion a mechanism whereby a diesel particulate standard can be set.'' (MSHA, 1988). In this regard, the MSHA Diesel Advisory Committee determined that because of inadequacies in the data on the health effects of diesel particulate matter and inadequacies in the technology for monitoring the amount of diesel particulate matter at that time, it could not recommend that MSHA promulgate a standard specifically limiting the level of diesel particulate matter in underground coal mines (*Id.* 64–65). Instead, the MSHA Diesel Advisory Committee recommended that MSHA ask NIOSH and the former Bureau of Mines to prioritize research in the development of sampling methods and devices for diesel particulate.

The MSHA Diesel Advisory Committee also recommended that MSHA request a study on the chronic and acute effects of diesel emissions (*Id.*). In addition, the MSHA Diesel Advisory Committee recommended that the control of diesel particulate ''be accomplished through a combination of measures including fuel requirements, equipment design, and in-mine controls such as the ventilation system and equipment maintenance in conjunction with undiluted exhaust measurements.'' The MSHA Diesel Advisory Committee further recommended that particulate emissions ''be evaluated in the equipment approval process and a particulate emission index reported.'' (*Id.* at 9).

In addition, the MSHA Diesel Advisory Committee recommended that ''the total respirable particulate, including diesel particulate, should not exceed the existing two milligrams per cubic meter respirable dust standard.'' (*Id.* at 9.) It should be noted that section 202(b)(2) of the Mine Act requires that coal mine operators maintain the average concentration of respirable dust at their mines at or below two milligrams per cubic meter which effectively prohibits diesel particulate matter in excess of two milligrams per cubic meter (30 U.S.C. 842(b)(2)).

As noted, the MSHA Diesel Advisory Committee issued its report in 1988. During that year, NIOSH issued a Current Intelligence Bulletin recommending that whole diesel exhaust be regarded as a potential carcinogen and controlled to the lowest feasible exposure level (NIOSH, 1988). In its bulletin, NIOSH concluded that although the excess risk of cancer in diesel exhaust exposed workers had not been quantitatively estimated, it is logical to assume that reductions in exposure to diesel exhaust in the workplace would reduce the excess risk. NIOSH stated that ''[g]iven what we currently know, there is an urgent need for efforts to be made to reduce occupational exposures to DEP [dpm] in mines.''

Consistent with the MSHA Diesel Advisory Committee's research recommendations, MSHA, in September 1988, formally requested NIOSH to

perform a risk assessment for exposure to diesel particulate. (57 FR 500). MSHA also requested assistance from NIOSH and the former BOM in developing sampling and analytical methodologies for assessing exposure to diesel particulate in mining operations. (*Id.*). In part, as a result of the MSHA Diesel Advisory Committee's recommendation, MSHA also participated in studies on diesel particulate sampling methodologies and determination of underground occupational exposure to diesel particulate.

On October 4, 1989, MSHA published a Notice of Proposed Rulemaking on approval requirements, exposure monitoring, and safety requirements for the use of diesel-powered equipment in underground coal mines. (54 FR 40950). The proposed rule, among other things, addressed, and in fact followed, the MSHA Diesel Advisory Committee's recommendation that MSHA promulgate regulations requiring the approval of diesel engines (54 FR 40951), limiting gaseous pollutants from diesel equipment, (*Id.*), establishing ventilation requirements based on approval plate dilution air quantities (54 FR 40990), requiring equipment maintenance (54 FR 40958), requiring that trained personnel work on diesel-powered equipment, (54 FR 40995), establishing fuel requirements, (*Id.*), establishing gaseous contaminant monitoring (54 FR 40989), and requiring that a particulate index indicating the quantity of air needed to dilute particulate emissions from diesel engines be established. (54 FR 40953).

On January 6, 1992, MSHA published an Advance Notice of Proposed Rulemaking (ANPRM) indicating it was in the early stages of developing a rule specifically addressing miners exposure to diesel particulate (57 FR 500). In the ANPRM, MSHA, among other things, sought comment on specific reports on diesel particulate prepared by NIOSH and the former BOM. MSHA also sought comment on reports on diesel particulate which were prepared by or in conjunction with MSHA (57 FR 501). The ANPRM also sought comments on the health effects, technological and economic feasibility, and provisions which should be considered for inclusion in a diesel particulate rule (57 FR 501). The notice also identified five specific areas where the agency was particularly interested in comments, and about which it asked a number of detailed questions: (1) Exposure limits, including the basis thereof; (2) the validity of the NIOSH risk assessment model and the validity of various types of studies; (3) information about non-cancer risks, non-lung routes of entry, and the confounding effects of tobacco smoking; (4) the availability, accuracy and proper use of sampling and monitoring methods for diesel particulate; and (5) the technological and economic feasibility of various types of controls, including ventilation, diesel fuel, engine design, aftertreatment devices, and maintenance by mechanics with specialized training. The notice also solicited specific information from the mining community on ''the need for a medical surveillance or screening program and on the use of respiratory equipment.'' (57 FR 500). The comment period on the ANPRM closed on July 10, 1992.

While MSHA was completing a ''comprehensive analysis of the comments and any other information received'' in response to the ANPRM (57 FR 501), it took also several actions to encourage the mining community to begin to deal with the problems identified.

In 1995, MSHA sponsored three workshops ''to bring together in a forum format the U.S. organizations who have a stake in limiting the exposure of miners to diesel particulate (including) mine operators, labor unions, trade organizations, engine manufacturers, fuel producers, exhaust aftertreatment manufacturers, and academia.'' (McAteer, 1995). The sessions provided an overview of the literature and of diesel particulate exposures in the mining industry, state-of-the-art technologies available for reducing diesel particulate levels, presentations on engineering technologies toward that end, and identification of possible strategies whereby miners' exposure to diesel particulate matter can be limited both practically and effectively.

The first workshop was held in Beckley, West Virginia on September 12 and 13, and the other two were held on October 6, and October 12 and 13, 1995, in Mt Vernon, Illinois and Salt Lake City, Utah, respectively. A transcript was made. During a speech early the next year, the Deputy Assistant Secretary for MSHA characterized what took place at these workshops:

> The biggest debate at the workshops was whether or not diesel exhaust causes lung cancer and whether MSHA should move to regulate exposures. Despite this debate, what emerged at the workshops was a general recognition and agreement that a health problem seems to exist with the current high levels of diesel exhaust exposure in the mines. One could observe that while all the debate about the studies and the level of risk was going on, something else interesting was happening at the workshops: one by one miners, mining companies, and manufacturers began describing efforts already underway to reduce exposures. Many are actively trying to solve what they clearly recognize is a problem. Some mine operators had switched to low sulfur fuel that reduces particulate levels. Some had increased mine ventilation. One company had tried a soy-based fuel and found it lowered particulate levels. Several were instituting better maintenance techniques for equipment. Another had hired extra diesel mechanics. Several companies had purchased electronically controlled, cleaner, engines. Another was testing a prototype of a new filter system. Yet another was using disposable diesel exhaust filters. These were not all flawless attempts, nor were they all inexpensive. But one presenter after another described examples of serious efforts currently underway to reduce diesel emissions. (Hricko, 1996).

In March of 1997, MSHA issued, in draft form, a publication entitled ''Practical Ways to Control Exposure to Diesel Exhaust in Mining—a Toolbox''. The draft publication was disseminated by MSHA to all underground mines known to use diesel equipment and posted on MSHA's Web site.

As explained in the publication, the Toolbox was designed to disseminate to the mining community information gained through the workshops about methods being used to reduce miner exposures to dpm. MSHA's Toolbox provided specific information about nine types of controls that can reduce dpm exposures: low emission engines; fuels; aftertreatment devices; ventilation; enclosed cabs; engine maintenance; work practices and training; fleet management; and respiratory protective equipment. Some of these approaches reduce emissions from diesel engines; others focus on reducing miner exposure to whatever emissions are present. Quotations from workshop participants were used to illustrate when and how such controls might be helpful.

As it clearly stated in its introductory section entitled ''How to Use This Publication,'' the Toolbox was not designed as a guide to existing or pending regulations. As MSHA noted in that regard:

> While the (regulatory) requirements that will ultimately be implemented, and the schedule of implementation, are of course uncertain at this time, MSHA encourages the mining community not to wait to protect miners' health. MSHA is confident that whatever the final requirements may be, the mining community will find this Toolbox information of significant value.

On October 25, 1996, MSHA published a final rule addressing approval, exhaust monitoring, and safety requirements for the use of diesel-powered equipment in underground coal mines (61 FR 55412). The final rule addresses, and in large part is consistent

with, the specific recommendations made by the MSHA Diesel Advisory Committee for limiting underground coal miners' exposure to diesel exhaust. As noted in section 7 of this part, the diesel safety rule was implemented in steps concluding in late 1999. Aspects of this diesel safety rule had a significant impact on this rulemaking.

In the Fall of 1997, following comment, MSHA's Toolbox was finalized and disseminated to the mining community. At the same time, MSHA made available to the mining community a software modeling tool developed by the Agency to facilitate dpm control. This model enables an operator to evaluate the effect which various alternative combinations of controls would have on the dpm concentration in a particular mine—before making the investment. MSHA refers to this model as ''the Estimator''. The Estimator is in the form of a template that can be used on standard computer spreadsheet programs. As information about a new combination of controls is entered, the results are promptly displayed.

Proposed Rulemaking on Dpm. On April 9, 1998, MSHA published a proposed rule to ''reduce the risks to underground coal miners of serious health hazards that are associated with exposure to high concentrations of diesel particulate matter'' (63 FR 17492).

MSHA went to some lengths to ensure the mining community would be able to review and comment on the proposed rule. The agency made copies of the proposal available for review by the mining community at each district and field office location, at the National Mine Safety and Health Academy, and at each technical support center. MSHA also provided the opportunity for comments to be accepted from the mining community at each of those locations, as well as through mail, e-mail and fax to the national office. MSHA also distributed the proposal to all underground mines, to mining associations and other interested parties. A copy was also posted on MSHA's website.

In order to further facilitate participation by the mining community, MSHA developed as an introduction to its preamble explaining the proposed rule a ''plain language'' questions and answers section.

The notice of proposed rulemaking reviewed and discussed the comments received in response to the ANPRM, including information on such control approaches as fuel type, fuel additives, and maintenance practices (63 FR 17512–17514). For the convenience of the mining community, a copy of MSHA's Toolbox was also reprinted as an Appendix at the end of the notice of proposed rulemaking (63 FR 17580 *et seq.*). A complete description of the Estimator, and several examples, were also presented in the preamble of the proposed dpm rule (63 FR 17565 *et seq.*).

The proposed dpm rule was fairly simple. In addition to miner training, the proposed rule would have required aftertreatment filters on all permissible equipment and, subsequently, on all heavy duty nonpermissible equipment. Throughout the preamble, MSHA discussed a number of other approaches that might have merit in limiting the concentration of dpm in underground coal mines. MSHA made it very clear to the mining community that the rule being proposed represented only one of the approaches which might ultimately be required by the final rule and on which comment was being solicited by the proposed rulemaking notice.

For example, the agency noted the following:

> ''MSHA recognizes that a specification standard does not allow for the use of future alternative technologies that might provide the same or enhanced protection at the same or lower cost. MSHA welcomes comment as to whether and how the proposed rule can be modified to enhance its flexibility in this regard * * *. (There are) two alternative specification standards which would provide somewhat more flexibility for coal mine operators. Alternative 1 would treat the filter and engine as a package that has to meet a particular emission standard. Instead of requiring that all engines be equipped with a high-efficiency filter, this approach would provide some credit for the use of lower-polluting engines. Alternative 2 would also provide credit for mine ventilation beyond that required.'' (63 FR 17498)

These alternatives were further discussed in a separate Question and Answer (#12). The agency was also clear it would welcome comment on ''whether there are some types of light-duty equipment whose dpm emissions should, and could feasibly, be controlled'', and ''whether it would be feasible for this sector to implement a requirement that any new light-duty equipment added to a mine's fleet be filtered'' Question and Answer (#6) (63 FR 17556).

MSHA also discussed and welcomed comment on a number of other alternatives: *e.g.,* restricting the exposure of underground coal mines to all fine particulates regardless of source (63 FR 17495); and the use of administrative controls (*e.g.,* rotation of personnel) and personal protective equipment (*e.g.,* respirators) to reduce the dpm exposure of miners. The Agency also sought comments on its risk assessment, presented in full in the preamble to the proposed rule (Part III). As noted therein, this was the first risk assessment ever performed by the agency to be peer reviewed. Such a review is not required under the agency's statute, but MSHA took the time to obtain such a review in this instance due to significant disagreement within the mining community about the health risks of exposure to dpm (63 FR 17521).

MSHA also asked for comment on its economic assumptions in the preamble. Two of the Questions and Answers (#5 and #7) were specifically devoted to cost impacts, including those on small mines. MSHA also specifically requested all members of the mining community to consider using the Estimator in developing comments on the proposed rulemaking (63 FR 17565).

On July 14, 1998, in accordance with the National Environmental Protection Act, MSHA published a notice in the **Federal Register** seeking comment on its preliminary determination that the proposed rule would not have a significant environmental impact (63 FR 37796).

The initial comment period was scheduled to last for 120 days until August 7, 1998. In response to requests from the public, on August 5, 1998, MSHA extended the initial comment period on the proposed rule (and the comment period on its preliminary determination of no significant environmental impact) for an additional 60 days, until October 9, 1998 (63 FR 41755). That notice also announced MSHA's intent to hold public hearings on the proposal.

On October 19, 1998, MSHA announced in the **Federal Register** locations of four public hearings on the proposed rule. The agency further announced that the close of the post-hearing comment period and rulemaking record would be on February 16, 1999 (63 FR 55811).

In November 1998, MSHA held hearings in Salt Lake City, Utah and Beckley, West Virginia. In December 1998, hearings were held in Mt. Vernon, Illinois, and Birmingham, Alabama.

These hearings were well attended. Testimony was presented by individual miners, representatives of miners, individual coal companies, mining industry associations, representatives of engine and equipment manufacturers and one individual manufacturer. Members of the mining community participating had an extensive opportunity to hear and respond to alternative views; some participated in several hearings. They also had an opportunity to engage in direct dialogue

with members of MSHA's rulemaking committee-responding to questions and asking questions on their own. There was extensive comment not only about the provisions of the proposed rule itself, but also about the need for diesel powered equipment in this sector, the risks associated with its use, the need for regulation in this sector, alternative approaches (including but not limited to those on which MSHA specifically sought comment), and the technological and economic feasibility of various alternatives.

During the hearings, MSHA made a number of requests that information provided at the hearing be supplemented by submission of cited sources, additional data, and in particular for data to support assertions made about various control technologies. MSHA again solicited information concerning the agency's cost assumptions, for the results of studies using MSHA's Estimator model, and also asked for any data on a number of other points. For example, the agency requested further information on the size distribution of particles from cleaner engines, on the viability of a fine particulate standard in lieu of a dpm standard, for a list of any studies concerning the risks of dpm or lack thereof, and data on equipment upgrades.

On February 12, 1999, (64 FR 7144) MSHA published a notice in the **Federal Register** announcing: (1) The availability of three additional studies discussed in the preamble of the proposed rule but not available at the time of publication; and (2) the extension of the post-hearing comment period and close of record for 60 additional days, until April 30, 1999.

On April 27, 1999, in response to requests from the public, MSHA extended the post-hearing comment period and close of record for 90 additional days, until July 26, 1999 (64 FR 22592).

On July 8, 1999, MSHA published a notice in the **Federal Register** correcting technical errors in the preamble discussion on the Diesel Emission Control Estimator formula in the Appendix to Part V of the proposed rulemaking notice, and correcting Figure V–5 of the preamble. Comments on these changes were solicited by July 26, 1999, the close of the rulemaking record (64 FR 36826). The Estimator model was subsequently published in the literature.

The rulemaking record closed on July 26, 1999, fifteen months after the date the proposed rule was published for public notice. The comments, like the hearings, reflected extensive participation in this effort by the full range of interests in the mining community and covered a full range of ideas and alternatives.

On June 30, 2000, the rulemaking record was reopened for 30 days in order to obtain public comment on certain additional documents which the agency determined should be placed in the rulemaking record. Those documents were MSHA's paper filter verification studies and the recent information from VERT on the performance of hot gas filters mentioned in section 6 of this Part. In addition, the notice provided an opportunity for comment on additional documents being placed in the rulemaking record for a related rulemaking for underground metal and nonmetal mines, and an opportunity to comment on some additional documents on risk being placed in both records. In this regard, the notice reassured the mining community that any comments filed on risk in either rulemaking proceeding would be placed in both records, since the two rulemakings utilize the same risk assessment.

Other Related Activity. On September 3, 1999, the United States Court of Appeals for the District of Columbia Circuit issued its decision on writ of mandamus sought by the United Mine Workers to compel MSHA to issue final regulations controlling gaseous emissions in the exhaust of diesel engines used in underground coal mines. (190 F.3d 545.) The UMWA argued that such action should have been completed some years before as part of MSHA's air quality rulemaking to update emissions limits on hundreds of exposure limits. The Court found that the Agency was in violation of the statute's requirement that the Secretary must either promulgate final regulations, or explain her decision not to promulgate them, within ninety days of the certification of the record of a hearing if one is held or the close of the public comment period if a hearing is not held 30 U.S.C. 811(a)(4). However, the Court declined to immediately issue the mandamus order sought in this case because, among other factors: (a) The UMWA agreed that the diesel equipment rules alone may have the desired effect of reducing exposure to these gases; (b) the UMWA further agreed that the control of diesel particulate matter and respirable mine dust rank as higher rulemaking priorities for MSHA; and (c) MSHA submitted a tentative schedule for such rulemaking that the court found to be reasonable. However, the court retained jurisdiction of the case to ensure MSHA would move forward on this matter, and ordered several reports by the agency on its progress on December 31, 1999, June 30, 2000, December 31, 2000, and December 31, 2001.

III. Risk Assessment

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Introduction

MSHA has reviewed the scientific literature to evaluate the potential health effects of occupational dpm exposures at levels encountered in the mining industry. This part of the preamble presents MSHA's review of the currently available information and MSHA's assessment of health risks associated with those exposures. All material submitted during the public comment periods was considered before MSHA drew its final conclusions.

The risk assessment begins in Section III.1, with a discussion of dpm exposure levels observed by MSHA in the mining industry. This is followed by a review, in Section III.2, of information available to MSHA on health effects that have been studied in association with dpm exposure. Finally, in Section III.3 entitled ''Characterization of Risk,'' the Agency considers three questions that must be addressed for rulemaking under the Mine Act and relates the available information about risks of dpm exposure at current levels to the regulatory requirements.

A risk assessment must be technical enough to present the evidence and describe the main controversies surrounding it. At the same time, an overly technical presentation could cause stakeholders to lose sight of the main points. MSHA is guided by the first principle the National Research Council established for risk characterization, that the approach be:

> [a] decision driven activity, directed toward informing choices and solving problems * * * Oversimplifying the science or skewing the results through selectivity can lead to the inappropriate use of scientific information in risk management decisions, but providing full information, if it does not address key concerns of the intended audience, can undermine that audience's trust in the risk analysis.

Although the final rule covers only one sector, this portion of the preamble was intended to enable MSHA and other interested parties to assess risks throughout the coal and M/NM mining industries. Accordingly, the risk assessment includes information pertaining to all sectors of the mining industry. All public comments on the exposures of miners and the health effects of dpm exposure—whether submitted specifically for the coal rulemaking or for the metal/nonmetal rulemaking—were incorporated into the record for each rulemaking and have been considered for this assessment.

MSHA had an earlier version of this risk assessment independently peer reviewed. The risk assessment as proposed incorporated revisions made in accordance with the reviewers' recommendations, and the final version presented here contains clarifications and other responses to public comments. With regard to the risk assessment as published in the proposed preamble, the reviewers stated that:

> * * * principles for identifying evidence and characterizing risk are thoughtfully set out. The scope of the document is carefully described, addressing potential concerns about the scope of coverage. Reference citations are adequate and up to date. The document is written in a balanced fashion, addressing uncertainties and asking for additional information and comments as appropriate. (Samet and Burke, Nov. 1997).

Some commenters generally agreed with this opinion. Dr. James Weeks, representing the UMWA, found the proposed risk assessment to be ''balanced, thorough, and systematic.'' Dr. Paul Schulte, representing NIOSH, stated that ''MSHA has prepared a thorough review of the health effects associated with exposure to high concentrations of dpm, and NIOSH concurs with the published [proposed] characterization of risks associated with these exposures.'' Dr. Michael Silverstein, representing the Washington State Dept. of Labor and Industries, found MSHA's ''regulatory logic * * * thoroughly persuasive.'' He commented that ''the best available scientific evidence shows that diesel particulate exposure is associated with serious material impairment of health * * * the evidence * * * is particularly strong and certainly provides a sufficient basis for regulatory action.''

Many commenters, however, vigorously criticized various aspects of the proposed assessment and some of the scientific studies on which it was based. MSHA's final assessment, published here, was modified to respond to all of these criticisms. Also, in response to commenters' suggestions, this assessment incorporates some research studies and literature reviews not covered or inadequately discussed in the previous version.

Some commenters expressed the opinion that the proposed risk assessment should have been peer-reviewed by a group representing government, labor, industry, and independent scientists. Since the rulemaking process included a pre-hearing comment period, eight public hearings (four for coal and four for M/NM), and two post-hearing comment periods, these constituencies had ample opportunity to review and comment upon MSHA's proposed risk assessment. The length of the comment period for the Coal Dpm proposal was 15 months. The length of the comment period for the Metal/Nonmetal Dpm proposal was nine months.

1. Exposures of U.S. Miners

Information about U.S. miner exposures comes from published studies and from additional mine investigations conducted by MSHA since 1993.[3] Previously published studies of exposures to dpm among U.S. miners are: Watts (1989, 1992), Cantrell (1992, 1993), Haney (1992), and Tomb and Haney (1995). MSHA has also conducted investigations subsequent to the period covered in Tomb and Haney (1995), and the previously unpublished data through mid-1998 are included here. Both the published and unpublished studies were placed in the record with the proposal, giving MSHA's stakeholders the opportunity to analyze and comment on all of the exposure data considered.

MSHA's field studies involved measuring dpm concentrations at a total of 50 mines: 27 underground metal and nonmetal (M/NM) mines, 12 underground coal mines, and 11 surface mining operations (both coal and M/NM). At all surface mines and all underground coal mines, dpm measurements were made using the size-selective method, based on gravimetric determination of the amount of submicrometer dust collected with an impactor. With few exceptions, dpm measurements at underground M/NM mines were made using the Respirable Combustible Dust (RCD) method (with

[3] MSHA has only limited information about miner exposures in other countries. Based on 223 personal and area samples, average exposures at 21 Canadian noncoal mines were reported to range from 170 to 1300 $\mu g/m^3$ (respirable combustible dust), with maximum measurements ranging from 1020 to 3100 $\mu g/m^3$ (Gangel and Dainty, 1993). Among 622 full shift measurements collected since 1989 in German underground noncoal mines, 91 (15%) exceeded 400 $\mu g/m^3$ (total carbon) (Dahmann et al., 1996). As explained elsewhere in this preamble, 400 $\mu g/m^3$ (total carbon) corresponds to approximately 500 $\mu g/m^3$ dpm.

no impactor). At two of the underground M/NM mines, measurements were made using the total carbon (TC) method, and at one, RCD measurements were made in one year and TC measurements in another. Measurements at the two remaining underground M/NM mines were made using the size-selective method, as in coal and surface mines.[4] Weighing errors inherent in the gravimetric analysis required for both size-selective and RCD methods become statistically insignificant at the relatively high dpm concentrations observed.

According to MSHA's experience, the dpm samples reflect exposures typical of mines known to use diesel equipment for face haulage in the U.S. However, they do not constitute a random sample of mines, and care was taken in the proposed risk assessment not to characterize results as necessarily representing conditions in all mines. Several commenters objected to MSHA's use of these exposure measurements in making comparisons to exposures reported in other industries and, for M/NM, in estimating the proposed rule's impact. These objections are addressed in Sections III.1.d and III.3.b.ii(3)(c) below. Comments related to the measurement methods used in underground coal and M/NM mines are addressed, respectively, in Sections III.1.b and III.1.c.

Each underground study typically included personal dpm exposure measurements for approximately five production workers. Also, area samples were collected in return airways of underground mines to determine diesel particulate emission rates.[5] Operational information such as the amount and type of equipment, airflow rates, fuel, and maintenance was also recorded. Mines were selected to obtain a wide range of diesel equipment usage and mining methods. Mines with greater than 175 horsepower and less than 175 horsepower production equipment were sampled. Single and multiple level mines were sampled. Mine level heights ranged from eight to one-hundred feet. In general, MSHA's studies focused on face production areas of mines, where the highest concentrations of dpm could be expected; but, since some miners do not spend their time in face areas, samples were collected in other areas as well, to get a more complete picture of miner exposure. Because of potential interferences from tobacco smoke in underground M/NM mines, samples were not collected on or near smokers.

Table III–1 summarizes key results from MSHA's studies. The higher concentrations in underground mines were typically found in the haulageways and face areas where numerous pieces of equipment were operating, or where airflow was low relative to the amount of equipment operating. In production areas and haulageways of underground mines where diesel powered equipment was used, the mean dpm concentration observed was 644 μg/m^3 for coal and 808 μg/m^3 for M/NM. In travelways of underground mines where diesel powered equipment was used, the mean dpm concentration (based on 112 area samples not included in Table III–1) was 517 μg/m^3 for M/NM and 103 μg/m^3 for coal. In surface mines, the higher concentrations were generally associated with truck drivers and front-end loader operators. The mean dpm concentration observed was less than 200 μg/m^3 at all eleven of the surface mines in which measurements were made. More information about the dpm concentrations observed in each sector is presented in the material that follows.

TABLE III–1.—FULL-SHIFT DIESEL PARTICULATE MATTER CONCENTRATIONS OBSERVED IN PRODUCTION AREAS AND HAULAGEWAYS OF 50 DIESELIZED U.S. MINES

Mine type	Number of mines	Number of samples	Mean exposure (μg/m^3)	Standard error of mean (μg/m^3)	Exposure range (μg/m^3)
Surface	11	45	88	11	9–380
Underground Coal[a]	12	226	644	41	0–3.650
Underground Metal and Nonmetal	27	355	808	39	10–5.570

Note: Intake and return area samples are excluded.

a. Underground Coal Mines

Approximately 145 out of the 910 existing underground coal mines currently utilize diesel powered equipment. Of these 145 mines, 32 mines currently use diesel equipment for face coal haulage. The remaining mines use diesel equipment for transportation, materials handling and other support operations. MSHA focused its efforts in measuring dpm concentrations in coal mines on mines that use diesel powered equipment for face coal haulage. Twelve mines using diesel-powered face haulage were sampled. Mines with diesel powered face haulage were selected because the face is an area with a high concentration of vehicles operating at a heavy duty cycle at the furthest end of the mine's ventilation system.

Diesel particulate levels in underground mines depend on: (1) The amount, size, and workload of diesel equipment; (2) the rate of ventilation; and, (3) the effectiveness of whatever diesel particulate control technology may be in place. In the dieselized mines studied by MSHA, the sections used either two or three diesel coal haulage vehicles. In eastern mines, the haulage vehicles were equipped with a nominal 100 horsepower engine. In western mines, the haulage vehicles were equipped with a nominal 150 horsepower engine. Ventilation rates ranged from the approval plate requirement, based on the 100–75–50 percent rule (Holtz, 1960), to ten times the approval plate requirement. In most cases, the section airflow was approximately twice the approval plate requirement. Other control technology included aftertreatment filters and fuel. Two types of aftertreatment filters were used. These filters included a disposable diesel emission filter (DDEF) and a Wire Mesh Filter (WMF). The DDEF is a commercially available product; the WMF was developed by and only used at one mine. Both low sulfur and high sulfur fuels were used.

Figure III–1 displays the range of exposure measurements obtained by MSHA in the field studies it conducted in underground coal mines. A study

[4] The various methods of measuring dpm are explained in section 3 of Part II of the preamble to the proposed rule. This explanation, along with additional information on these methods, is also provided in section 3 of Part II of the preamble to the final M/NM rule.

[5] Since area samples in return airways do not necessarily represent locations where miners normally work or travel, they were excluded from the present analysis. A number of area samples were included, however, as described in Sections III.1.b and III.1.c. The included area samples were all taken in production areas and haulageways.

normally consisted of collecting samples on the continuous miner operator and coal haulage vehicle operators for two to three shifts, along with area samples in the haulageways. A total of 142 personal samples and 84 area samples were collected, excluding any area samples taken in intake or return airways.

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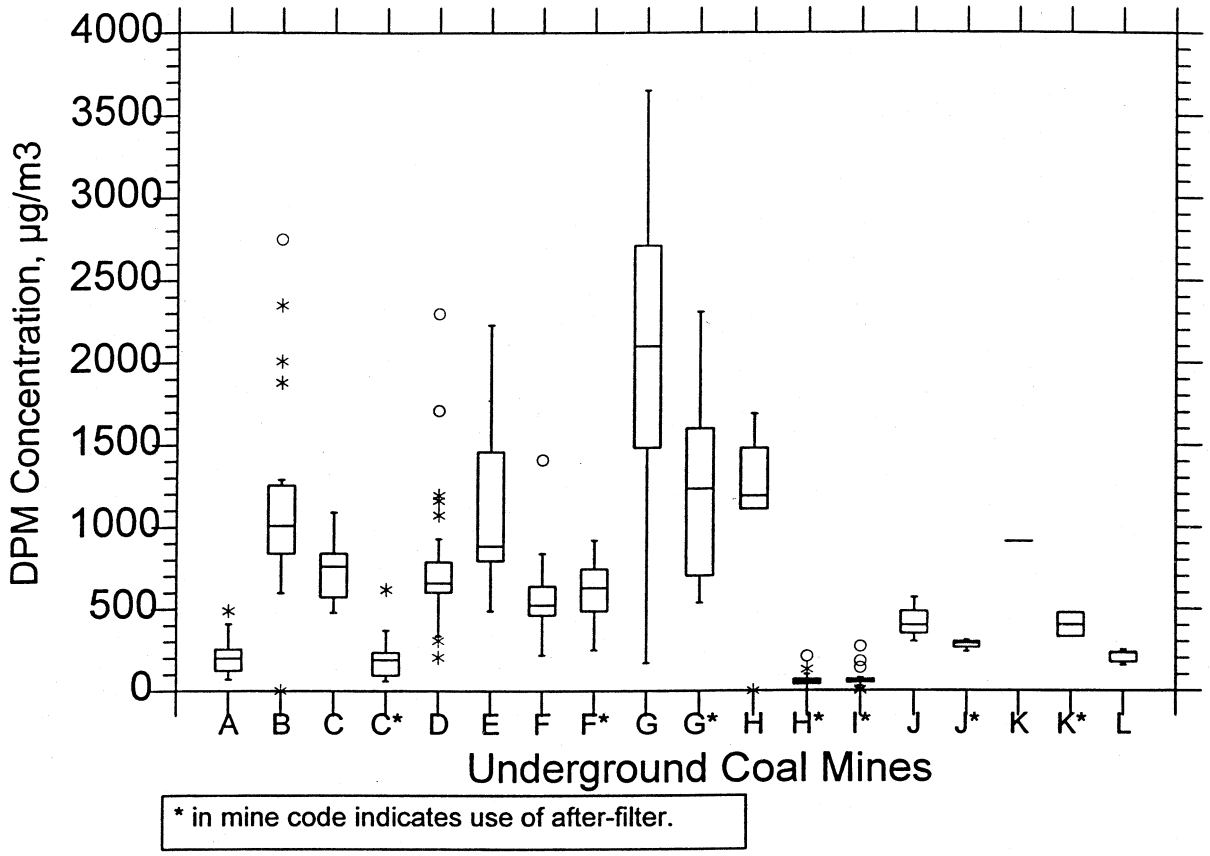

Figure 5 Box plots (Tukey, 1977) for dpm concentrations observed at 12 underground coal mines. Top and bottom of each box represent upper and lower quartiles, respectively. "Belt" inside box represents median. Vertical lines span nearly all measurements. Isolated points (either ✳ or ○) are outliers, representing unusually high or low measurements compared to other observations at the same mine. All dpm measurements were made using the size-selective method, based on gravimetric determination of the amount of submicrometer dust collected with an impactor.

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As stated in the proposed risk assessment, no statistically significant difference was observed in mean dpm concentration between the personal and area samples.[6] A total of 19 individual measurements exceeded 1500 µg/m³, still excluding intake and return area samples. Although the three highest of these were from area samples, nine of the 19 measurements exceeding 1500 µg/m³ were from personal samples.

In six mines, measurements were taken both with and without use of disposable after-treatment filters, so that a total of eighteen studies, carried out in twelve mines, are displayed. Without use of after-treatment filters, average observed dpm concentrations exceeded 500 µg/m³ in eight of the twelve mines and exceeded 1000 µg/m³ in four.[7] At five of the twelve mines, all dpm measurements were 300 µg/m³ or greater in the absence of after-treatment filters.

The highest dpm concentrations observed at coal mines were collected at Mine "G." Eight of these samples were collected during employment of WMFs, and eight were collected while filters were not being employed. Without filters, the mean dpm concentration observed at Mine "G" was 2052 µg/m³ (median = 2100 µg/m³). With

[6] One commenter (IMC Global) noted that MSHA had provided no data verifying this statement. For the 142 personal samples, the mean dpm concentration measurement was 608 µg/m³, with a standard error of 42.5 µg/m³. For the 84 area samples, the mean was 705 µg/m³, with a standard error of 82.1 µg/m³. The significance level (p-value) of a t-test comparing these means is 0.29 using a separate-variance test or 0.25 using a pooled-variance test. Therefore, a difference in population means cannot be inferred at any confidence level greater than 75%. Here, and in other sections of this risk assessment, MSHA has employed standard statistical methods described in textbooks on elementary statistical inference.

[7] In coal mine E, the average as expressed by the mean exceeded 1000 µg/m³, but the median did not.

employment of WMFs, the mean dropped to 1241 μg/m³ (median = 1235 μg/m³).

Filters were employed during three of the four studies showing median dpm concentration at or below 200 μg/m³. After adjusting for outby sources of dpm, exposures were found to be reduced by up to 95 percent in mines using the DDEF and by approximately 50 percent in the mine using the WMF.

The higher dpm concentrations observed at the mine using the WMF (Mine ''G*'') are attributable partly to the lower section airflow. The only study without filters showing a median concentration at or below 200 μg/m³ was conducted in a mine (Mine ''A'') which had section airflow approximately ten times the nameplate requirement. The section airflow at the mine using the WMF was approximately the nameplate requirement.

Some commenters [*e.g.,* WV Coal Assoc and Energy West] objected to MSHA's presentation of underground coal mine exposures based on measurements made using the size-selective method (gravimetric determination of the amount of submicrometer dust collected with an impactor). These commenters argued that the data were '' * * * collected with emissions monitoring devices discredited by MSHA itself in the preamble * * *'' and that these measurements do not reliably ''* * * distinguish it [dpm] from other particles in coal mine dust, at the critical upper end range of submicron particles.''

MSHA did not ''discredit'' use of the size-selective method for all purposes. As discussed elsewhere in this preamble, the size-selective method of measuring dpm was designed by the former BOM specifically for use in coal mines, and the size distribution of coal mine dust was taken into account in its development. Despite the recognized interference from a small fraction of coal mine dust particles, MSHA considers gravimetric size-selective measurements to be reasonably accurate in measuring dpm concentrations greater than 200 μg/m³, based on a full-shift sample, when coal mine dust concentrations are not excessive (*i.e.,* not greater than 2.0 mg/m³). Interference from submicrometer coal mine dust is counter-balanced, to some extent, by the fraction of larger size, uncaptured dpm. Coal mine dust concentrations were not excessive when MSHA collected its size-selective samples. Therefore, even if as much as 10 percent of the coal mine dust were submicrometer, this fraction would not have contributed significantly to the high concentrations observed at the sampled mines.

At lower concentrations, or shorter sampling times, random variability in the gravimetric determination of weight gain becomes significant, compared to the weight of dust accumulated on the filter. For this reason, MSHA has rejected the use of the gravimetric size-selective method for enforcement purposes.[8] This does not mean, however, that MSHA has ''discredited'' this method for other purposes, including detection of very high dpm concentrations at coal mines (i.e., greater than 500 μg/m³) and estimation of average dpm concentrations, based on multiple samples, when coal mine dust concentrations are not excessive. On the contrary, MSHA regards the gravimetric size-selective method as a useful tool for detecting and monitoring very high dpm concentrations and for estimating average exposures.

b. Underground Metal and Nonmetal Mines

Currently there are approximately 265 underground M/NM mines in the United States. Nearly all of these mines utilize diesel powered equipment, and 27 of those doing so were sampled by MSHA for dpm.[9] The M/NM studies typically included measurements of dpm exposure for dieselized production equipment operators (such as truck drivers, roof bolters, haulage vehicles) on two to three shifts. A number of area samples were also collected. None of the M/NM mines studied were using diesel particulate afterfilters.

Figure III–2 displays the range of dpm concentrations measured by MSHA in the 27 underground M/NM mines studied. A total of 275 personal samples and 80 area samples were collected, excluding intake and return area samples. Personal exposures observed ranged from less than 100 μg/m³ to more than 3500 μg/m³. Exposure measurements based on area samples ranged from less than 100 μg/m³ to more than 3000 μg/m³. With the exception of Mine ''V'', personal exposures were for face workers. Mine ''V'' did not use dieselized face equipment.

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[8] MSHA has concluded that random weighing variability would make it impractical to use the size-selective method to enforce compliance with any dpm concentration limit less than about 300 μg/m³. MSHA believes that, at such levels, single-sample noncompliance determinations based on the size-selective method could not be made at a sufficiently high confidence level.

[9] The proposal discussed data from 25 underground M/NM mines. Studies at two additional mines, carried out too late to be included in the proposal, were placed into the public record along with the earlier studies. During the proceedings, MSHA provided copies of all of these studies to stakeholders requesting them.

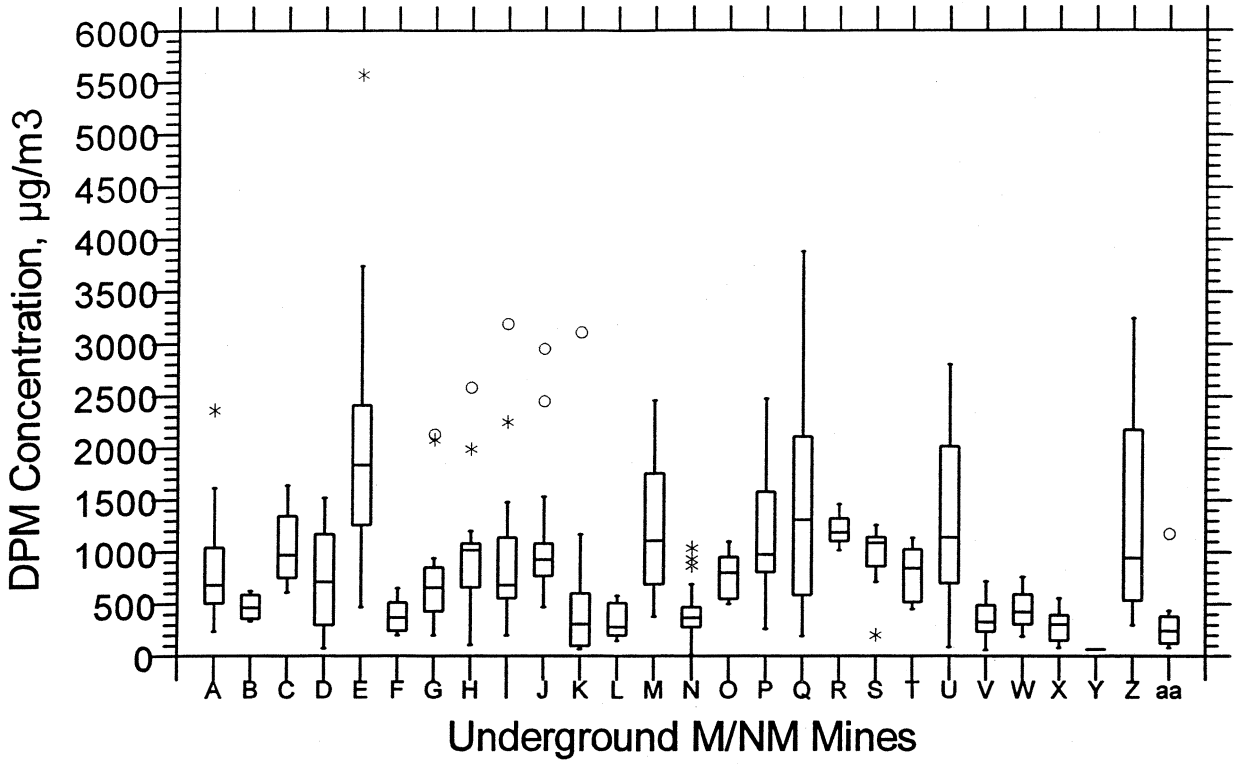

Figure 6 Box plots (Tukey, 1977) for dpm concentrations observed at 27 underground metal and nonmetal mines. Top and bottom of each box represent upper and lower quartiles, respectively. "Belt" inside box represents median. Vertical lines span nearly all measurements. Isolated points (either ✳ or ○) are outliers, representing unusually high or low measurements compared to other observations at same mine. Measurements at Mine "T" and on one visit to mine "D" were made using the size-selective method, based on gravimetric determinationof the amount of submicrometer dust collected with an impactor. Measurements on another visit to mine "D" and at Mines "Z" and "aa" were made using TC method. All other measurements were made using RCD method. Because of potential interferences from cigarette smoke, samples were not collected on or near smokers.

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As stated in the proposed risk assessment, no statistically significant difference was observed in mean dpm concentration between the personal and area samples.[10] A total of 45 individual measurements exceeded 1500 μg/m³, still excluding intake and return area samples. The three highest of these, all exceeding 3500 μg/m³, were from personal samples. Of the 45 measurements exceeding 1500 μg/m³, 30 were from personal samples and 15 were from area samples.

Average observed dpm concentrations exceeded 500 μg/m³ in 18 of the 27 underground M/NM mines and exceeded 1000 μg/m³ in 12.[11] At eight of the 27 mines, all dpm measurements exceeded 300 μg/m³. The highest dpm concentrations observed at M/NM mines were collected at Mine ''E''. Based on 16 samples, the mean dpm concentration observed at Mine ''E'' was 2008 μg/m³ (median = 1835 μg/m³). Twenty-five percent of the dpm measurements at this mine exceeded 2400 μg/m³. All four of these were based on personal samples.

As with underground coal mines, dpm levels in underground M/NM mines are related to the amount and size of equipment, to the ventilation rate, and to the effectiveness of the diesel particulate control technology employed. In the dieselized M/NM mines studied by MSHA, front-end-loaders were used either to load ore onto trucks or to haul and load ore onto belts. Additional pieces of diesel powered support equipment, such as bolters and mantrips, were also used at the mines. The typical piece of production equipment was rated at 150 to 350 horsepower. Ventilation rates in the M/NM mines studied mostly ranged from 100 to 200 cfm per horsepower of equipment. In only a few of the mines inventoried did ventilation exceed 200 cfm/hp. For single-level mines, working areas were ventilated in series (*i.e.*, the exhaust air from one area became the intake for the next working area). For multi-level mines, each level typically had a separate fresh air supply. One or two working areas could be on a level. Control technology used to reduce diesel particulate emissions in mines inventoried included oxidation catalytic converters and engine maintenance programs. Both low sulfur and high sulfur fuel were used; some mines used aviation grade low sulfur fuel.

Some commenters argued that, because of the limited number of underground M/NM mines sampled by MSHA, ''* * * results of MSHA's admittedly non-random sample cannot be extrapolated to other mines.'' [MARG] More specifically, IMC Global claimed that since only 25 [now 27] of about 260 underground M/NM mines were sampled,[12] then ''if the * * * measurements are correct, this information shows at best potential exposure problems to diesel particulate in only 10% of the miners working in the metal-nonmetal mining sector and then only for certain unlisted commodities.''[13] IMC Global went on to suggest that MSHA should ''perform sufficient additional exposure monitoring * * * to show that the diesel particulate exposures are representative of the entire industry before promulgating regulations that will be applicable to the entire industry.''

As mentioned earlier, MSHA acknowledges that the mines for which dpm measurements are available do not comprise a statistically random sample of all underground M/NM mines. MSHA also acknowledges that the results obtained for these mines cannot be extrapolated in a statistically rigorous way to the entire population of underground M/NM mines. According to MSHA's experience, however, the selected mines (and sampling locations within those mines) represent typical diesel equipment use conditions at underground M/NM mines. MSHA believes that results at these mines, as depicted in Figure III–2, in fact fairly reflect the variety of diesel equipment used by the industry, regardless of type of M/NM mine. Based on its extensive experience with underground mines, MSHA believes that this body of data better represents those diverse diesel equipment use conditions, with respect to dpm exposures, than any other body of data currently available.

MSHA strongly disagrees with IMC Global's contention that, ''* * * this information shows at best potential exposure problems to diesel particulate in only 10% of the miners working in the metal-nonmetal mining sector.'' IMC Global apparently drew this conclusion from the fact that MSHA sampled approximately ten percent of all underground M/NM mines. This line of argument, however, depends on an unwarranted and highly unrealistic assumption: Namely, that all of the underground M/NM mines not included in the sampled group of 25 experience essentially no ''potential [dpm] exposure problems.'' MSHA certainly did not go out and, by chance or design, pick for sampling just exactly those mines experiencing the highest dpm concentrations. IMC Global's argument fails to recognize that the sampled mines could be fairly representative without being randomly chosen.

MSHA also disagrees with the premise that 27 [or 25 as in the proposal] is an inherently insufficient number of mines to sample for the purpose of identifying an industry-wide dpm exposure problem that would justify regulation. The between-mine standard deviation of the 27 mean concentrations observed within mines was 450 μg/m³. Therefore, the standard error of the estimated grand mean, based on the variability observed between mines, was

$$450/\sqrt{27} = 87\ \mu g/m^3.$$ [14]

MSHA considers this degree of uncertainty to be acceptable, given that the overall mean concentration observed exceeded 800 μg/m³.

Several commenters questioned MSHA's use of the RCD and size-selective methods for measuring dpm exposures at underground M/NM mines. IMC Global indicated that MSHA's RCD measurements might systematically inflate the dpm concentrations presented in this section, because ''* * * estimates for the non-diesel particulate component of RCD actually vary between 10% to 50%, *averaging 33%*.''

[10] One commenter (IMC Global) noted that MSHA had provided no data verifying this statement. For the 275 personal samples, the mean dpm concentration measurement was 770 μg/m³, with a standard error of 42.8 μg/m³. For the 80 area samples, the mean was 939 μg/m³, with a standard error of 86.6 μg/m³. The significance level (p-value) of a t-test comparing these means is 0.08 using a separate-variance test or 0.07 using a pooled-variance test. Therefore, a difference in population means cannot be inferred at a 95% confidence level.

[11] At M/NM mines C, I, J, P, and Z the average as expressed by the mean exceeded 1000 μg/m³ but the median did not. At M/NM mines H and S, the median exceeded 1000 μg/m³ but the mean did not. At M/NM mine K, the mean exceeded 500 μg/m³, but the median did not.

[12] Three underground M/NM mine surveys, carried out too late to be included in the discussion, were placed into the public record and provided to interested stakeholders. These surveys contained data from two additional underground M/NM mines (''Z'' and ''aa'') and additional data for a mine (''d'') that had previously been surveyed. The risk assessment has now been updated to include these data, representing a total of 27 underground M/NM mines.

[13] A breakdown by commodity is given at the end of this subsection.

[14] This quantity, 87 μg/m³, differs from the standard error of the mean of individual measurements for underground M/NM mines, presented in Table III–1. The tabled value is based on 355 measurements whose standard deviation is 727 μg/m³. Therefore, the standard error of the mean of all individual measurements is $_{727}/\sqrt{_{355}}$ = 39 μg/m³, as shown in the table. Similarly, the mean of all individual measurements (listed in Table III–1 as 808 μg/m³) differs from the grand mean of individual mean concentrations observed within mines, which is 838 μg/m³.

MSHA considers the size-selective, gravimetric method capable of providing reasonably accurate measurements when the dpm concentration is greater than 200 μg/m³, interferences are adequately limited, and the measurement is based on a full-shift sample. Relatively few M/NM measurements were made using this method, and none at the mines showing the highest dpm concentrations. No evidence was presented that the size distribution of coal mine dust (for which the impactor was specifically developed) differs from that of other mineral dusts in a way that significantly alters the impactor's performance. Similarly, MSHA considers the RCD method, when properly applied, to be capable of providing reasonably accurate dpm measurements at concentrations greater than 200 μg/m³. As with the size selective method, however, random weighing errors can significantly reduce the precision of even full-shift RCD measurements at lower dpm concentrations. For this reason, in order to maintain a sufficiently high confidence level for its noncompliance determinations, MSHA will not use the RCD method for enforcement purposes. This does not mean, however, that MSHA has ''discredited'' the RCD measurements for all other purposes, including detection of very high dpm concentrations (i.e., greater than 300 μg/m³) and estimation of average concentrations based on multiple samples. On the contrary, MSHA considers the RCD method to be a useful tool for detecting and monitoring very high dpm concentrations in appropriate environments and for estimating average exposures when those exposures are excessive.

MSHA did not employ an impactor in its RCD measurements, and it is true that some of these measurements may have been subject to interference from lubrication oil mists. However, MSHA believes that the high estimates sometimes made of the non-dpm component of RCD (cited by IMC Global) do not apply to the RCD measurements depicted in Figure III–2. MSHA has three reasons for believing these RCD measurements consisted almost entirely of dpm:

(1) MSHA took special care to sample only environments where interferences would not be significant. No samples were taken near pneumatic drills or smoking miners.

(2) There was no interference from carbonates. The RCD analysis was performed at 500° C, and carbonates are not released below 1000° C. (Gangel and Dainty, 1993)

(3) Although high sulphur fuel was used in some mines, thereby adding sulfates to the RCD measurement, these sulfates are considered part of the dpm, as explained in section 2 of Part II of this preamble. Sulfates should not be regarded as an interference in RCD measurements of dpm.

Commenters presented no evidence that there were substantial interferences in MSHA's RCD measurements, and, as stated above, MSHA was careful to avoid them. Therefore, MSHA considers it reasonable, in the context of this risk assessment, to assume that all of the RCD was in fact dpm. Moreover, in the majority of underground M/NM mines sampled, even if the RCD measurements were reduced by ⅓, the mine's average would still be excessive: it would still exceed the maximum exposure level reported for non-mining occupations presented in Section III.1.d.

The breakdown, as suggested by IMC Global, of sampled underground M/NM mines by commodity is as follows:

Commodity	Number of mines
Copper	2
Gold	1
Lead/Zinc	6
Limestone	6
Potash	2
Salt	6
Trona (soda ash)	2
Other Nonmetal	2
Total	27

c. Surface Mines

Currently, there are approximately 12,620 surface mining operations in the United States. The total consists of approximately 1,550 coal mines and 11,070 M/NM mines. Virtually all of these mines utilize diesel powered equipment.

MSHA conducted dpm studies at eleven surface mining operations: eight coal mines and three M/NM mines. MSHA deliberately directed its surface sampling efforts toward occupations likely to experience high dpm concentrations. To help select such occupations, MSHA first made a visual examination (based on blackness of the filter) of surface mine respirable dust samples collected during a November 1994 study of surface coal mines. This preliminary screening of samples indicated that relatively high surface mine dpm concentrations are typically associated with front-end-loader operators and haulage-truck operators; accordingly, sampling focused on these operations. A total of 45 samples was collected.

Figure III–3 displays the range of dpm concentrations measured at the eleven surface mines. The average dpm concentration observed was less than 200 μg/m³ at all mines sampled. The maximum dpm concentration observed was less than or equal to 200 μg/m³ in 8 of the 11 mines (73%). The surface mine studies suggest that even when sampling is performed at the areas of surface mines believed most likely to have high exposures, dpm concentrations are generally likely to be less than 200 μg/m³.

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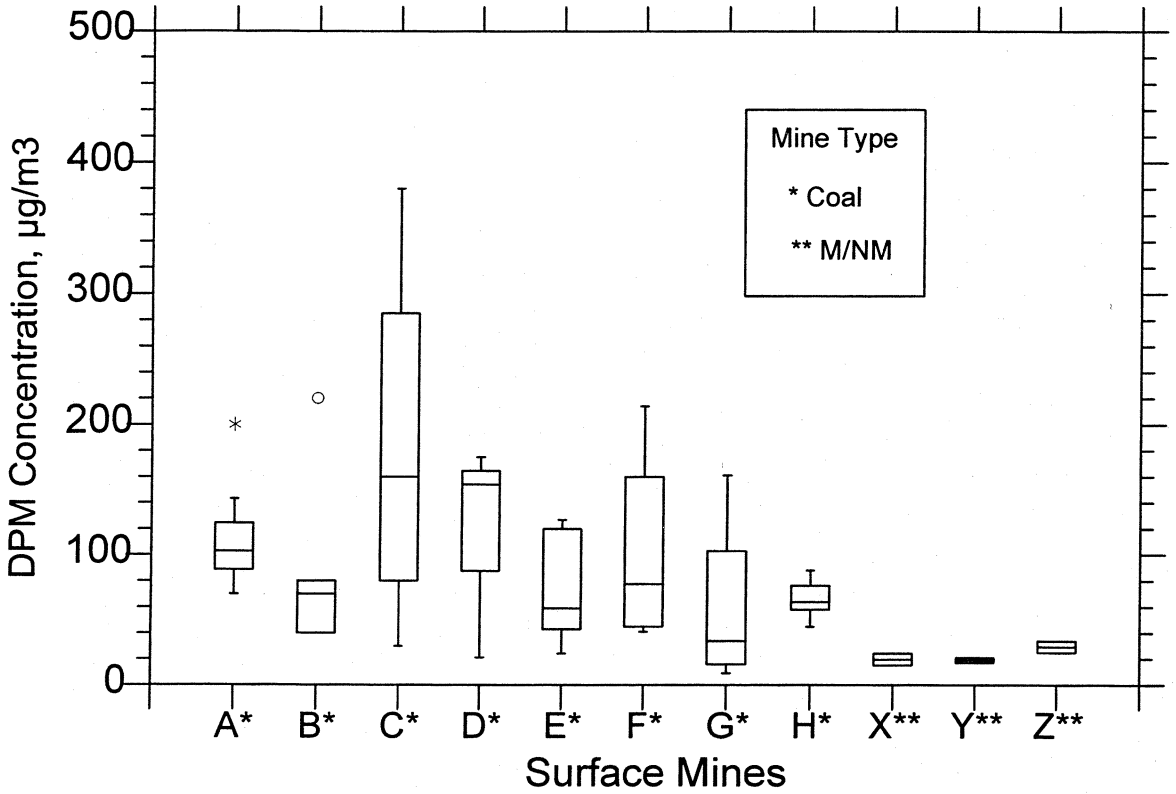

Figure 7 Box plots (Tukey, 1977) for dpm concentrations observed at 11 surface mines. Top and bottom of each box represent upper and lower quartiles, respectively. "Belt" inside box represents median. Vertical lines span nearly all measurements. Isolated points (either ✳ or ○) are outliers, representing unusually high or low measurements compared to other observations at the same mine. All dpm measurements were made using the size-selective method, based on gravimetric determination of the amount of submicrometer dust collected with an impactor. Because of potential interferences from cigarette smoke, samples were not collected on smokeres who worked inside enclosures.

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d. Miner Exposures Compared to Exposures of Other Groups

Occupational exposure to diesel particulate primarily originates from industrial operations employing equipment powered with diesel engines. Diesel engines are used to power ships, locomotives, heavy duty trucks, heavy machinery, as well as a small number of light-duty passenger cars and trucks. NIOSH has estimated that approximately 1.35 million workers are occupationally exposed to the combustion products of diesel fuel in approximately 80,000 workplaces in the United States. (NIOSH 1988) Workers who are likely to be exposed to diesel emissions include: mine workers; bridge and tunnel workers; railroad workers; loading dock workers; truck drivers; fork-lift drivers; farm workers; and, auto, truck, and bus maintenance garage workers (NIOSH, 1988). Besides miners, groups for which occupational exposures have been reported and health effects have been studied include loading dock workers, truck drivers, and railroad workers.

As estimated by the reported geometric mean,[15] the median site-specific occupational exposures for loading dock workers operating or otherwise exposed to unfiltered diesel fork lift trucks ranged from 23 to 55 μg/m^3, as measured by submicrometer elemental carbon (EC) (NIOSH, 1990). Reported geometric mean concentrations of submicrometer EC ranged from 2.0 to 7.0 μg/m^3 for truck drivers and from 4.8 to 28 μg/m^3 for truck mechanics, depending on weather conditions (Zaebst et al., 1991).

Because these exposure averages, unlike those for railroad workers and miners, were reported in terms of EC, it is necessary, for purposes of comparison, to convert them to estimates of total dpm. Watts (1995) states that ''elemental carbon generally accounts for about 40% to 60% of diesel particulate mass.'' Therefore, in earlier versions of this risk assessment, a 2.0 conversion factor was assumed for dock workers, truck drivers, and truck mechanics, based on the midpoint of the 40–60% range proposed by Watts.

Some commenters objected to MSHA's use of this conversion factor. IMC Global, for example, asserted that Watts' ''* * * 40 to 60% relationship between elemental carbon and diesel particulate mass * * * applies only to underground coal mines where diesel haulage equipment is used.'' IMC Global, and other commenters, also objected to MSHA's use of a single conversion factor for ''* * * different types of diesel engines under different duty cycles with different fuels and different types of emission control devices (if any) subjected to varying degrees of maintenance.''

MSHA's quotation from Watts (1995) was taken from the ''Summary'' section of his paper. That paper covers a variety of occupational environments, and the summary makes no mention of coal mines. The sentence immediately preceding the quoted passage refers to the ''occupational environment'' in general, and there is no indication that Watts meant to restrict the 40- to 60-percent range to any specific environment. It seems clear that the 40- to 60-percent range refers to average values across a spectrum of occupational environments.

IMC Global mistakenly attributed to MSHA ''the blanket statement'' that the same ratio of elemental carbon to dpm applies ''for all diesel engines in different industries for all patterns of use.'' MSHA made no such statement. On the contrary, MSHA agrees with Watts (and IMC Global) that ''the percentage of elemental carbon in total diesel particulate matter fluctuates'' depending on ''engine type, duty cycle, fuel, lube oil consumption, state of engine maintenance, and the presence or absence of an emission control device.'' (Watts, op cit.) Indeed, MSHA acknowledges that, because of these factors, the percentage on a particular day in a particular environment may frequently fall outside the stated range. But MSHA is not applying a single conversion factor to individual elemental carbon measurements and claiming knowledge of the total dpm corresponding to each separate measurement. Instead, MSHA is applying an average conversion factor to an average of measurements in order to derive an estimate of an average dpm exposure. Averages are always less widely dispersed than individual values.

[15] Median concentrations were not reported. The geometric mean provides a smoothed estimate of the median.

Still, MSHA agrees with IMC Global that better estimates of dpm exposure levels are attainable by applying conversion factors more specifically related to the separate categories within the trucking industry: dock workers, truck drivers, and truck mechanics. Based on a total of 63 field measurements, the mean ratios (in percent) of EC to total carbon (TC) reported for these three categories were 47.3, 36.6, and 34.2, respectively (Zaebst et al., 1991).[16] As explained elsewhere in this preamble, TC amounts to approximately 80 percent, by weight, of total dpm. Therefore, each of these ratios must be multiplied by 0.8 in order to estimate the corresponding percentage of EC in dpm.

It follows that the median mass concentration of dpm can be estimated as 2.64 (i.e., 1/(0.473×0.8)) times the geometric mean EC reported for dock workers, 3.42 times the geometric mean EC for truck drivers, and 3.65 times the geometric mean EC for truck mechanics. Applying the 2.64 conversion factor to the range of geometric mean EC concentrations reported for dock workers (i.e., 23 to 55 μg/m^3) results in an estimated range of 61 to 145 μg/m^3 in median dpm concentrations at various docks. Similarly, the estimated range of median dpm concentrations is calculated to be 6.8 to 24 μg/m^3 for truck drivers and 18 to 102 μg/m^3 for truck mechanics. It should be noted that MSHA is using conversion factors only for those occupational groups whose geometric mean exposures have been reported in terms of EC measurements.

Average exposures of railroad workers to dpm were estimated by Woskie et al. (1988) and Schenker et al. (1990). As measured by total respirable particulate matter other than cigarette smoke, Woskie et al. reported geometric mean concentrations for various occupational categories of exposed railroad workers ranging from 49 to 191 μg/m^3.

For comparison with the exposures reported for these other industries, median dpm exposures measured within sampled mines were calculated directly from the data described in subsections a, b, and c above. The median within each mine is shown as the horizontal ''belt'' plotted for the mine in Figures III–1, III–2, and III–3.

Figure III–4 compares the range of median dpm concentrations observed for mine workers within different mines to a range of dpm exposure levels estimated for urban ambient air and to the ranges of median dpm concentrations estimated for loading dock workers operating or otherwise exposed to diesel fork lift trucks, truck drivers, truck mechanics, and railroad workers. The range for ambient air, 1 to 10 μg/m^3, was obtained from Cass and Gray (1995). For dock workers, truck drivers, truck mechanics, and railroad workers, the estimated ranges of median dpm exposures are, respectively: 61 to 145 μg/m^3, 6.8 to 24 μg/m^3, 18 to 102 μg/m^3 and 49 to 191 μg/m^3. The range of median dpm concentrations observed at different underground coal mines is 55 to 2100 μg/m^3, with filters employed at mines showing the lower concentrations.[17] For underground M/NM mines, the corresponding range is 68 to 1835 μg/m^3, and for surface mines it is 19 to 160 μg/m^3. Since each range plotted is a range of median values or (for ambient air) mean values, the plots do not encompass all of the individual measurements reported.

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[16] MSHA calculated the ratio for truck drivers by taking a weighted average of the ratios reported for ''local drivers'' and ''road drivers.''

[17] One commenter misinterpreted the tops of the ranges plotted in Figure III–4. This commenter apparently mistook the top of the range depicted for underground coal mines as the mean or median dpm exposure concentration measured across all underground coal mines. The top of this range (at 2100 μg/m^3, actually represents the highest median concentration at any of the coal mines sampled. It corresponds to the ''belt'' plotted for Mine ''G'' (with no after-filters) in Figure III–1. The bottom of the same bar, at 55 μg/m^3, corresponds to the ''belt'' plotted for Mine H * (with after-filters) in Figure III–1.

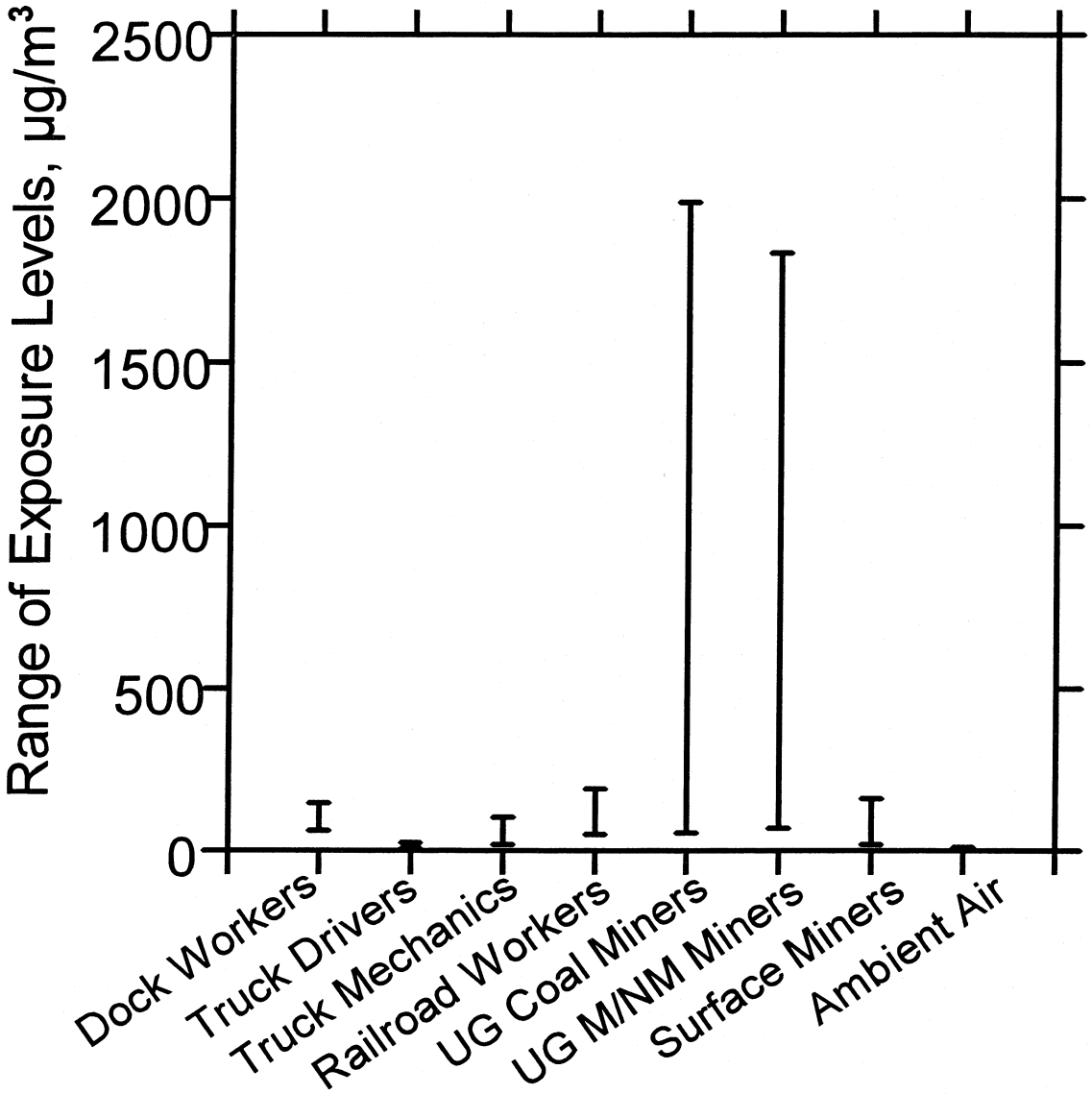

Figure III-4. — Range of median dpm exposure levels observed within various mines for underground and surface miners compared to range of median dpm exposure levels estimated for other occupations. Range of dpm exposure levels for ambient air is for urban environments only and is based on the monthly mean for different months and locations in Southern California. Range for ambient air is roughly 1 to 10 $\mu g/m^3$.

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As shown in Figure III–4, some miners are exposed to far higher concentrations of dpm than are any other populations for which exposure data have been reported. Indeed, median dpm concentrations observed in some underground mines are up to 200 times as high as mean environmental exposures in the most heavily polluted urban areas,[18] and up to 10 times as high as median exposures estimated for the most heavily exposed workers in other occupational groups.

Several commenters objected to Figure III–4 and, more generally, to MSHA's comparison of dpm exposure levels for miners against the levels reported for other occupations. The objections to MSHA's method of estimating ranges of median dpm exposure for job categories within the trucking industry have already been discussed and addressed above. Other objections to the comparison were based on claims of insufficient accuracy in the RCD and gravimetric size selective measurements MSHA used to measure dpm levels for miners. MSHA considers its use of these methods appropriate for purposes of this comparison and has responded to criticisms of the dpm measurements for miners in Subsections 1.a and 1.b of this risk assessment.[19]

Some commenters objected to MSHA's basing a characterization of dpm exposures to miners on data spanning a ten-year period. These commenters contended that, in at least some M/NM mines, dpm levels had improved substantially during that period. No data were submitted, however, to support the premise that dpm exposures throughout the mining industry have declined to the levels reported for other occupations. As stated in the proposal and emphasized above, MSHA's dpm measurements were not technically designed as a random or statistically representative sample of the industry. They do show, however, that very high exposures have recently occurred in some mines. For example, as shown in Figure III–2, more than 25 percent of MSHA's dpm measurements exceeded 2000 μg/m^3 at underground M/NM mines ''U'' and ''Z''—and these measurements were made in 1996–7. In M/NM mines where exposures are actually commensurate with other industries already, little or nothing would need to be changed to meet the exposure limits.

IMC Global further objected to Figure III–4 on the grounds that ''* * * the assumptions that MSHA used to develop that figure are grossly inaccurate and do not make sense in the context of a dose-response relationship between lung cancer and Dpm exposure.'' IMC Global suggested that the comparison in Figure III–4 be deleted for this reason. MSHA believes that the comparison is informative and that empirical evidence should be used, when it is available, even though the evidence was not generated under ideal, theoretical dose-response model conditions. The issue of whether Figure III–4 is consistent with an exposure-response relationship for dpm is addressed in Subsection 3.a.iii(4) of this risk assessment.

2. Health Effects Associated With Dpm Exposures

This section reviews the various health effects (of which MSHA is aware) that may be associated with dpm exposures. The review is divided into three main sections: acute effects, such as diminished pulmonary function and eye irritation; chronic effects, such as lung cancer; and mechanisms of toxicity. Prior to that review, however, the relevance of certain types of information will be considered. This discussion will address the relevance of health effects observed in animals, health effects that are reversible, and health effects associated with fine particulate matter in the ambient air.

Several commenters described medical surveillance studies that NIOSH and/or the former Bureau of Mines had carried out in the late 1970s and early 1980s on underground miners employed in western, dieselized coal mines. These commenters urged MSHA to make these studies available and to consider the results in this rulemaking. Some of these commenters also suggested that these data would provide a useful baseline for pulmonary function and lung diseases among miners exposed to dpm, and recommended that follow-up examinations now be conducted to evaluate the possible effects of chronic dpm exposure.

In response to such comments presented at some of the public hearings, another commenter wrote:

> First of all, MSHA is not a research agency, it is a regulatory agency, so that it would be inappropriate for MSHA to initiate research. MSHA did request that NIOSH conduct a risk assessment on the health effects of diesel exhaust and encouraged NIOSH and is currently collaborating with NIOSH (and NCI) on research of other underground miners exposed to diesel exhaust. And third, research on the possible carcinogenicity of diesel particulate matter was not undertaken on coal miners in the West or anywhere else because of the confounding exposure to crystalline silica, also considered a carcinogen, because too few coal miners have been exposed, and for too short a time to conduct a valid study. It was not arbitrariness or indifference on MSHA's part that it did not initiate research on coal miners; it was not within their mandate and it is inappropriate in any event. [UMWA]

Three reports summarizing and presenting results from these medical surveillance studies related to dpm exposures in coal mines were, in fact, utilized and cited in the proposed risk assessment (Ames *et al.,* 1982; Reger *et al.,* 1982; Ames *et al.,* 1984). Ames *et al.* (1982) evaluated acute respiratory effects, and their results are considered in Subsection 2.b.ii of this risk assessment. Reger *et al.* (1982) and Ames *et al.* (1984) evaluated chronic effects, and their results are considered in Subsection 2.c.i(1).

A fourth report (Glenn *et al.*, 1983) summarized results from the overall research program of which the coal mine studies were a part. This health and environmental research program included not only coal miners, but also workers at potash, trona, salt, and metal mines. All subjects were given chest radiographs and spirometric tests and were questioned about respiratory symptoms, smoking and occupational history. In conjunction with these medical evaluations, industrial hygiene surveys were conducted to characterize the mine environments where diesel equipment was used. Diesel exhaust exposure levels were characterized by area and personal samples of NO2 (and, in some cases, additional gasses), aldehydes, and both respirable and total dust. For the evaluations of acute effects, exposure measures were based on the shift concentrations to which the examined workers were exposed. For the evaluations of chronic effects, exposures were usually estimated by summing the products of time spent in various locations by each miner by concentrations estimated for the various locations. Results of studies on acute effects in salt mines were reported by Gamble *et al.* (1978) and are considered

[18] It should be noted, however, that 24-hour environmental exposures for a full lifetime are not directly comparable with workday exposures over an occupational lifetime. If it is assumed that air inhaled during a work shift comprises half the total air inhaled during a 24-hour day, then the amount of air inhaled over the course of a 70-year lifetime is approximately 4.7 times the amount inhaled over a 45-year occupational lifetime with 240 working days per year.

[19] One commenter pointed out that the measurements for miners included both area and personal samples but provided no evidence that this would invalidate the comparison. As pointed out in Subsections 1.a and 1.b, area samples did not dominate the upper end of MSHA's dpm measurements. Furthermore, Figure III–4 presents a comparison of medians rather than means or individual measurements, so inclusion of the area samples has very little impact on the results.

in Subsection 2.b.ii of this risk assessment. Attfield (1979), Attfield *et al.* (1982), and Gamble *et al.* (1983) evaluated effects in M/NM mines, and their results are considered in Subsection 2.c.i(1). The general summary provided by Glenn *et al.* (1983) was among the reports that one commenter (MARG) listed as having received inadequate attention in the proposed risk assessment. In that context, the general results summarized in this report are discussed, under the heading of ''Counter-Evidence,'' in Subsection 2.c.i(2)(a) of this risk assessment.

a. Relevancy Considerations

i. Animal Studies

Since the lungs of different species may react differently to particle inhalation, it is necessary to treat the results of animal studies with some caution. Evidence from animal studies can nevertheless be valuable—both in helping to identify potential human health hazards and in providing a means for studying toxicological mechanisms. Respondents to MSHA's ANPRM who addressed the question of relevancy urged consideration of all animal studies related to the health effects of diesel exhaust.

Unlike humans, laboratory animals are bred to be homogeneous and can be randomly selected for either non-exposure or exposure to varying levels of a potentially toxic agent. This permits setting up experimental and control groups of animals that exhibit relatively little biological variation prior to exposure. The consequences of exposure can then be determined by comparing responses in the experimental and control groups. After a prescribed duration of deliberate exposure, laboratory animals can also be sacrificed, dissected, and examined. This can contribute to an understanding of mechanisms by which inhaled particles may exert their effects on health. For this reason, discussion of the animal evidence is placed in the section entitled ''Mechanisms of Toxicity'' below.

Animal evidence also can help isolate the cause of adverse health effects observed among humans exposed to a variety of potentially hazardous substances. If, for example, the epidemiologic data are unable to distinguish between several possible causes of increased risk of disease in a certain population, then controlled animal studies may provide evidence useful in suggesting the most likely explanation—and provide that information years in advance of definitive evidence from human observations.

Furthermore, results from animal studies may also serve as a check on the credibility of observations from epidemiologic studies of human populations. If a particular health effect is observed in animals under controlled laboratory conditions, this tends to corroborate observations of similar effects in humans.

One commenter objected to MSHA's reference to using animal studies as a ''check'' on epidemiologic studies. This commenter emphasized that animal studies provide far more than just corroborative information and that researches use epidemiologic and animal studies ''* * * to help understand different aspects of the carcinogenic process.'' [20] MSHA does not dispute the utility of animal studies in helping to provide an understanding of toxicological processes and did not intend to belittle their importance for this purpose. In fact, MSHA places the bulk of its discussion of these studies in a section entitled ''Mechanisms of Toxicity.'' However, MSHA considers the use of animal studies for corroborating epidemiologic associations to be also important—especially with respect to ruling out potential confounding effects and helping to establish causal linkages. Animal studies make possible a degree of experimental design and statistical rigor that is not attainable in human studies.

Other commenters disputed the relevance of at least some animal data to human risk assessment. For example, The West Virginia Coal Association indicated the following comments by Dr. Peter Valberg:

> * * * scientists and scientific advisory groups have treated the rat bioassay for inhaled particles as unrepresentative of human lung-cancer risks. For example, the Presidential/Congressional Commission on Risk Assessment and Risk Management (''CCRARM'') noted that the response of rat lungs to inhaled particulate in general is not likely to be predictive of human cancer risks. More specific to dpm, the Clean Air Scientific Advisory Committee (''CASAC''), a peer-review group for the U.S. EPA, has commented on two drafts (1995 and 1998) of the EPA's Health Assessment Document on Diesel Exhaust. On both occasions, CASAC emphasized that the data from rats are not relevant for human risk assessment. Likewise, the Health Effects Institute also has concluded that rat data should not be used for assessing human lung cancer risk.

Similarly, the NMA commented that the 1998 CASAC review ''makes it crystal clear that the rat studies cited by MSHA should not be relied upon as a legitimate indicators of the carcinogenicity of Dpm in humans.'' The Nevada Mining Association, endorsing Dr. Valberg's comments, added:

> * * * to the extent that MSHA wishes to rest its case on rat studies, Dr. Valberg, among others, has impressively demonstrated that these studies are worthless for human comparison because of rats' unique and species-specific susceptibility to inhaled insoluble particles.

However, neither Dr. Valberg nor the Nevada Mining Association provided evidence that rats' susceptibility to inhaled insoluble particles was ''unique'' and that humans, for example, were not also susceptible to lung overload at sufficiently high concentrations of fine particles. Even if (as has apparently been demonstrated) some species (such as hamsters) do not exhibit susceptibility similar to rats, this by no means implies that rats are the only species exhibiting such susceptibility.

These commenters appear at times to be saying that, because studies of lung cancer in rats are (in the commenters' view) irrelevant to humans, MSHA should completely ignore all animal studies related to dpm. To the extent that this was the position advocated, the commenters' line of reasoning neglects several important points:

1. The animal studies under consideration are not restricted to studies of lung cancer responses in rats. They include studies of bioavailability and metabolism as well as studies of immunological and genotoxic responses in a variety of animal species.

2. The context for the determinations cited by Dr. Valberg was risk assessment at ambient levels, rather than the much higher dpm levels to which miners are exposed. The 1995 HEI report to which Dr. Valberg alludes acknowledged a potential mechanism of lung overload in humans at dpm concentrations exceeding 500 $\mu g/m^3$ (HEI, 1995). Since miners may concurrently be exposed to concentrations of mineral dusts significantly exceeding 500 $\mu g/m^3$, evidence related to the consequences of lung overload has special significance for mining environments.

3. The scientific authorities cited by Dr. Valberg and other commenters objected to using existing animal studies for quantitative human risk assessment. MSHA has not proposed doing that. There is an important distinction between extrapolating results from the rat studies to human populations and using them to confirm epidemiologic

[20] This risk assessment is not limited to cancer effects, but the commenter's point can be generalized.

findings and to identify and explore potential mechanisms of toxicity.

MSHA by no means ''wishes to rest its case on rat studies,'' and it has no intention of doing so. MSHA does believe, however, that judicious consideration of evidence from animal studies is appropriate. The extent to which MSHA utilizes such evidence to help draw specific conclusions will be clarified below in connection with those conclusions.

ii. Reversible Health Effects

Some reported health effects associated with dpm are apparently reversible—*i.e.*, if the worker is moved away from the source for a few days, the symptoms dissipate. A good example is eye irritation.

In response to the ANPRM, questions were raised as to whether so-called ''reversible'' effects can constitute a ''material'' impairment. For example, a predecessor constituent of the National Mining Association (NMA) argued that ''it is totally inappropriate for the agency to set permissible exposure limits based on temporary, reversible sensory irritation'' because such effects cannot be a ''material'' impairment of health or functional capacity within the definition of the Mine Act (American Mining Congress, 87–0–21, Executive Summary, p. 1, and Appendix A).

MSHA does not agree with this categorical view. Although the legislative history of the Mine Act is silent concerning the meaning of the term ''material impairment of health or functional capacity,'' and the issue has not been litigated within the context of the Mine Act, the statutory language about risk in the Mine Act is similar to that under the OSH Act. A similar argument was dispositively resolved in favor of the Occupational Safety and Health Administration (OSHA) by the 11th Circuit Court of Appeals in *AFL–CIO* v. *OSHA,* 965 F.2d 962, 974 (1992).

In that case, OSHA proposed new limits on 428 diverse substances. It grouped these into 18 categories based upon the primary health effects of those substances: *e.g.,* neuropathic effects, sensory irritation, and cancer. (54 FR 2402). Challenges to this rule included the assertion that a ''sensory irritation'' was not a ''material impairment of health or functional capacity'' which could be regulated under the OSH Act. Industry petitioners argued that since irritant effects are transient in nature, they did not constitute a ''material impairment.'' The Court of Appeals decisively rejected this argument.

The court noted OSHA's position that effects such as stinging, itching and burning of the eyes, tearing, wheezing, and other types of sensory irritation can cause severe discomfort and be seriously disabling in some cases. Moreover, there was evidence that workers exposed to these sensory irritants could be distracted as a result of their symptoms, thereby endangering other workers and increasing the risk of accidents. (*Id.* at 974). This evidence included information from NIOSH about the general consequences of sensory irritants on job performance, as well as testimony by commenters on the proposed rule supporting the view that such health effects should be regarded as material health impairments. While acknowledging that ''irritation'' covers a spectrum of effects, some of which can be minor, OSHA had concluded that the health effects associated with exposure to these substances warranted action—to ensure timely medical treatment, reduce the risks from increased absorption, and avoid a decreased resistance to infection (*Id.* at 975). Finding OSHA's evaluation adequate, the Court of Appeals rejected petitioners' argument and stated the following:

> We interpret this explanation as indicating that OSHA finds that although minor irritation may not be a material impairment, there is a level at which such irritation becomes so severe that employee health and job performance are seriously threatened, even though those effects may be transitory. We find this explanation adequate. OSHA is not required to state with scientific certainty or precision the exact point at which each type of sensory or physical irritation becomes a material impairment. Moreover, section 6(b)(5) of the Act charges OSHA with addressing all forms of ''material impairment of health or functional capacity,'' and not exclusively ''death or serious physical harm'' or ''grave danger'' from exposure to toxic substances. See 29 U.S.C. 654(a)(1), 655(c). [*Id.* at 974].

In its comments on the proposed rule, the NMA claimed that MSHA had overstated the court's holding. In making this claim, the NMA attributed to MSHA an interpretation of the holding that MSHA did not put forth. In fact, MSHA agrees with the NMA's interpretation as stated in the following paragraph and takes special note of the NMA's acknowledgment that transitory or reversible effects can sometimes be so severe as to seriously threaten miners' health and safety:

> NMA reads the Court's decision to mean (as it stated) that ''minor irritation may not be a material impairment'' * * * but that irritation can reach ''a level at which [it] becomes so severe that employee health and job performance are seriously threatened even though those effects may be transitory.'' * * * AMC in 1992 and NMA today are fully in accord with the view of the 11th Circuit that when health effects, transitory or otherwise, become so ''severe'' as to ''seriously threaten'' a miner's health or job performance, the materiality threshold has been met.

The NMA, then, apparently agrees with MSHA that sensory irritations and respiratory symptoms can be so severe that they cross the material impairment threshold, regardless of whether they are ''reversible.'' Therefore, as MSHA has maintained, such health effects are highly relevant to this risk assessment—especially since impairments of a miner's job performance in an underground mining environment could seriously threaten the safety of both the miner and his or her co-workers. Sensory irritations may also impede miners' ability to escape during emergencies.

The NMA, however, went on to emphasize that ''* * * federal appeals courts have held that 'mild discomfort' or even 'moderate irritation' do not constitute 'significant' or 'material' health effects'':

> In International Union v. Pendergrass, 878 F. 2d 389 (1989), the D.C. Circuit upheld OSHA's formaldehyde standard against a challenge that it did not adequately protect against significant noncarcinogenic health effects, even though OSHA had found that, at the permissible level of exposure, ''20% of workers suffer 'mild discomfort', while 30% more experience 'slight discomfort'.'' Id. at 398. Likewise, in *Texas Independent Ginners Ass'n.* v. *Marshall,* 630 F, 2d 398 (1980), the Fifth Circuit Court of Appeals held that minor reversible symptoms do not constitute material impairment unless OSHA shows that those effects might develop into chronic disease. Id. at 408–09.

MSHA is fully aware of the distinction that courts have made between mild discomfort or irritation and transitory health effects that can seriously threaten a miner's health and safety. MSHA's position, after reviewing the scientific literature, public testimony, and comments, is that all of the health effects considered in this risk assessment fall into the latter category.

iii. Health Effects Associated with $PM_{2.5}$ in Ambient Air

There have been many studies in recent years designed to determine whether the mix of particulate matter in ambient air is harmful to health. The evidence linking particulates in air pollution to health problems has long been compelling enough to warrant direction from the Congress to limit the concentration of such particulates (see part II, section 5 of this preamble). In recent years, the evidence of harmful effects due to airborne particulates has increased, suggesting that ''fine'' particulates (i.e., particles less than 2.5

μm in diameter) are more strongly associated than ''coarse'' respirable particulates (i.e., particles greater than 2.5 μm but less than 10 μm in diameter) with the adverse health effects observed (EPA, 1996).

MSHA recognizes that there are two difficulties involved in utilizing the evidence from such studies in assessing risks to miners from occupational dpm exposures. First, although dpm is a fine particulate, ambient air also contains fine particulates other than dpm. Therefore, health effects associated with exposures to fine particulate matter in air pollution studies are not associated specifically with exposures to dpm or any other one kind of fine particulate matter. Second, observations of adverse health effects in segments of the general population do not necessarily apply to the population of miners. Since, due to age and selection factors, the health of miners differs from that of the public as a whole, it is possible that fine particles might not affect miners, as a group, to the same degree as the general population.

Some commenters reiterated these two points, recognized by MSHA in the proposal, without addressing MSHA's stated reasons for including health effects associated with fine particulates in this risk assessment. There are compelling reasons why MSHA considered this body of evidence in this rulemaking.

Since dpm is a type of respirable particle, information about health effects associated with exposures to respirable particles, and especially to fine particulate matter, is certainly relevant, even if difficult to apply directly to dpm exposures. Adverse health effects in the general population have been observed at ambient atmospheric particulate concentrations well below the dpm concentrations studied in occupational settings. The potency of dpm differs from the total fine particulate found in ambient air. This makes it difficult to establish a specific exposure-response relationship for dpm that is based on fine particle results. However, this does not mean that these results should be ignored in a dpm risk assessment. The available evidence of adverse health effects associated with fine particulates is still highly relevant for dpm hazard identification. Furthermore, as shown in Subsection 3.c.ii of this risk assessment, the fine particle research findings can be used to construct a rough exposure-response relationship for dpm, showing significantly increased risks of material impairment among exposed miners. MSHA's estimates are based on the best available epidemiologic evidence and show risks high enough to warrant regulatory action.

Moreover, extensive scientific literature shows that occupational dust exposures contribute to the development of Chronic Obstructive Pulmonary Diseases (COPD), thereby compromising the pulmonary reserve of some miners. Miners experience COPD at a significantly higher rate than the general population (Becklake 1989, 1992; Oxman 1993; NIOSH 1995). In addition, many miners also smoke tobacco. This places affected miners in subpopulations specifically identified as susceptible to the adverse health effects of respirable particle pollution (EPA, 1996). Some commenters (*e.g.,* MARG) repeated MSHA's observation that the population of miners differs from the general population but failed to address MSHA's concern for miners' increased susceptibility due to COPD incidence and/or smoking habits. The Mine Act requires that standards ''* * * most adequately assure on the basis of the best available evidence that no miner suffer material impairment of health or functional capacity * * *'' (Section 101(a)(6), emphasis added). This most certainly authorizes MSHA to protect miners who have COPD and/or smoke tobacco.

MARG also submitted the opinion that if ''* * * regulation of fine particulate matter is necessary, it [MSHA] should propose a rule dealing specifically with the issue of concern, rather than a rule that limits total airborne carbon or arbitrarily singles out diesel exhaust * * *.'' MSHA's concern is not with ''total airborne carbon'' but with dpm, which consists mostly of submicrometer airborne carbon. At issue here, however, are the adverse health effects associated with dpm exposure. Dpm is a type of fine particulate, and there is no evidence to suggest that the dpm fraction contributes less than other fine particulates to adverse health effects linked to exposures in ambient air.

For this reason, and because miners may be especially susceptible to fine particle effects, MSHA has concluded, after considering the public comments, that the body of evidence from air pollution studies is highly relevant to this risk assessment. The Agency is, therefore, taking the evidence fully into account.

b. Acute Health Effects

Information pertaining to the acute health effects of dpm includes anecdotal reports of symptoms experienced by exposed miners, studies based on exposures to diesel emissions, and studies based on exposures to particulate matter in the ambient air. These will be discussed in turn. Subsection 2.a.iii of this risk assessment addressed the relevance to dpm of studies based on exposures to particulate matter in the ambient air.

Only the evidence from human studies will be addressed in this section. Data from genotoxicity studies and studies on laboratory animals will be discussed later, in Subsection 2.d on mechanisms of toxicity. Section 3.a and 3.b contain MSHA's interpretation of the evidence relating dpm exposures to acute health hazards.

i. Symptoms Reported by Exposed Miners

Miners working in mines with diesel equipment have long reported adverse effects after exposure to diesel exhaust. For example, at the dpm workshops conducted in 1995, a miner reported headaches and nausea experienced by several operators after short periods of exposure (dpm Workshop; Mt. Vernon, IL, 1995). Another miner reported that smoke from poorly maintained equipment, or from improper fuel use, irritates the eyes, nose, and throat. ''We've had people sick time and time again * * * at times we've had to use oxygen for people to get them to come back around to where they can feel normal again.'' (dpm Workshop; Beckley, WV, 1995). Other miners (dpm Workshops; Beckley, WV, 1995; Salt Lake City, UT, 1995), reported similar symptoms in the various mines where they worked.

At the 1998 public hearings on MSHA's proposed dpm rule for coal mines, one miner, with work experience in a coal mine utilizing diesel haulage equipment at the face, testified that

> * * * unlike many, I have not experienced the headaches, the watering of the eyes, the cold-like symptoms and walking around in this cloud of smoke. Maybe it's because of the maintenance programs. Maybe it's because of complying with ventilation. * * * after 25 years, I have not shown any effects. [SLC, 1998]

Other miners working at dieselized coal mines testified at those hearings that they had personally experienced eye irritation and/or respiratory ailments immediately after exposure to diesel exhaust, and they attributed these ailments to their exposure. For example, one miner attributed a case of pneumonia to a specific episode of unusually high exposure. (Birm., 1998) The safety and training manager of the mining company involved noted that ''there had been a problem recognized in review with that exhaust system on that particular piece of equipment'' and that the pneumonia may have

developed due to ''idiosyncracy of his lungs that respond to any type of a respiratory irritant.'' The manager suggested that this incident should not be generalized to other situations but provided no evidence that the miner's lungs were unusually susceptible to irritation.[21]

Another miner, who had worked at the same underground mine before and after diesel haulage equipment was introduced, indicated that he and his co-workers began experiencing acute symptoms after the diesel equipment was introduced. This miner suggested that these effects were linked to exposure, and referring to a co-worker stated:

> * * * had respiratory problems, after * * * diesel equipment was brought into that mine—he can take off for two weeks vacation, come back—after that two weeks, he felt pretty good, his respiratory problems would straighten up, but at the very instant that he gets back in the face of diesel-powered equipment, it starts up again, his respiratory problems will flare up again, coughing, sore throat, numerous problems in his chest. (Birm., 1998).

Several other underground miners asserted there was a correlation between diesel exposure levels and the frequency and/or intensity of respiratory symptoms, eye irritations, and chest ailments. One miner, for example, stated:

> I've experienced [these symptoms] myself. * * * other miners experience the same kind of distresses * * * Some of the stresses you actually can feel—you don't need a gauge to measure this—your burning eyes, nose, throat, your chest irritation. The more you're exposed to, the higher this goes. This includes headaches and nausea and some lasting congestion, depending on how long you've been exposed per shift or per week.
>
> The men I represent have experienced more cold-like symptoms, especially over the past, I would say, eight to ten years, when diesel has really peaked and we no longer really use much of anything else. [SLC, 1998]

Kahn *et al.* (1988) conducted a study of the prevalence and seriousness of such complaints, based on United Mine Workers of America records and subsequent interviews with the miners involved. The review involved reports at five underground coal mines in Utah and Colorado between 1974 and 1985. Of the 13 miners reporting symptoms: 12 reported mucous membrane irritation, headache and light-headiness; eight reported nausea; four reported heartburn; three reported vomiting and weakness, numbness, and tingling in extremities; two reported chest tightness; and two reported wheezing (although one of these complained of recurrent wheezing without exposure). All of these incidents were severe enough to result in lost work time due to the symptoms (which subsided within 24 to 48 hours).

In comments submitted for this rulemaking, the NMA pointed out, as has MSHA, that the evidence presented in this subsection is anecdotal. The NMA, further, suggested that the cited article by Kahn *et al.* typified this kind of evidence in that it was ''totally devoid of any correlation to actual exposure levels.'' A lack of concurrent exposure measurements is, unfortunately, not restricted to anecdotal evidence; and MSHA must base its evaluation on the available evidence. MSHA recognizes the scientific limitations of anecdotal evidence and has, therefore, compiled and considered it separately from more formal evidence. MSHA nevertheless considers such evidence potentially valuable for identifying acute health hazards, with the understanding that confirmation requires more rigorous investigation.[22]

With respect to the same article (Kahn *et al.,* 1988), and notwithstanding the NMA's claim that the article was totally devoid of any correlation to exposure levels, the NMA also stated that MSHA:

> * * * neglects to include in the preamble the article's description of the conditions under which the ''overexposures'' occurred, *e.g.,* ''poor engine maintenance, poor maintenance of emission controls, prolonged idling of machinery, engines pulling heavy loads, use of equipment during times when ventilation was disrupted (such as during a move of longwall machinery), use of several pieces of equipment exhausting into the fresh-air intake, and use of poor quality fuel. The NMA asserted that these conditions, cited in the article, ''have been addressed by MSHA's final standards for diesel equipment in underground coal mines issued October 25, 1996.''[23] Furthermore, despite its reservations about anecdotal evidence:
>
> NMA is mindful of the testimony of several miners in the coal proceeding who complained of transient irritation owing to exposure to diesel exhaust. * * * the October 1996 regulations together with the phased-in introduction of catalytic converters on all outby equipment and the introduction of such devices on permissible equipment when such technology becomes available will address the complaints raised by the miners.

The NMA provided no evidence, however, that elimination of the conditions described by Kahn *et al.*, or implementation of the 1996 diesel regulations for coal mines, would reduce dpm levels sufficiently to prevent the sensory irritations and respiratory symptoms described. MSHA completed an analysis of the impact of the 1996 diesel regulations for underground coal mines (See Part II, Section 7). We do expect that the concentrations of diesel emissions at the section loading point and during longwall moves will be reduced as these provisions are fully implemented. These dpm levels, though reduced, are still above the exposures expected to cause sensory irritations and respiratory symptoms (See Section 3(d)(5)). MSHA did not explicitly consider the risks to miners of a working lifetime of dpm exposure at very high levels, nor the actions that could be taken to specifically reduce dpm exposure levels in underground coal mines when developing the 1996 underground coal diesel regulations. It was understood that the agency would be taking a separate look at the health risks of dpm exposure. In addition, the NMA did not provide evidence that these are the only conditions under which complaints of sensory irritations and respiratory symptoms occur, or explain why eliminating them would reduce the need to prevent excessive exposures under other conditions.

In the proposal for the present rule, MSHA requested additional information about such effects from medical personnel who have treated miners. IMC Global submitted letters from four healthcare practitioners in Carlsbad, NM, including three physicians. None of these practitioners attributed any cases of respiratory problems or other acute symptoms to dpm exposure. Three of the four practitioners noted that they had observed respiratory symptoms among exposed miners but attributed these symptoms to chronic lung conditions, smoking, or other factors. One physician stated that ''[IMC Global], which has used diesel equipment in its mining operations for over 20 years, has never experienced a single case of injury or illness caused by exposures to diesel particulates.''

ii. Studies Based on Exposures to Diesel Emissions

Several experimental and statistical studies have been conducted to investigate acute effects of exposure to

[21] MSHA realizes the incidents related in this subsection are anecdotal and draws no statistical conclusions from them. Since they pertain to specific experiences, however, they can be useful in identifying a potential hazard.

[22] MSHA sees potential value in anecdotal evidence when it relates to immediate experiences. MSHA regards anecdotal evidence to be less appropriate for identifying chronic health effects, since chronic effects cannot readily be linked to specific experiences. Accordingly, this risk assessment places little weight on anecdotal evidence for the chronic health hazards considered.

[23] The 1996 regulations to which the NMA was referring do not apply to M/NM mines.

diesel emissions. These more formal studies provide data that are more scientifically rigorous than the anecdotal evidence presented in the preceding subsection. Unless otherwise indicated, diesel exhaust exposures were determined qualitatively.

In a clinical study (Battigelli, 1965), volunteers were exposed to three concentrations of diluted diesel exhaust and then evaluated to determine the effects of exposure on pulmonary resistance and the degree of eye irritation. The investigators stated that ''levels utilized for these controlled exposures are comparable to realistic values such as those found in railroad shops.'' No statistically significant change in pulmonary function was detected, but exposure for ten minutes to diesel exhaust diluted to the middle level produced ''intolerable'' irritation in some subjects while the average irritation score was midway between ''some'' irritation and a ''conspicuous but tolerable'' irritation level. Diluting the concentration by 50% substantially reduced the irritation. At the highest exposure level, more than 50 percent of the volunteers discontinued the experiment before 10 minutes because of ''intolerable'' eye irritation.

A study of underground iron ore miners exposed to diesel emissions found no difference in spirometry measurements taken before and after a work shift (Jörgensen and Svensson 1970). Similarly, another study of coal miners exposed to diesel emissions detected no statistically significant relationship between exposure and changes in pulmonary function (Ames *et al.* 1982). However, the authors noted that the lack of a statistically significant result might be due to the low concentrations of diesel emissions involved.

Gamble *et al.* (1978) observed decreases in pulmonary function over a single shift in salt miners exposed to diesel emissions. Pulmonary function appeared to deteriorate in relation to the concentration of diesel exhaust, as indicated by NO_2; but this effect was confounded by the presence of NO_2 due to the use of explosives.

Gamble *et al.* (1987a) assessed response to diesel exposure among 232 bus garage workers by means of a questionnaire and before- and after-shift spirometry. No significant relationship was detected between diesel exposure and change in pulmonary function. However, after adjusting for age and smoking status, a significantly elevated prevalence of reported symptoms was found in the high-exposure group. The strongest associations with exposure were found for eye irritation, labored breathing, chest tightness, and wheeze. The questionnaire was also used to compare various acute symptoms reported by the garage workers and a similar population of workers at a lead acid battery plant who were not exposed to diesel fumes. The prevalence of work-related eye irritations, headaches, difficult or labored breathing, nausea, and wheeze was significantly higher in the diesel bus garage workers, but the prevalence of work-related sneezing was significantly lower.

Ulfvarson *et al.* (1987) studied effects over a single shift on 47 stevedores exposed to dpm at particle concentrations ranging from 130 μ/m^3 to 1000 μ/m^3. Diesel particulate concentrations were determined by collecting particles on glass fiber filters of unspecified efficiency. A statistically significant loss of pulmonary function was observed, with recovery after 3 days of no occupational exposure.

To investigate whether removal of the particles from diesel exhaust might reduce the ''acute irritative effect on the lungs'' observed in their earlier study, Ulfvarson and Alexandersson (1990) compared pulmonary effects in a group of 24 stevedores exposed to unfiltered diesel exhaust to a group of 18 stevedores exposed to filtered exhaust, and to a control group of 17 occupationally unexposed workers. The filters used were specially constructed from 144 layers of glass fiber with ''99.97% degrees of retention of dioctylphthalate mist with particle size 0.3 μm.'' Workers in all three groups were nonsmokers and had normal spirometry values, adjusted for sex, age, and height, prior to the experimental workshift.

In addition to confirming the earlier observation of significantly reduced pulmonary function after a single shift of occupational exposure, the study found that the stevedores in the group exposed only to filtered exhaust had 50–60% less of a decline in forced vital capacity (FVC) than did those stevedores who worked with unfiltered equipment. Similar results were observed for a subgroup of six stevedores who were exposed to filtered exhaust on one shift and unfiltered exhaust on another. No loss of pulmonary function was observed for the unexposed control group. The authors suggested that these results ''support the idea that the irritative effect of diesel exhausts [sic] to the lungs is the result of an interaction between particles and gaseous components and not of the gaseous components alone.'' They concluded that ''* * * it should be a useful practice to filter off particles from diesel exhausts in work places even if potentially irritant gases remain in the emissions'' and that ''removal of the particulate fraction by filtering is an important factor in reducing the adverse effect of diesel exhaust on pulmonary function.''

Rudell *et al.* (1996) carried out a series of double-blind experiments on 12 healthy, non-smoking subjects to investigate whether a particle trap on the tailpipe of an idling diesel engine would reduce acute effects of diesel exhaust, compared with exposure to unfiltered exhaust. Symptoms associated with exposure included headache, dizziness, nausea, tiredness, tightness of chest, coughing, and difficulty in breathing. The most prominent symptoms were found to be irritation of the eyes and nose, and a sensation of unpleasant smell. Among the various pulmonary function tests performed, exposure was found to result in significant changes only as measured by increased airway resistance and specific airway resistance. The ceramic wall flow particle trap reduced the number of particles by 46 percent, but resulted in no significant attenuation of symptoms or lung function effects. The authors concluded that diluted diesel exhaust caused increased irritant symptoms of the eyes and nose, unpleasant smell, and bronchoconstriction, but that the 46-percent reduction in median particle number concentration observed was not sufficient to protect against these effects in the populations studied.

Wade and Newman (1993) documented three cases in which railroad workers developed persistent asthma following exposure to diesel emissions while riding immediately behind the lead engines of trains having no caboose. None of these workers were smokers or had any prior history of asthma or other respiratory disease. Asthma diagnosis was based on symptoms, pulmonary function tests, and measurement of airway hyperreactivity to methacholine or exercise.

Although MSHA is not aware of any other published report directly relating diesel emissions exposures to the development of asthma, there have been a number of recent studies indicating that dpm exposure can induce bronchial inflammation and respiratory immunological allergic responses in humans. Studies published through 1997 are reviewed in Peterson and Saxon (1996) and Diaz-Sanchez (1997).

Diaz-Sanchez *et al.* (1994) challenged healthy human volunteers by spraying

300 μg dpm into their nostrils.[24] Immunoglobulin E (IgE) binds to mast cells where it binds antigen leading to secretion of biologically active amines (*e.g.,* histamine) causing dilation and increased permeability of blood vessels. These amines are largely responsible for clinical manifestations of such allergic reactions as hay fever, asthma, and hives. Enhanced IgE levels were found in nasal washes in as little as 24 hours, with peak production observed 4 days after the dpm was administered.[25] No effect was observed on the levels of other immunoglobulin proteins. The selective enhancement of local IgE production was demonstrated by a dramatic increase in IgE-secreting cells. The authors suggested that dpm may augment human allergic disease responses by enhancing the production of IgE antibodies. Building on these results, Diaz-Sanchez *et al.* (1996) measured cytokine production in nasal lavage cells from healthy human volunteers challenged with 150 μg dpm sprayed into each nostril. Based on the responses observed, including a broad increase in cytokine production, along with the results of the 1994 paper, the authors concluded that dpm exposure contributes to enhanced local IgE production and thus plays a role in allergic airway disease.

Salvi *et al.* (1999) exposed healthy human volunteers to diluted diesel exhaust at a dpm concentration of 300 μg/m^3 for one hour with intermittent exercise. Although there were no changes in pulmonary function, there were significant increases in various markers of allergic response in airway lavage fluid. Bronchial biopsies obtained six hours after exposure also showed significant increases in markers of immunologic response in the bronchial tissue. Significant increases in other markers of immunologic response were also observed in peripheral blood following exposure. A marked cellular inflammatory response in the airways was reported. The authors concluded that ''at high ambient concentrations, acute short-term DE [diesel exhaust] exposure produces a well-defined and marked systemic and pulmonary inflammatory response in healthy human volunteers, which is underestimated by standard lung function measurements.''

iii. Studies Based on Exposures to Particulate Matter in Ambient Air

Due to an incident in Belgium's industrial Meuse Valley, it was known as early as the 1930s that large increases in particulate air pollution, created by winter weather inversions, could be associated with large simultaneous increases in mortality and morbidity. More than 60 persons died from this incident, and several hundred suffered respiratory problems. The mortality rate during the episode was more than ten times higher than normal, and it was estimated that over 3,000 sudden deaths would occur if a similar incident occurred in London. Although no measurements of pollutants in the ambient air during the episode are available, high PM levels were obviously present (EPA, 1996).

A significant elevation in particulate matter (along with SO_2 and its oxidation products) was measured during a 1948 incident in Donora, PA. Of the Donora population, 42.7 percent experienced some acute adverse health effect, mainly due to irritation of the respiratory tract. Twelve percent of the population reported difficulty in breathing, with a steep rise in frequency as age progressed to 55 years (Schrenk, 1949).

Approximately as projected by Firket (1931), an estimated 4,000 deaths occurred in response to a 1952 episode of extreme air pollution in London. The nature of these deaths is unknown, but there is clear evidence that bronchial irritation, dyspnea, bronchospasm, and, in some cases, cyanosis occurred with unusual prevalence (Martin, 1964).

These three episodes ''left little doubt about causality in regard to the induction of serious health effects by very high concentrations of particle-laden air pollutant mixtures'' and stimulated additional research to characterize exposure-response relationships (EPA, 1996). Based on several analyses of the 1952 London data, along with several additional acute exposure mortality analyses of London data covering later time periods, the U.S. Environmental Protection Agency (EPA) concluded that increased risk of mortality is associated with exposure to combined particulate and SO_2 levels in the range of 500–1000 μg/m^3. The EPA also concluded that relatively small, but statistically significant increases in mortality risk exist at particulate (but not SO_2) levels below 500 μg/m$_3$, with no indications of a specific threshold level yet indicated at lower concentrations (EPA, 1986).

Subsequently, between 1986 and 1996, increasingly sophisticated techniques of particulate measurement and statistical analysis have enabled investigators to address these questions more quantitatively. The studies on acute effects carried out since 1986 are reviewed in the 1996 EPA Air Quality Criteria for Particulate Matter, which forms the basis for the discussion below (EPA, 1996).

At least 21 studies have been conducted that evaluate associations between acute mortality and morbidity effects and various measures of fine particulate levels in the ambient air. These studies are identified in Tables III–2 and III–3. Table III–2 lists 11 studies that measured primarily fine particulate matter using filter-based optical techniques and, therefore, provide mainly qualitative support for associating observed effects with fine particles. Table III–3 lists quantitative results from 10 studies that reported gravimetric measurements of either the fine particulate fraction or of components, such as sulfates, that serve as indicators or surrogates of fine particulate exposures.

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[24] Assuming that a working miner inhales approximately 1.25 m^3 of air per hour, this dose corresponds to a 1-hour exposure at a dpm concentration of 240 μg/m^3.

[25] IgE is one of five types of immunoglobulin, which are proteins produced in response to allergens. Cytokine (mentioned later) is a substance involved in regulating IgE production.

Table III-2. — Studies of acute health effects using filter based optical indicators of fine particles in the ambient air.

City	Study Years	Indicator*	Reference†
Acute Mortality			
London	1963-1972 (winters) 1965-1972 (winters)	BS	Thurston et al., 1989 Ito et al., 1993
Athens	1975-1987 July, 1987 1984-1988	BS	Katsouyanni et al., 1990 Katsouyanni et al., 1993 Touloumi et al., 1994
Los Angeles	1970-1979 1970-1979	KM	Shumway et al., 1988 Kinney and Ozkaynak, 1991
Santa Clara	1980-1986 (winters)	COH	Fairley, 1990
Increased Hospitalization			
Barcelona	1985-1989	BS	Sunyer et al., 1993
Acute Change in Pulmonary Function			
Wageningen, Netherlands		BS	Hoek and Brunkreef, 1993
Netherlands		BS	Roemer et al., 1993

† All references are from EPA, 1996

*BS (black smoke), KM (carbonaceous material), and COH (coefficient of haze) are optical measurements that are most directly related to elemental carbon concentrations, but only indirectly to mass. Site specific calibrations and/or comparisons of such optical measurements with gravimetric mass measurements in the same time and city are needed to make inferences about particle mass. However, all three of these indicators preferentially measure carbon particles found in the fine fraction of total airborne particulate matter. (EPA, 1996).

Table III-3. —Studies of acute health effects using gravimetric indicators of fine particles in the ambient air.

Study	Indicator	RR per 25 $\mu g/m^3$ $PM_{2.5}$ Increase (95% Confidence Interval)	Mean $PM_{2.5}$ Levels (Min/Max)†
Acute Mortality			
Six Cities[A] (overall)	$PM_{2.5}$	1.038 (1.026, 1.055)	
Portage, WI	$PM_{2.5}$	1.030 (0.993, 1.071)	11.2 (±7.8)
Topeka, KS	$PM_{2.5}$	1.020 (0.951, 1.092)	12.2 (±7.4)
Boston, MA	$PM_{2.5}$	1.056 (1.038, 1.071)	15.7 (±9.2)
St. Louis, MO	$PM_{2.5}$	1.028 (1.010, 1.043)	18.7 (±10.5)
Kingston/Knoxville, TN	$PM_{2.5}$	1.035 (1.005, 1.066)	20.8 (±9.6)
Steubenville, OH	$PM_{2.5}$	1.025 (0.998, 1.053)	29.6 (±21.9)
Increased Hospitalization			
Ontario, CAN[B]	$SO_4^=$	1.03 (1.02, 1.04)	Min/Max = 3.1 - 8.2
Ontario, CAN[C]	$SO_4^=$ O_3	1.03 (1.02, 1.04) 1.03 (1.02, 1.05)	Min/Max = 2.0 - 7.7
NYC/Buffalo, NY[D]	$SO_4^=$	1.05 (1.01, 1.10)	NR
Toronto, CAN[D]	H^+(Nmol/m^3) $SO_4^=$ $PM_{2.5}$	1.16 (1.03, 1.30)* 1.12 (1.00, 1.24) 1.15 (1.02, 1.78)	28.8 (NR, 391) 7.6 (NR, 48.7) 18.6 (NR, 66.0)
Increased Respiratory Symptoms			
Southern California[F]	$SO_4^=$	1.48 (1.14, 1.91)	R = 2 - 37
Six Cities[G] (Cough)	$PM_{2.5}$ $PM_{2.5}$ Sulfur H^+	1.19 (1.01, 1.42)** 1.23 (0.95, 1.59)** 1.06 (0.87, 1.29)**	18.0 (7.2, 37)*** 2.5 (3.1, 61)*** 18.1 (0.8, 5.9)***
Six Cities[G] (Lower Resp. Symp.)	$PM_{2.5}$ $PM_{2.5}$ Sulfur H^+	1.44 (1.15 - 1.82)** 1.82 (1.28 - 2.59)** 1.05 (0.25 - 1.30)**	18.0 (7.2, 37)*** 2.5 (0.8, 5.9)*** 18.1 (3.1, 61)***
Denver, CO[P] (Cough, adult asthmatics)	$PM_{2.5}$ $SO_4^=$ H^+	0.0012 (0.0043)**** 0.0042 (0.00035)**** 0.0076 (0.0038)****	0.41 - 73 0.12 - 12 2.0 - 41
Decreased Lung Function			
Uniontown, PA[E]	$PM_{2.5}$	PEFR 23.1 (-0.3,36.9) (per 25 $\mu g/m^3$)	25/88 (NR/88)
Seattle, WA[Q] (Asthmatics)	$b_{ext.}$ calibrated by $PM_{2.5}$	FEV1 42 ml (12,73) FVC 45 ml (20,70)	5/45

References from EPA, 1996, Staff Report

[A] Schwartz et al. (1996a)

[B] Burnett et al. (1994)

[C] Burnett et al. (1995) O_3

[D] Thurston et al. (1992, 1994)

[E] Neas et al. (1995)

[F] Ostro et al. (1993)

[G] Schwartz et al. (1994)

[P] Ostro et al. (1991)

[Q] Koenig et al. (1993)

† Min/Max 24-hr PM indicator level shown in parentheses unless otherwise noted as (±S.D.), 10 and 90 percentile (10,90).

* Change per 100 nmoles/m^3.

** Change per 20 $\mu g/m^3$ for $PM_{2.5}$; per 5 $\mu g/m^3$ for $PM_{2.5}$ sulfur; per 25 nmoles/m^3 for H^+.

*** 50th percentile value (10,90 percentile).

**** Coefficient and SE in parenthesis.

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A total of 38 studies examining relationships between short-term particulate levels and increased mortality, including nine with fine particulate measurements, were published between 1988 and 1996 (EPA, 1996). Most of these found statistically significant positive associations. Daily or several-day elevations of particulate concentrations, at average levels as low as 18–58 μg/m^3, were associated with increased mortality, with stronger relationships observed in those with preexisting respiratory and cardiovascular disease. Overall, these studies suggest that an increase of 50 μg/m^3 in the 24-hour average of PM_{10} is associated with a 2.5 to 5-percent increase in the risk of mortality in the general population, excluding accidents, suicides, and homicides. Based on Schwartz et al. (1996), the relative risk of mortality in the general population increases by about 2.6 to 5.5 percent per 25 μg/m^3 of fine particulate ($PM_{2.5}$) (EPA, 1996). More specifically, Schwartz *et al.* (1996) reported significantly elevated risks of mortality due to pneumonia, chronic obstructive pulmonary disease (COPD), and ischemic heart disease (IHD). For these three causes of death, the estimated increases in risk per incremental increase of 10 μg/m^3 in the concentration of $PM_{2.5}$ were 4.0 percent, 3.3 percent, and 2.1 percent, respectively. Each of these three results was statistically significant at a 95-percent confidence level.

A total of 22 studies were published on associations between short-term particulate levels and hospital admissions, outpatient visits, and emergency room visits for respiratory disease, Chronic Obstructive Pulmonary Disease (COPD), pneumonia, and heart disease (EPA, 1996). Fifteen of these studies were focused on the elderly. Of the seven that dealt with all ages (or in one case, persons less than 65 years old), all showed positive results. All of the five studies relating fine particulate measurements to increased hospitalization, listed in Tables III–2 and III–3, dealt with general age populations and showed statistically significant associations. The estimated increase in risk ranges from 3 to 16 percent per 25 μg/m^3 of fine particulate. Overall, these studies are indicative of acute morbidity effects being related to fine particulate matter and support the mortality findings.

Most of the 14 published quantitative studies on ambient particulate exposures and acute respiratory diseases were restricted to children (EPA, 1996, Table 12–12). Although they generally showed positive associations, and may be of considerable biological relevance, evidence of toxicity in children is not necessarily applicable to adults. The few studies on adults have not produced statistically significant evidence of a relationship.

Thirteen studies since 1982 have investigated associations between ambient particulate levels and loss of pulmonary function (EPA, 1996, Table 12–13). In general, these studies suggest a short term effect, especially in symptomatic groups such as asthmatics, but most were carried out on children only. In a study of adults with mild COPD, Pope and Kanner (1993) found a 29 ± 10 ml decrease in 1-second Forced Expiratory Volume (FEV_1) per 50 μg/m^3 increase in PM_{10}, which is similar in magnitude to the change generally observed in the studies on children. In another study of adults, with PM_{10} ranging from 4 to 137 μg/m^3, Dusseldorp et al. (1995) found 45 and 77 ml/sec decreases, respectively, for evening and morning Peak Expiratory Flow Rate (PEFR) per 50 μg/m^3 increase in PM_{10} (EPA, 1996). In the only study carried out on adults that specifically measured fine particulate ($PM_{2.5}$), Perry et al. (1983) did not detect any association of exposure with loss of pulmonary function. This study, however, was conducted on only 24 adults (all asthmatics) exposed at relatively low concentrations of $PM_{2.5}$ and, therefore, had very little power to detect any such association.

c. Chronic Health Effects

During the 1995 dpm workshops, miners reported observable adverse health effects among those who have worked a long time in dieselized mines. For example, a miner (dpm Workshop; Salt Lake City, UT, 1995), stated that miners who work with diesel ''have spit up black stuff every night, big black—what they call black (expletive) * * * [they] have the congestion every night * * * the 60-year-old man working there 40 years.'' Similarly, in comments submitted in response to MSHA's proposed dpm regulations, several miners reported cancers and chronic respiratory ailments they attributed to dpm exposure.

Scientific investigation of the chronic health effects of dpm exposure includes studies based specifically on exposures to diesel emissions and studies based more generally on exposures to fine particulate matter in the ambient air. Only the evidence from human studies will be addressed in this section of the risk assessment. Data from genotoxicity studies and studies on laboratory animals will be discussed later, in Subsection 2.d on mechanisms of toxicity. Subsection 3.a(iii) contains MSHA's interpretation of the evidence relating dpm exposures to one chronic health hazard: lung cancer.

i. Studies Based on Exposures to Diesel Emissions

The discussion will (1) summarize the epidemiologic literature on chronic effects other than cancer, and then (2) concentrate on the epidemiology of cancer in workers exposed to dpm.

(1) Chronic Effects Other Than Cancer

A number of epidemiologic studies have investigated relationships between diesel exposure and the risk of developing persistent respiratory symptoms (*i.e.*, chronic cough, chronic phlegm, and breathlessness) or measurable loss in lung function. Three studies involved coal miners (Reger *et al.,* 1982; Ames et al., 1984; Jacobsen *et al.,* 1988); four studies involved metal and nonmetal miners (Jörgenson & Svensson, 1970; Attfield, 1979; Attfield *et al.,* 1982; Gamble *et al.,* 1983). Three studies involved other groups of workers—railroad workers (Battigelli *et al.,* 1964), bus garage workers (Gamble *et al.,* 1987), and stevedores (Purdham *et al.,* 1987).

Reger et al. (1982) examined the prevalence of respiratory symptoms and the level of pulmonary function among more than 1,600 underground and surface U.S. coal miners, comparing results for workers (matched for smoking status, age, height, and years worked underground) at diesel and non-diesel mines. Those working at underground dieselized mines showed some increased respiratory symptoms and reduced lung function, but a similar pattern was found in surface miners who presumably would have experienced less diesel exposure. Miners in the dieselized mines, however, had worked underground for less than 5 years on average.

In a study of 1,118 U.S. coal miners, Ames et al. (1984) did not detect any pattern of chronic respiratory effects associated with exposure to diesel emissions. The analysis, however, took no account of baseline differences in lung function or symptom prevalence, and the authors noted a low level of exposure to diesel-exhaust contaminants in the exposed population.

In a cohort of 19,901 British coal miners investigated over a 5-year period, Jacobsen *et al.* (1988) found increased work absence due to self-reported chest illness in underground workers exposed to diesel exhaust, as compared to surface workers, but found

no correlation with their estimated level of exposure.

Jörgenson & Svensson (1970) found higher rates of chronic productive bronchitis, for both smokers and nonsmokers, among Swedish underground iron ore miners exposed to diesel exhaust as compared to surface workers at the same mine. No significant difference was found in spirometry results.

Using questionnaires collected from 4,924 miners at 21 U.S. metal and nonmetal mines, Attfield (1979) evaluated the effects of exposure to silica dust and diesel exhaust and obtained inconclusive results with respect to diesel exposure. For both smokers and non-smokers, miners occupationally exposed to diesel for five or more years showed an elevated prevalence of persistent cough, persistent phlegm, and shortness of breath, as compared to miners exposed for less than five years, but the differences were not statistically significant. Four quantitative indicators of diesel use failed to show consistent trends with symptoms and lung function.

Attfield et al. (1982) reported on a medical surveillance study of 630 white male miners at 6 U.S. potash mines. No relationships were found between measures of diesel use or exposure and various health indices, based on self-reported respiratory symptoms, chest radiographs, and spirometry.

In a study of U.S. salt miners, Gamble and Jones (1983) observed some elevation in cough, phlegm, and dyspnea associated with mines ranked according to level of diesel exhaust exposure. No association between respiratory symptoms and estimated cumulative diesel exposure was found after adjusting for differences among mines. However, since the mines varied widely with respect to diesel exposure levels, this adjustment may have masked a relationship.

Battigelli et al. (1964) compared pulmonary function and complaints of respiratory symptoms in 210 U.S. railroad repair shop employees, exposed to diesel for an average of 10 years, to a control group of 154 unexposed railroad workers. Respiratory symptoms were less prevalent in the exposed group, and there was no difference in pulmonary function; but no adjustment was made for differences in smoking habits.

In a study of workers at four diesel bus garages in two U.S. cities, Gamble et al. (1987b) investigated relationships between job tenure (as a surrogate for cumulative exposure) and respiratory symptoms, chest radiographs, and pulmonary function. The study population was also compared to an unexposed control group of workers with similar socioeconomic background. After indirect adjustment for age, race, and smoking, the exposed workers showed an increased prevalence of cough, phlegm, and wheezing, but no association was found with job tenure. Age- and height-adjusted pulmonary function was found to decline with duration of exposure, but was elevated on average, as compared to the control group. The number of positive radiographs was too small to support any conclusions. The authors concluded that the exposed workers may have experienced some chronic respiratory effects.

Purdham et al. (1987) compared baseline pulmonary function and respiratory symptoms in 17 exposed Canadian stevedores to a control group of 11 port office workers. After adjustment for smoking, there was no statistically significant difference in self-reported respiratory symptoms between the two groups. However, after adjustment for smoking, age, and height, exposed workers showed lower baseline pulmonary function, consistent with an obstructive ventilatory defect, as compared to both the control group and the general metropolitan population.

In a review of these studies, Cohen and Higgins (1995) concluded that they did not provide strong or consistent evidence for chronic, nonmalignant respiratory effects associated with occupational exposure to diesel exhaust. These reviewers stated, however, that ''several studies are suggestive of such effects * * * particularly when viewed in the context of possible biases in study design and analysis.'' Glenn et al (1983) noted that the studies of chronic respiratory effects carried out by NIOSH researchers in coal, salt, potash, and trona mines all ''revealed an excess of cough and phlegm in the diesel exposed group.'' IPCS (1996) noted that ''[a]lthough excess respiratory symptoms and reduced pulmonary function have been reported in some studies, it is not clear whether these are long-term effects of exposure.'' Similarly, Morgan et al. (1997) concluded that while there is ''some evidence that the chronic inhalation of diesel fumes leads to the development of cough and sputum, that is chronic bronchitis, it is usually impossible to show a cause and effect relationship * * *.'' MSHA agrees that these dpm studies are not conclusive but considers them to be suggestive of adverse chronic, non-cancerous respiratory effects.

(2) Cancer

Because diesel exhaust has long been known to contain carcinogenic compounds (*e.g.,* benzene in the gaseous fraction and benzopyrene and nitropyrene in the dpm fraction), a great deal of research has been conducted to determine if occupational exposure to diesel exhaust actually results in an increased risk of cancer. Evidence that exposure to dpm increases the risk of developing cancer comes from three kinds of studies: human studies, genotoxicity studies, and animal studies. In this risk assessment, MSHA has placed the most weight on evidence from the human epidemiologic studies and views the genotoxicity and animal studies as lending support to the epidemiologic evidence.

In the epidemiologic studies, it is generally impossible to disassociate exposure to dpm from exposure to the gasses and vapors that form the remainder of whole diesel exhaust. However, the animal evidence shows no significant increase in the risk of lung cancer from exposure to the gaseous fraction alone (Heinrich et al., 1986, 1995; Iwai et al., 1986; Brightwell et al., 1986). Therefore, dpm, rather than the gaseous fraction of diesel exhaust, is usually assumed to be the agent associated with any excess prevalence of lung cancer observed in the epidemiologic studies. Subsection 2.d of this risk assessment contains a summary of evidence supporting this assumption.

(a) Lung Cancer

MSHA evaluated 47 epidemiologic studies examining the prevalence of lung cancer within groups of workers occupationally exposed to dpm. This includes four studies not included in MSHA's risk assessment as originally proposed.[26] The earliest of these studies was published in 1957 and the latest in 1999. The most recent published reviews of these studies are by Mauderly (1992), Cohen and Higgins (1995), Muscat and Wynder (1995), IPCS (1996), Stöber and Abel (1996), Cox (1997), Morgan et al. (1997), Cal–EPA (1998), ACGIH (1998), and U.S. EPA (1999). In response to both the ANPRM and the 1998 proposals, several commenters also provided MSHA with

[26] One of these studies (Christie et al., 1995) was cited in the discussion on mechanisms of toxicity but not considered in connection with studies involving dpm exposures. Several commenters advocated that it be considered. The other three were published in 1997 or later. Johnston et al. (1997) was introduced to these proceedings in 64 FR 7144. Säverin et al. (1999) is the published English version of a Germany study submitted as part of the public comments by NIOSH on May 27, 1999. The remaining study is Brüske-Hohlfeld et al. (1999).

their own reviews of many of these studies. In arriving at its conclusions, MSHA considered all of these reviews, including those of the commenters, as well as the 47 source studies available to MSHA.

In addition, MSHA relied on two comprehensive statistical ''meta-analyses'' [27] of the epidemiologic literature: Lipsett and Campleman (1999) thru [28] and Bhatia et al. (1998).[29] These meta-analyses, which weight, combine, and analyze data from the various epidemiologic studies, were themselves the subject of considerable public comment and are discussed primarily in Subsection 3.a.iii of this risk assessment. The present section tabulates results of the studies and addresses their individual strengths and weaknesses. Interpretation and evaluation of the collective evidence, including discussion of potential publication bias or any other systematic biases, is deferred to Subsection 3.a.iii.

Tables III–4 (27 cohort studies) and III–5 (20 case-control studies) identify all 47 known epidemiologic studies that MSHA considers relevant to an assessment of lung cancer risk associated with dpm exposure.[30] These tables include, for each of the 47 studies listed, a brief description of the study and its findings, the method of exposure assessment, and comments on potential biases or other limitations. Presence or absence of an adjustment for smoking habits is highlighted, and adjustments for other potentially confounding factors are indicated when applicable. Although MSHA constructed these tables based primarily on its own reading of the 48 source publications, the tables also incorporate strengths and weaknesses noted in the literature reviews and/or in the public comments submitted.

Some degree of association between occupational dpm exposure and an excess prevalence of lung cancer was reported in 41 of the 47 studies reviewed by MSHA: 22 of the 27 cohort studies and 19 of the 20 case-control studies. Despite some commenters' use of conflicting terminology, which will be addressed below, MSHA refers to these 41 studies as ''positive.'' The 22 positive cohort studies in Table III–4 are identified as those reporting a relative risk (RR) or standardized mortality ratio (SMR) exceeding 1.0. The 19 positive case-control studies in Table III–5 are identified as those reporting an RR or odds ratio (OR) exceeding 1.0. A study does not need to be statistically significant (at the 0.05 level) or meet all criteria described, in order to be considered a ''positive'' study. The six remaining studies were entirely negative: they reported a deficit in the prevalence of lung cancer among exposed workers, relative to whatever population was used in the study as a basis for comparison. These six negative studies are identified as those reporting no relative risk (RR), standard mortality ratio (SMR), or odds ratio (OR) greater than 1.0.[31]

MSHA recognizes that these 47 studies are not of equal importance for determining whether dpm exposure leads to an increased risk of lung cancer. Some of the studies provide much better evidence than others. Furthermore, since no epidemiologic study can be perfectly controlled, the studies exhibit various strengths and weaknesses, as described by both this risk assessment and a number of commenters. Several commenters, and some of the reviewers cited above, focused on the weaknesses and argued that none of the existing studies is conclusive. MSHA, in accordance with other reviewers and commenters, maintains: (1) That the weaknesses identified in both negative and positive studies mainly cause underestimation of risks associated with high occupational dpm exposure; (2) that it is legitimate to base conclusions on the combined weight of all available evidence and that, therefore, it is not necessary for any individual study to be conclusive; and (3) that even though the 41 positive studies vary a great deal in strength, nearly all of them contribute something to the weight of positive evidence.

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[27] MSHA restricts the term ''meta-analysis'' to formal, statistical analyses of the pooled data taken from several studies. Some commenters (and Cox in the article itself) referred to the review by Cox (op.cit.) as a meta-analysis. Although this article seeks to identify characteristics of the individual studies that might account for the general pattern of results, it performs no statistical analysis on the pooled epidemiologic data. For this reason, MSHA does not regard the Cox article as a meta-analysis in the same sense as the two studies so identified. MSHA does, however, recognize that the Cox article evaluates and rejects the collective evidence for causality, based on the common characteristics identified. In that context, Cox's arguments and conclusions are addressed in Subsection 3.a.iii. Cox also presents a statistical analysis of data from one of the studies, and that portion of the article is considered here, along with his observations about other individual studies.

[28] MSHA's risk assessment as originally proposed cited an unpublished version, attributed to Lipsett and Alexexeff (1998), of essentially the same meta-analysis. Both the 1999 and 1998 versions are now in the public record.

[29] Silverman (1998) reviewed the meta-analysis by Bhatia et al. (op cit.) and discussed, in general terms, the body of available epidemiologic evidence on which it is based. Some commenters stated that MSHA had not sufficiently considered Silverman's views on the limitations of this evidence. MSHA has thoroughly considered these views and addresses them in Subsection 3.a.(iii).

[30] For simplicity, the epidemiologic studies considered here are placed into two broad categories. A *cohort study* compares the health of persons having different exposures, diets, etc. A *case-control study* starts with two defined groups known to differ in health and compares their exposure characteristics.

[31] The six entirely negative studies are: Kaplan (1959); DeCoufle et al. (1977); Waller (1981); Edling et al. (1987); Bender et al. (1989); Christie et al. (1995).

Table III-4. — Summary of information from 27 cohort studies on lung cancer and occupational exposure to diesel exhaust.

Study	Occupation	No. of Subjects	Follow-up period	Exposure Assessment	Smk. Adj.	Findings[a]	Stat. Sig.[b]	Comments
Ahlberg et al. (1981)	Male truck drivers	35,883	1961-73	Occupation only		RR = 1.33 for drivers of "ordinary" trucks.	*	Risk relative to males employed in trades thought to have no exposure to "petroleum products or other chemicals." Comparison controlled for age and province of residence (Sweden). Based on comparison of smoking habits between truck drivers and general Stockholm population, authors concluded that excess rate of lung cancer could not be entirely attributed to smoking.
Ahlman et al. (1991)	Underground sulfide ore miners	597	1968-86	Job histories from personnel records. Measurements of alpha energy concentration from radon daughters at each mine worked.		RR = 1.45 overall. RR = 2.9 for 45-64 age group. (calculated by MSHA)		Age-adjusted relative risk compared to males living in same area of Finland. No excess observed among 338 surface workers at same mines, with similar smoking and alcohol consumption, based on questionnaire. Based on calculation of expected lung cancers due to radon, excess risk attributed by author partly to radon exposure and partly to diesel exhaust & silica exposure.
Balarajan & McDowall (1988)	Professional drivers	3,392	1950-84	Occupation only		SMR = 0.86 for taxi drivers. SMR = 1.42 for bus drivers. SMR = 1.59 for truck drivers.	*	Possibly higher rates of smoking among bus and truck drivers than among taxi drivers.
Bender et al. (1989)	Highway maintenance workers	4,849	1945-84	Occupation only		SMR = 0.69		No adjustment for healthy worker effect.
Boffetta et al. (1988)	Railroad worker Truck drivers Heavy Eq. Op's. Miners	2,973 16,208 855 2,034	1982-84	Occupation and diesel exposure by questionnaire	✔	RR = 1.24 for truck drivers. RR = 1.59 for railroad workers. RR = 2.60 for heavy Eq. Op's. RR = 2.67 for miners.	* *	Risk relative to workers reporting that they never worked in these four occupations and were never occupationally exposed to diesel exhaust. Adjusted for age and smoking only.
	All workers	476,648				RR = 1.05 for 1-15 years. RR = 1.21 for 16+ years.		Based on self-reported exposure, relative to unexposed workers. Adjusted for occupational exposures to asbestos, coal and stone dusts, coal tar & pitch, and gasoline exhaust (in addition to age and smoking). Possible biases due to volunteered participation and elevated lung cancer rate among 98,026 subjects with unknown dpm exposure.
Christie et al. (1994, 1995)	Coal miners	23,630	1973-92	Occupation only		SMR = 0.76		No adjustment for healthy worker effect. Cohort includes workers who entered workforce up through 1992. SMR reported to be greater than for occupationally unexposed petroleum workers.

Dubrow & Wegman (1984)	Truck & tractor drivers	not reported	1971-73	Occupation only		sMOR = 1.73 based on 176 deaths.	*	Excess cancers observed over the entire respiratory system and upper alimentary tract.
Edling et al. (1987)	Bus workers	694	1951-83	Occupation only		SMR = 0.7 for overall cohort		Small size of cohort lacks statistical power to detect excess risk of lung cancer. No adjustment for healthy worker effect.
Garshick et al. (1988, 1991)	Railroad workers	55,395 (1991 report)	1959-80	Job in 1959 & years of diesel exposure since 1959		RR = 1.31 for 1-4 years. RR = 1.28 for 5-9 years. RR = 1.19 for 10-14 years. RR = 1.40 for 15 or more years.	* * * *	Adjusted for attained age (1991 report). Cumulative diesel exposure-years lagged by 5 years. Subjects with likely asbestos exposure excluded from cohort. Statistically significant results corroborated if 12,872 shopworkers and hostlers possibly exposed to asbestos are also excluded. Missing 12% of death certificates. Cigarette smoking judged to be uncorrelated with diesel exposure within cohort. Higher RR for each exposure group if shopworkers and hostlers are excluded.
Guberan et al. (1992)	Professional drivers	1,726	1961-86	Occupation only		SMR = 1.50	*	Approximately 1/3 to 1/4 of cohort reported to be long-haul truck drivers. SMR based on regional lung cancer mortality rate.
Gustafsson et al. (1986)	Dock workers	6,071	1961-80	Occupation only		SMR = 1.32 (mortality). SMR = 1.68 (morbidity).	* *	No adjustment for healthy worker effect.
Gustavsson et al. (1990)	Bus garage workers	708	1952-86	Semi-quantitative, based on job history & exposure intensity estimated for each job.		SMR = 1.22 for overall cohort. SMR = 1.27 for highest-exposed subgroup.		Lack of statistical significance may be attributed to small size of cohort.
Hansen (1993)	Truck drivers	14,225	1970-80	Occupation only		SMR = 1.60 for overall cohort. Some indication of increasing SMR with age (i.e., greater cumulative exposure).	*	Compared to unexposed control group of 38,301 laborers considered to "resemble the group of truck drivers in terms of work-related demands on physical strength and fitness, educational background, social class, and life style." Correction for estimated differences in smoking habits between cohort and control group reduces SMR from 1.60 to 1.52. Results judged "unlikely *** [to] have been seriously confounded by smoking habit differences."

Howe et al. (1983)	Railroad workers	43,826	1965-77	Jobs classified by diesel exposure		RR = 1.20 for "possibly exposed." RR = 1.35 for "probably exposed."	* *	Risk is relative to unexposed subgroup of cohort. Similar results obtained for coal dust exposure. Possible confounding with asbestos and coal dust.
Johnston et al. (1997)	Underground coal miners	18,166	1950-85	Quantitative, based on detailed job history & surrogate dpm measurements	✔	mine-adjusted model: RR = 1.156 per g-hr/m^3 mine-unadjusted model: RR = 1.227 per g-hr/m^3		Risk is relative to unexposed workers in cohort. Adjusted for age, smoking habit & intensity, mine site, and cohort entry date. Mine site highly correlated with dpm exposure. Both models lag exposure by 15 years.
Kaplan (1959)	Railroad workers	Approx. 32000	1953-58	Jobs classified by diesel exposure		SMR=0.88 for operationally exposed. SMR = 0.72 for somewhat exposed. SMR = 0.80 for rarely exposed.		No adjustment for healthy worker effect. Clerks (in rarely exposed group) found more likely to have had urban residence than occupationally exposed workers. No attempt to distinguish between diesel and coal-fired locomotives. Results may be attributable to short duration of exposure and/or inadequate follow-up time.
Leupker & Smith (1978)	Truck drivers	183,791	May-July, 1976	Occupation only		SMR = 1.21		Lack of statistical significance may be due to inadequate follow-up period. Retirees excluded from cohort, so lung cancers occurring after retirement were not included.
Lindsay et al. (1993)	Truck drivers	not reported	1965-79	Occupation only		SMR = 1.15	*	
Menck & Henderson (1976)	Truck drivers	34,800 estimated	1968-73	Occupation only		SMR = 1.65	*	Number of subjects in cohort estimated from census data.
Raffle (1957)	Transport engineers	2,666 estimated from manyears at risk	1950-55	Occupation only		SMR = 1.42		SMR calculated by combining data presented for four quadrants of London. Excluded most retirees and lung cancers occurring after retirement.
Rafnsson & Gunnarsdottir (1991)	Truck drivers	868	1951-88	Occupation only		SMR = 2.14	*	No trend of increasing risk with increased duration of employment or increased follow-up time. Based on survey of smoking habits in cohort compared to general male population, and fact that there were fewer than expected deaths from respiratory disease, authors concluded that differences in smoking habits were unlikely to be enough to explain excess rate of lung cancer. However, not all trucks were diesel prior to 1951, and there is possible confounding by asbestos exposure.

Rushton et al. (1983)	Bus maintenance workers	8,480	5.9 yrs (mean)	Occupation only		SMR = 1.01 for overall cohort. SMR = 1.33 for "general hand" subgroup.	*	Short follow-up period. SMR based on comparison to national rates, with no adjustment for regional or socioeconomic differences, which could account for excess lung cancers observed among general hands. No adjustment for healthy worker effect.
Säverin et al. (1999)	Underground potash miners	5,536	1970-94	Quantitative, based on TC measurements & detailed job history		RR = 2.17 for highest compared to least exposed categories. RR=1.03 to 1.225 per mg-yr/m^3, depending on statistical model & inclusion criteria.		Based on routine measurements, miners determined to have had no occupational exposure to radon progeny. Authors judged asbestos exposure minor, with negligible effects. Cigarette smoking determined to be uncorrelated with cumulative TC exposure within cohort.
Schenker et al. (1984)	Railroad workers	2,519	1967-79	Job histories, with exposure classified as unexposed, high, low, or undefined.		RR = 1.50 for low exposure subgroup. RR = 2.77 for high exposure subgroup.		Risk relative to unexposed subgroup. Jobs considered to have similar socioeconomic status. Differences in smoking calculated to be insufficient to explain findings. Possible confounding by asbestos exposure.
Waller (1981)	Bus workers	16,828 Est. from manyears at risk	1950-74	Occupation only		SMR = 0.79 for overall cohort.		Lung cancers occurring after retirement or resignation from London Transport Authority were not counted. No adjustment for healthy worker effect.
Waxweiler et al. (1973)	Potash miners	3,886	1941-67	Miners classified as underground or surface		SMR = 1.1 for both underground and surface miners.		No adjustment for healthy worker effect. SMR based on national lung cancer mortality, which is about 1/3 higher than lung cancer mortality rate in New Mexico, where miners resided. Authors judged this to be balanced by smoking among miners. A substantial percentage of the underground subgroup may have had little or no occupational exposure to diesel exhaust.
Wong et al. (1985)	Heavy equipment operators	34,156	1964-78	Job histories, latency, & years of union membership		SMR = 0.99 for overall cohort. SMR = 1.07 for ≥20 yr member. SMR = 1.12 for ≥20 yr. latency. SMR = 1.30 for 4,075 "normal" retirees. SMR = 3.43 for "high exposure" dozer operators with 15-19 yr union membership & ≥20 yr latency.	* *	Increasing trend in SMR with latency and (up to 15 yr) with duration of union membership. No adjustment for healthy worker effect.

[a] RR = Relative Risk; SMR = Standardized Mortality Ratio. Values greater than 1.0 indicate excess prevalence of lung cancer associated with diesel exposure.

[b] An asterisk (*) indicates statistical significance based on 2-tailed test at confidence level of at least 95%.

Table III-5. — Summary of published information from 20 case-control studies on lung cancer and exposure to diesel exhaust.

Study	Cases	Controls	No. of Cases	No. of Controls	Exposure Assessment	Matching		Findings[a]	Stat. Sig.[b]	Comments
						Smk.	Additional			
Benhamou et al. (1988)	Histologically confirmed lung cancers	Non-tobacco related diseases	1,625	3,091	Occupational history by questionnaire.	✔	Sex, age at diagnosis, hospital, interviewer.	RR = 2.14 for miners RR = 1.42 for professional drivers.	* *	Mine type not reported. No evidence of an increase in risk with duration of exposure
Boffetta et al. (1990)	Hospitalized males with histologically confirmed lung cancer	Hospitalized males with no tobacco related disease	2,584	5,099	Occupation classified by probability of diesel exposure	✔	Sex, age within 2 yr, hospital, year of interview.	OR = 0.95 for 13 jobs with probable exposure. OR = 1.49 for more than 30 yr in "probable" jobs.		Adjusted for race, asbestos exposure, education, & number of cigarettes per day.
			477	846	Occupational history & duration of diesel exposure by interview			OR = 1.21 for any self-reported diesel exposure. OR = 2.39 for more than 30 yr of self-reported diesel exposure.		
Brüske-Hohlfeld et al. (1999)	Cytologically and/or histologically confirmed lung cancers	Randomly selected from compulsory registries of residents.	3,498	3,541	Occupational history by interview; total duration of diesel exposure compiled from individual job episodes.	✔	Sex, age, region of residence.	OR = 1.43 for any occupational diesel exposure during lifetime. OR = 1.56 for West German professional drivers post-1955. OR = 2.88 for > 20 yr in "traffic-related" jobs other than driving. OR = 6.81 for > 30 yr as full-time driver of farm tractors. OR = 4.30 for > 20 yr as heavy equipment operator.	* * * * *	Adjusted for cumulative smoking & asbestos exposure. All interviews conducted directly with cases and controls. Lack of elevated risk for East German professional drivers attributed to relatively low traffic density & low proportion of vehicles with diesel engines in East Germany. Non-driving "traffic-related jobs" include switchmen & operators of diesel locomotives & forklifts.
Buiatti et al. (1985)	Histologically confirmed lung cancers	Patients at same hospital	376	892	Occupational history from interview	✔	Sex, age, admission date.	OR = 1.8 for taxi drivers.		Adjusted for current and past smoking patterns and for asbestos exposure.

Coggon et al. (1984)	Lung cancer deaths of males under 40	Deaths from other causes in males under 40	598	1,180	Occupation from death certificate, classified as high, low, or no diesel exposure		Sex, death year, region, and birth year (approx.)	RR = 1.3 for all jobs with diesel exposure. RR=1.1 for jobs classified as high exposure.	*	Only most recent full-time occupation recorded on death certificate.
Damber & Larsson (1985)	Male patients with lung cancer	One living and one deceased without lung cancer	604	1,071	Job, with tenure, from mailed questionnaire	✔	Sex, death year, age, municipality	RR = 1.9 for non-smoking truck drivers aged <70 yr. RR = 4.5 for non-smoking truck drivers aged ≥70 yr.	*	Ex-smokers who did not smoke for at least last 10 years included with non-smokers.
DeCoufle et al. (1977)	Male patients with lung cancer	Non-neoplastic disease patients	6,434	Not reported	Occupation only, from questionnaire	✔	Unmatched	RR = 0.92 for bus, taxi, and truck drivers. RR = 0.94 for locomotive engineers.		Selected occupation compared to clerical workers. Positive associations found before smoking adjustment.
Emmelin et al. (1993)	Deaths from primary lung cancer among dock workers	Dock workers without lung cancer	50	154	Semi-quantitative from work history & records of diesel fuel usage	✔	Date of birth, port, and survival to within 2 years of case's diagnosis of lung cancer	RR = 1.6 for "medium" duration of exposure. RR = 2.9 for "high" duration of exposure.		Increasing relative risk also observed using exposure estimates based on machine usage & diesel fuel consumption. Confounding from asbestos may be significant.
Garshick et al. (1987)	Deaths with primary lung cancer among railroad workers	Deaths from other than cancer, suicide, accidents, or unknown causes	1,256	2,385	Job history and tenure combined with current exposure levels measured for each job	✔	Date of birth and death	RR = 1.41 for 20+ diesel-years in workers aged ≤ 64 yr. RR = 0.91 for 20+ diesel-years in workers aged ≥65 yr.	*	Adjusted for asbestos exposure. Older workers had relatively short diesel exposure, or none.
Gustavsson et al. (1990)	Deaths from lung cancer among bus garage workers	Non-cases within cohort mortality study	20	120	Semi-quantitative based on job, tenure, & exposure class for each job		Born within two years of case.	RR = 1.34, 1.81, and 2.43 for increasing cumulative diesel exposure categories, relative to lowest exposure category.	*	Authors judged smoking habits to be similar for different exposure categories. RR did not increase with increasing asbestos exposure
Hall & Wynder (1984)	Hospitalized males with lung cancer	Hospitalized males with no tobacco-related diseases	502	502	Usual occupation by interview	✔	Age, race, hospital, and hospital room status	RR = 1.4 for jobs with diesel exposure. RR = 1.9 for heavy equipment operators & repairmen.		Confounding with other occupational exposures possible.

Hayes et al. (1989)	Lung cancer deaths pooled from 3 studies	Various -- lung disease excluded	2,291	2,570	Occupational history by interview	✔	Sex, age, and either race or area of residence	OR = 1.5 for ≥10 yr truck driving. OR = 2.1 for ≥10 yr operating heavy equipment. OR = 1.7 for ≥10 yr bus driving.	*	OR adjusted for birth-year cohort and state of residence (FL, NJ, or LA), in addition to average cigarette use. Smaller OR for <10 yr in these jobs.
Lerchen et al. (1987)	New Mexico residents with lung cancer	Medicare recipients	506	771	Occupational history, industry, & self-reported exposure, by interview	✔	Sex, age, ethnicity	OR = 0.6 for ≥1 yr occupational exposure to diesel exhaust. OR = 2.1 for underground non-uranium mining.		Small number of cases and controls in diesel-exposed jobs. Possibly insufficient exposure duration. Not matched on date of birth or death.
Milne et al. (1983)	Lung cancer deaths	Deaths from any other cancer	925	6,565	Occupation from death certificate		None	OR = 3.5 for bus drivers. OR = 1.6 for truck drivers.	*	Inadequate latency allowance.
Morabia et al. (1992)	Male lung cancer patients	Patients without lung cancer or other tobacco-related condition	1,793	3,228	Job, with coal and asbestos exposure durations, by interview	✔	Race, age, hospital, and smoking history	OR = 2.3 for miners. OR = 1.1 for bus drivers. OR = 1.0 for truck or tractor drivers.		Mine type not specified. Potential confounding by other occupational exposures for miners.
Pfluger and Minder (1994)	Professional drivers	Workers in occupational categories with no known excess lung cancer risk.	284	1,301	Occupation only, from death certificate.		None.	OR = 1.48 for professional drivers.	*	Stratified by age. Indirectly adjusted for smoking, based on smoking-rate for occupation.
Siemiatycki et al. (1988)	Squamous cell lung cancer patients by type of lung cancer	Other cancer patients	359	1,523	Semi-quantitative, from occupational history by interview, & exposure class for each job	✔	None	OR = 1.2 for diesel exposure; OR = 2.8 for mining.		Stratified by age, socioeconomic status, ethnicity, and blue- vs. white-collar job history. Examination of files indicated that most miners "were exposed to diesel exhaust for short periods of time." Mining included quarrying, so result is likely to be confounded by silica exposure.

Steenland et al. (1990, 1992, 1998)	Deaths from lung CA among Teamsters	Deaths other than lung or bladder cancer or motor vehicle accidents	996	1,085	Occupational history and tenure from next-of-kin, supplemented by IH data	✔	Time of death within 2 years	OR = 1.27 for diesel truck drivers with 1-24 yr tenure. OR = 1.26 for diesel truck drivers with 25-34 yr tenure. OR = 1.89 for diesel truck drivers with ≥35 yr tenure. OR = 1.50 for truck mechanics with ≥18 yr tenure after 1959.	*	Years of tenure not necessarily all at main job (i.e., diesel truck driver). OR adjusted for asbestos exposure.
Swanson et al. (1993) See also Burns & Swanson (1991)	Histologically confirmed Detroit metro area lung cancers	Colon or rectal cancer cases	3,792 males 5,935 total	1,966 males 3,956 total	Occupational history from interview	✔	None	OR = 1.4 for heavy truck drivers with 1-9 yr tenure. OR = 1.6 for heavy truck drivers with 10-19 yr tenure. OR = 2.5 for heavy truck drivers with ≥20 yr tenure. OR = 1.2 for railroad workers with 1-9 yr tenure. OR = 2.5 for railroad workers with ≥10 yr tenure. OR = 2.98 for mining industry workers. OR = 5.03 for mining machinery operators.	* * *	OR for truck drivers & RR workers is for white males, relative to corresponding group with <1 yr tenure, adjusted for age at diagnosis. Pattern of increasing risk with duration of employment also reported for black male railroad workers, based on fewer cases. (1993 report) OR for mining machinery operators and mining is for all males, adjusted for race and age at diagnosis. Type of mining not reported. Potential confounding by other occupational exposures. (1991 report)
Williams et al. (1977)	Male lung cancer patients	Other male cancer patients	432	2,817	Main lifetime occupation from interview	✔	Sex	OR = 1.52 for male truck drivers.		Controlled for age, race, alcohol use, and socioeconomic status. Unexplained discrepancies in reported number of controls.

[a] RR = Relative Risk; OR = Odds Ratio. Values greater than 1.0 indicate excess prevalence of lung cancer associated with diesel exposure.

[b] An asterisk (*) indicates statistical significance based on 2-tailed test at confidence level of at least 95%.

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(i) Evaluation Criteria

Several commenters contended that MSHA paid more attention to positive studies than to negative ones and indicated that MSHA had not sufficiently explained its reasons for discounting studies they regarded as providing negative evidence. MSHA used five principal criteria to evaluate the strengths and weaknesses of the individual studies:

(1) power of the study to detect an exposure effect;

(2) composition of comparison groups;

(3) exposure assessment;

(4) statistical significance; and

(5) potential confounders.

These criteria are consistent with those proposed by the HEI Diesel Epidemiology Expert Panel (HEI, 1999). To help explain MSHA's reasons for valuing some studies over others, these five criteria will now be discussed in turn.

Power of the Study

There are several factors that contribute to a study's power, or ability to detect an increased risk of lung cancer in an exposed population. First is the study's size—i.e., the number of subjects in a cohort or the number of lung cancer cases in a case-control study. If few subjects or cases are included, then any statistical relationships are likely to go undetected. Second is the duration and intensity of exposure among members of the exposed group. The greater the exposure, the more likely it is that the study will detect an effect if it exists. Conversely, a study in which few members of the exposed group experienced cumulative exposures significantly greater than the background level is unlikely to detect an exposure effect. Third is the length of time the study allows for lung cancer to exhibit a statistical impact after exposure begins. This involves a latency period, which is the time required for lung cancer to develop in affected individuals, or (mainly pertaining to cohort studies) a follow-up period, which is the time allotted, including latency, for lung cancers in affected individuals to show up in the study. It is generally acknowledged that lung cancer studies should, at the very minimum, allow for a latency period of at least 10 years from the time exposure begins and that it is preferable to allow for latency periods of at least 20 years. The shorter the latency allowance, the less power the study has to detect any increased risk of lung cancer that may be associated with exposure.

As stated above, six of the 47 studies did not show positive results: One of these studies (Edling et al.) was based on a small cohort of 694 bus workers, thus having little statistical power. Three other of these studies (DeCoufle, Kaplan, and Christie) included exposed workers for whom there was an inadequate latency allowance (*i.e.,* less than 10 years). The entire period of follow-up in the Kaplan study was 1953–1958. The Christie study was designed in such a way as to provide for neither a minimum period of exposure nor a minimum period of latency: the report covers lung cancers diagnosed only through 1992, but the ''exposed'' cohort includes workers who may have entered the work force (and thus begun their exposure) as late as Dec. 31, 1992. Such workers would not be expected to develop lung cancer during the study period. The remaining two negative studies (Bender, 1989 and Waller, 1981) appear to have included a reasonably adequate number of exposed workers and to have allowed for an adequate latency period.

Some of the 41 positive studies also had little power, either because they included relatively few exposed workers (*e.g.,* Lerchen et al., 1987, Ahlman et al., 1991; Gustavsson et al., 1990) or an inadequate latency allowance or follow-up period (*e.g.,* Leupker and Smith (1978); Milne, 1983; Rushton et al., 1983). In those based on few exposed workers, there is a strong possibility that the positive association arose merely by chance.[32] The other studies, however, found increased prevalence of lung cancer despite the relatively short periods of latency and follow-up time involved. It should be noted that, for reasons other than lack of power, MSHA places very little weight on the Milne and Rushton studies. As mentioned in Table III–4, the Rushton study compared the cohort to the national population, with no adjustment for regional or socioeconomic differences. This may account for the excess rate of lung cancers reported for the exposed ''general hand'' job category. The Milne study did not control for potentially important ''confounding'' variables, as explained below in MSHA's discussion of that criterion.

Composition of Comparison Groups

This criterion addresses the question of how equitable is the comparison between the exposed and unexposed populations in a cohort study, or between the subjects with lung cancer (*i.e.,* the ''cases'') and the subjects without lung cancer (*i.e.,* the ''controls'') in a case-control study. MSHA includes bias due to confounding variables under this criterion if the groups differ systematically with respect to such factors as age or exposure to non-diesel carcinogens. For example, unless adequate adjustments are made, comparisons of underground miners to the general population may be systematically biased by the miners' greater exposure to radon gas. Confounding not built into a study's design or otherwise documented is considered potential rather than systematic and is considered under a separate criterion below. Other factors included under the present criterion are systematic (*i.e.,* ''differential'') misclassification of those placed into the ''exposed'' and ''unexposed'' groups, selection bias, and bias due to the ''healthy worker effect.''

In several of the studies, a group identified with diesel exposure may have systematically included workers who, in fact, received little or no occupational diesel exposure. For example, a substantial percentage of the ''underground miner'' subgroup in Waxweiler et al. (1973) worked in underground mines with no diesel equipment. This would have diluted any effect of dpm exposure on the group of underground miners as a whole.[33] Similarly, the groups classified as miners in Benhamou et al. (1988), Boffetta et al. (1988), and Swanson et al. (1993) included substantial percentages of miners who were probably not occupationally exposed to diesel emissions. Potential effects of exposure misclassification are discussed further under the criterion of ''Exposure Assessment'' below.

Selection bias refers to systematic differences in characteristics of the comparison groups due to the criteria and/or methods used to select those included in the study. For example, three of the cohort studies (Raffle, 1957; Leupker and Smith, 1976; Waller, 1981) systematically excluded retirees from the cohort of exposed workers—but not

[32] As noted in Table III–4, the underground sulfide ore miners studied by Ahlman et al. (1991) were exposed to radon in addition to diesel emissions. The total number of lung cancers observed, however, was greater than what was attributable to the radon exposure, based on a calculation by the authors. Therefore, the authors attributed a portion of the excess risk to diesel exposure.

[33] Furthermore, as pointed out in comments submitted by Dr. Peter Valberg through the NMA, the subgroup of underground miners working at mines with diesel engines was small, and the exposure duration in one of the mines with diesel engines was only ten years. Therefore, the power of the study was inadequate to detect an excess risk of lung cancer for that subgroup by itself.

from the population used for comparison. Therefore, cases of lung cancer that developed after retirement were counted against the comparison population but not against the cohort. This artificially reduced the SMR calculated for the exposed cohort in these three studies.

Another type of selection bias may occur when members of the control group in a case-control study are non-randomly selected. This happens when cases and controls are selected from the same larger population of patients or death certificates, and the controls are simply selected (prior to case matching) from the group remaining after those with lung cancer are removed. Such selection can lead to a control group that is biased with respect to occupation and smoking habits. Specifically, ''* * * a severely distorted estimate of the association between exposure to diesel exhaust and lung cancer, and a severely distorted picture of the direction and degree of confounding by cigarette smoking, can come from case-control studies in which the controls are a collection of 'other deaths' '' when the cause of most ''other deaths'' is itself correlated with smoking or occupational choice (HEI, 1999). This selection bias can distort results in either direction.

MSHA judged that seven of the 20 available case-control studies were susceptible to this type of selection bias because controls were drawn from a population of ''other deaths'' or ''other patients.'' [34] These control groups were likely to have over-represented cases of cardiovascular disease, which is known to be highly correlated with smoking and is possibly also correlated with occupation. The only case-control study not reporting a positive result (DeCoufle et al., 1977) fell into this group of seven. The remaining 13 case-control studies all reported positive results.

It is ''well established that persons in the work force tend to be 'healthier' than persons not employed, and therefore healthier than the general population. Worker mortality tends to be below average for all major causes of death.'' (HEI, 1999) Because workers tend to be healthier than non-workers, the prevalence of disease found among workers exposed to a toxic substance may be lower than the rate prevailing in the general population, but higher than the rate occurring in an unexposed population of similar workers. This phenomenon is called the ''healthy worker effect.''

All five cohort studies reporting entirely negative results drew comparisons against the general population and made no adjustments to take the healthy worker effect into account. (Kaplan, 1959; Waller (1981); Edling et al. (1987); Bender et al. (1989); Christie et al. (1995)). The sixth negative study (DeCoufle, 1977) was a case-control study in which vehicle drivers and locomotive engineers were compared to clerical workers. As mentioned earlier, this study did not meet the criterion for a minimum 10-year latency period. All other studies in which exposed workers were compared against similar but unexposed workers reported some degree of elevated lung cancer risk for exposed workers.

Many of the 41 positive studies also drew comparisons against the general population with no compensating adjustment for the healthy worker effect. But the healthy worker effect can influence results even when the age-adjusted mortality or morbidity rate observed among exposed workers is greater than that found in the general population. In such studies, comparison with the general population tends to reduce the excess risk attributable to the substance being investigated. For example, Gustafsson et al. (1986), Rushton et al. (1983), and Wong et al. (1985) each reported an unadjusted SMR exceeding 1.0 for lung cancer in exposed workers and an SMR significantly less than 1.0 for all causes of death combined. Since the SMR for all causes is less than 1.0, there is evidence of a healthy worker effect. Therefore, the SMR reported for lung cancer was probably lower than if the comparison had been made against a more similar population of unexposed workers. Bhatia et al. (1998) constructed a simple estimate of the healthy worker effect evident in these studies, based on the SMR for all causes of death except lung cancer. This estimate was then used to adjust the SMR reported for lung cancer. For the three positive studies mentioned, the adjustment raised the SMR from 1.29 to 1.48, from 1.01 to 1.23, and from 1.07 to 1.34, respectively. [35]

Exposure Assessment

Many commenters suggested that a lack of concurrent exposure measurements in available studies limits their utility for quantitative risk assessment (QRA). MSHA is fully aware of these limitations but also recognizes that less desirable surrogates of exposure must frequently be employed out of practical necessity. As stated by HEI's expert panel on diesel epidemiology:

> Quantitative measures of exposures are important in any epidemiologic study used for QRA. The greater the detail regarding specific exposure, including how much, for how long, and at what concentration, the more useful the study is for this purpose. Frequently, however, individual measurements are not available, and surrogate measures or markers are used. For example, the most general surrogate measures of exposure in occupational epidemiologic studies are job classification and work location. (HEI, 1999)

It is important to distinguish, moreover, between studies used to identify a hazard (i.e., to establish that dpm exposure is associated with an excess risk of lung cancer) and studies used for QRA (i.e., to quantify the amount of excess risk corresponding to a given level of exposure). Although detailed exposure measurements are desirable in any epidemiologic study, they are more important for QRA than for identifying and characterizing a hazard. Conversely, epidemiologic studies can be highly useful for purposes of hazard identification and characterization even if a lack of personal exposure measurements renders them less than ideal for QRA.

Still, MSHA agrees that the quality of exposure assessment affects the value of a study for even hazard identification. Accordingly, MSHA has divided the 47 studies into four categories, depending on the degree to which exposures were quantified for the specific workers included. This ranking refers only to exposure assessment and does not necessarily correspond to the overall weight MSHA places on any of the studies.

The highest rank, with respect to this criterion, is reserved for studies having quantitative, concurrent exposure measurements for specific workers or for specific jobs coupled with detailed work histories. Only two studies (Johnston et al., 1997 and Säverin et al., 1999) fall into this category.[36] Both of these recent cohort studies took smoking habits into account. These

[34] These were: Buiatti et al. (1985), Coggan et al. (1984), DeCoufle et al. (1977), Garshick et al. (1987), Hayes et al. (1989), Lerchen et al. (1987), and Steenland et al. (1990).

[35] A similar adjustment was applied to the SMR for lung cancer reported in one of the negative studies (Edling et al., 1987). This raised the SMR from 0.67 to 0.80. Because of insufficient data, Bhatia et al. did not carry out the adjustment for the three other studies they considered with potentially important healthy worker effects. (Bhatia et al., 1998)

[36] The study of German potash miners by Säverin et al. was introduced by NIOSH at the Knoxville public hearing prior to publication. The study, as cited, was later published in English. Although the dpm measurements (total carbon) were all made in one year, the authors provide a justification for assuming that the mining technology and type of machinery used did not change substantially during the period miners were exposed (ibid., p.420).

studies both reported an excess risk of lung cancer associated with dpm exposure.

The second rank is defined by semi-quantitative exposure assessments, based on job history and an estimated exposure level for each job. The exposure estimates in these studies are crude, compared to those in the first rank, and they are subject to many more kinds of error. This severely restricts the utility of these studies for QRA (i.e., for quantifying the change in risk associated with various specified exposure levels). For purposes of hazard identification and characterization, however, crude exposure estimates are better than no exposure estimates at all. MSHA places two cohort studies and five case-control studies into this category.[37] All seven of these studies reported an excess risk of lung cancer risk associated with diesel exposure. Thus, results were positive in all nine studies with quantitative or semi-quantitative exposure assessments.

The next rank belongs to those studies with only enough information on individual workers to construct estimates of exposure duration. Although these studies present no data relating excess risk to specific exposure levels, they do provide excess risk estimates for those working a specified minimum number of years in a job associated with diesel exposure. One cohort study and five case-control studies fall into this category, and all six of them reported an excess risk of lung cancer.[38] With one exception (Benhamou et al. 1988), these studies also presented evidence of increased age-adjusted risk for workers with longer exposures and/or latency periods.

The bottom rank, with respect to exposure assessment, consists of studies in which no exposure information was collected for individual workers. These studies used only job title to distinguish between exposed and unexposed workers. The remaining 32 studies, including five of the six with entirely negative results, fall into this category.

Studies basing exposure assessments on only a current job title (or even a history of job titles) are susceptible to significant misclassification of exposed and unexposed workers. Unless the study is poorly designed, this misclassification is ''nondifferential'' i.e., those who are misclassified are no more and no less likely to develop lung cancer (or to have been exposed to carcinogens such as tobacco smoke) than those who are correctly classified. If workers are sometimes misclassified nondifferentially, then this will tend to mask or dilute any excess risk attributable to exposure. Furthermore, differential misclassification in these studies usually consists of systematically including workers with little or no diesel exposure in a job category identified as ''exposed.'' This too would generally mask or dilute any excess risk attributable to exposure. Therefore, MSHA assumes that in most of these studies, more rigorous and detailed exposure assessments would have resulted in somewhat higher estimates of excess risk.

IMC Global, MARG, and some other commenters expressed special concern about potential exposure misclassification and suggested that such misclassification might be partly responsible for results showing excess risk. IMC Global, for example, quoted a textbook observation that, contrary to popular misconceptions, nondifferential exposure misclassification can sometimes bias results away from the null. MSHA recognizes that this can happen under certain special conditions. However, there is an important distinction between ''can sometimes'' and ''can frequently.'' There is an even more important distinction between ''can sometimes'' and ''in this case does.'' As noted by the HEI Expert Panel on Diesel Epidemiology (HEI, 1999, p.48), ''* * * nondifferential misclassification most often leads to an overall underestimation of effect.'' Similarly, Silverman (1998) noted, specifically with respect to the diesel studies, that ''* * * this [exposure misclassification] bias is most likely to be nondifferential, and the effect would probably have been to bias point estimates [of excess risk] toward the null value.''

Statistical Significance

A ''statistically significant'' finding is a finding unlikely to have arisen by chance in the particular group, or statistical sample, of persons being studied. An association arising by chance would have no predictive value for exposed workers outside the sample. However, a specific epidemiologic study may fail to achieve statistical significance for two very different reasons: (1) there may be no real difference in risk between the two groups being compared, or (2) the study may lack the power needed to detect whatever difference actually exists. As described earlier, a lack of sufficient power comes largely from limitations such as a small number of subjects in the sample, low exposure and/or duration of exposure, or too short a period of latency or follow-up time. Therefore, a lack of statistical significance in an individual study does not demonstrate that the results of that study were due merely to chance—only that the study (viewed in isolation) is statistically inconclusive.

As explained earlier, MSHA classifies a reported RR, SMR, or OR (i.e., the point estimate of relative risk) as ''positive'' if it exceeds 1.0 and ''negative'' if it is less than or equal to 1.0. By common convention, a positive result is considered statistically significant if its 95-percent confidence interval does not overlap 1.0. If all other relevant factors are equal, then a statistically significant positive result provides stronger evidence of an underlying relationship than one that is not statistically significant. On the other hand, a study must meet two requirements in order to provide statistically significant evidence of no positive relationship: (1) the upper limit of its 95-percent confidence interval must not exceed 1.0 by an appreciable amount[39] and (2) it must have allowed for sufficient exposure, latency, and follow-up time to have detected an existing relationship.

As shown in Tables III–4 and III–5, statistically significant positive results were reported in 25 of the 47 studies: 11 of the 19 positive case-control studies and 14 of the 22 positive cohort studies. In 16 of the 41 studies showing a positive association, the association observed was not statistically significant. Results in five of the six negative studies were not statistically significant. One of the six negative studies (Christie et al., 1995, in full version), reported a statistically significant deficit in lung cancer for miners. This study, however, provided for no minimum period of exposure or latency and, therefore, lacked the power necessary to provide statistically significant evidence.[40]

Whether or not a study provides statistically significant evidence is dependent upon many variables, such as study size, adequate follow-up time (to account for enough exposure and latency), and adequate case ascertainment. In the ideal world, a

[37] The cohort studies are Garshick et al. (1988) and Gustavsson et al. (1990). The case-control studies are Emmelin et al. (1993), Garshick et al.(1997), Gustavsson et al. (1990), Siemiatycki et al. (1988), and Steenland et al. (1990, 1992).

[38] The cohort study is Wong et al. (1985). The case-control studies are Brüske-Hohlfeld et al. (1999), Benhamou et al. (1988), Boffetta et al. (1990), Hayes et al. (1989), and Swanson et al. (1993).

[39] As a matter of practicality, MSHA places the threshold at 1.05.

[40] More detailed discussion of this study appears later in this subsection.

sufficiently powerful study that failed to demonstrate a statistically significant positive relationship would, by its very failure, provide statistically significant evidence that an underlying relationship between an exposure and a specific disease was unlikely. It is important to note that MSHA regards a real 10-percent increase in the risk of lung cancer (i.e., a relative risk of 1.1) as constituting a clearly significant health hazard. Therefore, ''sufficiently powerful'' in this context means that the study would have to be of such scale and quality as to detect a 10-percent increase in risk if it existed. The outcome of such a study could plausibly be called ''negative'' even if the estimated RR slightly exceeded 1.0—so long as the lower confidence limit did not exceed 1.0 and the upper confidence limit did not exceed 1.05. Rarely does an epidemiological study fall into this ''ideal'' study category. MSHA reviewed the dpm epidemiologic studies to determine which of them could plausibly be considered to be negative.

For example, one study (Waxweiller et al., 1973) reported positive but statistically non-significant results corresponding to an RR of about 1.1. Among the studies MSHA counts as positive, this is the one that is numerically closest to being ''negative''. This study, however, relied on a relatively small cohort containing an indeterminate but probably substantial percentage of occupationally unexposed workers. Furthermore, there was no minimum latency allowance for the exposed workers. Therefore, even if MSHA were to use 1.1 rather than 1.05 as a threshold for significant relative risk, the study had insufficient statistical power to merit ''negative'' status.

One commenter (Dr. James Weeks, representing the UMWA) argued that ''MSHA's reliance on * * * statistical significance is somewhat misplaced. Results that are not significant statistically * * * can nevertheless indicate that the exposure in question caused the outcome.'' MSHA agrees that an otherwise sound study may yield positive (or negative) results that provide valuable evidence for (or against) an underlying relationship but fail, because of an insufficient number of exposed study subjects, to achieve statistical significance. In the absence of other evidence to the contrary, a single positive but not statistically significant result could even show that a causal relationship is more likely than not. By definition, however, such a result would not be conclusive at a high level of confidence. A finding of even very high excess risk in a single, well-designed study would be far from conclusive if based on a very small number of observed lung cancer cases or if it were in conflict with evidence from toxicity studies.

MSHA agrees that evidence should not be ignored simply because it is not conclusive at a conventional but arbitrary 95-percent confidence level. Lower confidence levels may represent weaker but still important evidence. Nevertheless, to rule out chance effects, the statistical significance of individual studies merits serious consideration when only a few studies are available. That is not the case, however, for the epidemiology literature relating lung cancer to diesel exposure. Since many studies contribute to the overall weight of evidence, the statistical significance of individual studies is far less important than the statistical significance of all findings combined. Statistical significance of the combined findings is addressed in Subsection 3.a.iii of this risk assessment.

Potential Confounders

There are many variables, both known and unknown, that can potentially distort the results of an epidemiologic study. In studies involving lung cancer, the most important example is tobacco smoking. Smoking is highly correlated with the development of lung cancer. If the exposed workers in a study tend to smoke more (or less) than the population to which they are being compared, then smoking becomes what is called a ''confounding variable'' or ''confounder'' for the study. In general, any variable affecting the risk of lung cancer potentially confounds observed relationships between lung cancer and diesel exposure. Conspicuous examples are age, smoking habits, and exposure to airborne carcinogens such as asbestos or radon progeny. Diet and other lifestyle factors may also be potential confounders, but these are probably less important for lung cancer than for other forms of cancer, such as bladder cancer.

There are two ways to avoid distortion of study results by a potential confounder: (1) Design the study so that the populations being compared are essentially equivalent with respect to the potentially confounding variable; or (2) allow the confounding to take place, but adjust the results to compensate for its effects. Obviously, the second approach can be applied only to known confounders. Since no adjustment can be made for unknown confounders, it is important to minimize their effects by designing the comparison groups to be as similar as possible.

The first approach requires a high degree of control over the two groups being compared (exposed and unexposed in a cohort study; with and without lung cancer in a case-control study). For example, the effects of age in a case-control study can be controlled by matching each case of lung cancer with one or more controls having the same year of birth and age in year of diagnosis or death. Matching on age is never perfect, because it is generally not feasible to match within a day or even a month. Similarly, the effects of smoking in a case-control study can be imperfectly controlled by matching on smoking habits to the maximum extent possible.[41] In a cohort study, there is no confounding unless the exposed cohort and the comparison group differ with respect to a potential confounder. For example, if both groups consist entirely of never-smokers, then smoking is not a confounder in the study. If both groups contain the same percentage of smokers, then smoking is still an important confounder to the extent that smoking intensity and history differ between the two groups. In an attempt to minimize such differences (along with potentially important differences in diet and lifestyle) some studies restrict comparisons to workers of similar socioeconomic status and area of residence. Studies may also explicitly investigate smoking habits and histories and forego any adjustment of results if these factors are found to be homogeneously distributed across comparison groups. In that case, smoking would not actually appear to function as a confounder, and a smoking adjustment might not be required or even desirable. Nevertheless, a certain amount of smoking data is still necessary in order to check or verify homogeneity. The study's credibility may also be an important consideration. Therefore, MSHA agrees with the HEI's expert panel that even when smoking appears not to be a confounder,

> * * * a study is open to criticism if no smoking data are collected and the association between exposure and outcome is weak. * * * When the magnitude of the association of interest is weak, uncontrolled confounding, particularly from a strong confounder such as cigarette smoking, can have a major impact on the study's results and on the credibility of their use. [HEI, 1999]

However, this does not mean that a study cannot, by means of an efficient study design and/or statistical verification of homogeneity,

[41] If cases and controls cannot be closely matched on smoking or other potentially important confounder, then a hybrid approach is often taken. Cases and controls are matched as closely as possible, differences are quantified, and the study results are adjusted to account for the differences.

demonstrate adequate control for smoking without applying a smoking adjustment.

The second approach to dealing with a confounder requires knowledge or estimation both of the differences in group composition with respect to the confounder and of the effect that the confounder has on lung cancer. Ideally, this would entail specific, quantitative knowledge of how the variable affects lung cancer risk for each member of both groups being compared. For example, a standardized mortality ratio (SMR) can be used to adjust for age differences when a cohort of exposed workers with known birth dates is compared to an unexposed reference population with known, age-dependent lung cancer rates.[42] In practice, it is not usually possible to obtain detailed information, and the effects of smoking and other known confounders cannot be precisely quantified.

Stoäber and Abel (1996) argue, along with Morgan *et al.* (1997) and some commenters, that even in those epidemiologic studies that are adjusted for smoking and show a statistically significant association, the magnitude of relative or excess risk observed is too small to demonstrate any causal link between dpm exposure and cancer. Their reasoning is that in these studies, errors in the collection or interpretation of smoking data can create a bias in the results larger than any potential contribution attributable to diesel particulate. They propose that studies failing to account for smoking habits should be disqualified from consideration, and that evidence of an association from the remaining, smoking-adjusted studies should be discounted because of potential confounding due to erroneous, incomplete, or otherwise inadequate characterization of smoking histories.

It should be noted, first of all, that five of the six negative studies neither matched nor adjusted for smoking.[43] But more importantly, MSHA concurs with IARC (1989), Cohen and Higgins (1995), IPCS (1996), CAL–EPA (1998), ACGIH (1998), Bhatia et al. (1998), and Lipsett and Campleman (1999) in not accepting the view that studies should automatically be disqualified from consideration because of potential confounders. MSHA recognizes that unknown exposures to tobacco smoke or other human carcinogens can distort the results of some lung cancer studies. MSHA also recognizes, however, that it is not possible to design a human epidemiologic study that perfectly controls for all potential confounders. It is also important to note that a confounding variable does not necessarily inflate an observed association. For example, if the exposed members of a cohort smoke less than the reference group to which they are compared, then this will tend to reduce the apparent effects of exposure on lung cancer development. In the absence of evidence to the contrary, it is reasonable to assume that a confounder is equally likely to inflate or to deflate the results.

As shown in Tables III–4 and III–5, 18 of the published epidemiologic studies involving lung cancer did, in fact, control or adjust for exposure to tobacco smoke, and five of these 18 also controlled or adjusted for exposure to asbestos and other carcinogenic substances (Garshick et al., 1987; Boffetta et al., 1988; Steenland et al., 1990; Morabia et al., 1992; Brüske-Hohlfeld et al., 1999). These results are less likely to be confounded than results from most of the studies with no adjustment. All but one of these 18 studies reported some degree of excess risk associated with occupational exposure to diesel particulate, with statistically significant results reported in eight.

In addition, several of the studies with no smoking adjustment took the first approach described above for preventing or substantially mitigating potential confounding by smoking habits: they drew comparisons against internal control groups or other control groups likely to have similar smoking habits as the exposed groups (*e.g.,* Garshick et al., 1988; Gustavsson et al., 1990; Hansen, 1993; and Säverin et al., 1999). Therefore, MSHA places more weight on these studies than on studies drawing comparisons against dissimilar groups with no smoking controls or adjustments. This emphasis is in accordance with the conclusion by Bhatia et al. (1998) that smoking homogeneity typically exists within cohorts and is associated with a uniform lifestyle and social class. Although it was not yet available at the time Bhatia et al. performed their analysis, an analysis of smoking patterns by Säverin et al. (op cit.) within the cohort they studied also supports this conclusion.

IMC Global and MARG objected to MSHA's position on potential confounders and submitted comments in general agreement with the views of Morgan et al. (op cit.) and Stöbel and Abel (op cit.). Specifically, they suggested that studies reporting relative risks solely between 1.0 and 2.0 should be discounted because of potential confounders. Of the 41 positive studies considered by MSHA, 22 fall into this category (16 cohort and 6 case-control). In support of their suggestion, IMC Global quoted Speizer (1986), Muscat and Wynder (1995), Lee (1989), WHO (1980), and NCI (1994). These authorities all urged great caution when interpreting the results of such studies, because of potential confounders. MSHA agrees that none of these studies, considered individually, is conclusive and that each result must be considered with due caution. None of the quoted authorities, however, proposed that such studies should automatically be counted as ''negative'' or that they could not add incrementally to an aggregate body of positive evidence.

IMC Global also submitted the following reference to two Federal Court decisions pertaining to estimated relative risks less than 2.0:

> The Ninth Circuit concluded in Daubert v. Merrell Dow Pharmaceuticals'' that ''for an epidemiologic study to show causation * * * the relative risk * * * arising from the epidemiologic data will, at a minimum, have to exceed 2.'' Similarly, a District Court stated in Hall v. Baxter Healthcare Corp.49: The threshold for concluding that an agent was more likely the cause of the disease than not is relative risk greater than 2.0. Recall that a relative risk of 1.0 means that the agent has no affect on the incidence of disease. When the relative risk reaches 2.0. the agent is responsible for an equal number of cases of disease as all other background causes. Thus a relative risk of 2.0 implies a 50% likelihood that an exposed individual's disease was caused by the agent. [IMC Global]

In contrast with the two cases cited, the purpose of this risk assessment is not to establish civil liabilities for personal injury. MSHA's concern is with reducing the risk of lung cancer, not with establishing the specific cause of lung cancer for an individual miner. The excess risk of an outcome, given an excessive exposure, is not the same thing as the likelihood that an excessive exposure caused the outcome in a given case. To understand the difference, it may be helpful to consider two analogies: (1) The likelihood that a given death was caused by a lightning strike is relatively low, yet exposure to lightning is rather hazardous; (2) a specific smoker may not be able to prove that his or her lung cancer was

[42] Since these rates may vary by race, geographic region, or other factors, the validity of this adjustment depends heavily on choice of an appropriate reference population. For example, Waxweiler et al. (1973) based SMRs for a New Mexico cohort on national lung cancer mortality rates. Since the national age-adjusted rate of lung cancer is about ⅓ higher than the New Mexico rate, the reported SMRs were roughly ¾ of what they would have been if based on rates specific to New Mexico.

[43] The exception is DeCoufle *et al.* (1977), a case-control study that apparently did not match or otherwise adjust for age.

''more likely than not'' caused by radon exposure, yet radon exposure significantly increases the risk—especially for smokers. Lung cancer has a variety of alternative causes, but this fact does not reduce the risk associated with any one of them.

Furthermore, there is ample precedent for utilizing epidemiologic studies reporting relative risks less than 2.0 in making clinical and public policy decisions. For example, the following table contains the RR for death from cardiovascular disease associated with cigarette smoking reported in several prospective epidemiologic studies:

Study on cigarette smoking	Estimate of RR of death from cardiovascular disease
British doctors	1.6
Males in 25 states:	
Ages 45–64	2.08
Ages 65–79	1.36
U.S. Veterans	1.74
Japanese study	1.96
Canadian veterans	1.6
Males in nine states	1.70
Swedish males	1.7
Swedish females	1.3
California occupations	2.0

Source: U.S. Department of Health and Human Services (1989).

By IMC Global's rule of thumb, all but one or two of these studies would be discounted as evidence of increased risk attributable to smoking. These studies, however, have not been widely discounted by scientific authorities. To the contrary, they have been instrumental in establishing that cigarette smoking is a principal cause of heart disease.

A second example is provided by the increased risk of lung cancer found to be caused by residential exposure to radon progeny. As in the case of dpm, tobacco smoking has been an important potential confounder in epidemiological studies used to investigate whether exposures to radon concentrations at residential levels can cause lung cancer. Yet, in the eight largest residential epidemiological studies used to help establish the reality of this now widely accepted risk, the reported relative risks were all less than 2.0. Based on a meta-analysis of these eight studies, the combined relative risk of lung cancer attributable to residential radon exposure was 1.14. This elevation in the risk of lung cancer, though smaller than that reported in most studies of dpm effects, was found to be statistically significant at a 95-percent confidence level (National Research Council, 1999, Table G–25).

(ii) Studies Involving Miners

In the proposed risk assessment, MSHA identified seven epidemiologic studies reporting an excess risk of lung cancer among miners thought to have been exposed occupationally to diesel exhaust. As stated in the proposal, two of these studies specifically investigated miners, and the other five treated miners as a subgroup within a larger population of workers.[44] MSHA placed two additional studies specific to exposed coal miners (Christie et al., 1995; Johnston et al.,1997) into the public record with its Feb. 12, 1999 **Federal Register** notice. Another study,[45] investigating lung cancer in exposed potash miners, was introduced by NIOSH at the Knoxville public hearing on May 27, 1999 and later published as Säverin et al., 1999. Finally, one study reporting an excess risk of lung cancer for presumably exposed miners was listed in Table III–5 as originally published, and considered by MSHA in its overall assessment, but inadvertently left out of the discussion on studies involving miners in the previous version of this risk assessment.[46] There are, therefore, available to MSHA a total of 11 epidemiologic studies addressing the risk of lung cancer for miners, and five of these studies are specific to miners.

Five cohort studies (Waxweiler et al.,1973; Ahlman et al., 1991; Christie et al., 1996; Johnston et al., 1997; Saverin et al., 1999) were performed specifically on groups of miners, and one (Boffetta et al., 1988) addressed miners as a subgroup of a larger population. Except for the study by Christie et al., the cohort studies all showed elevated lung cancer rates for miners in general or for the most highly exposed miners within a cohort. In addition, all five case-control studies reported elevated rates of lung cancer for miners (Benhamou et al.,1988; Lerchen et al., 1987; Siemiatycki et al.,1988; Morabia et al., 1992; Burns and Swanson, 1991).

Despite the risk assessment's emphasis on human studies, some members of the mining community apparently believed that the risk assessment relied primarily on animal studies and that this was because studies on miners were unavailable. Canyon Fuels, for example, expressed concerns about relying on animal studies instead of studies on western diesel-exposed miners:

> Since there are over a thousand miners here in the West that have fifteen or more years of exposure to diesel exhaust, why has there been no study of the health status of those miners? Why must we rely on animal studies that are questionable and inconclusive?

Actually, western miners were involved in several studies of health effects other than cancer, as described earlier in this risk assessment. With respect to lung cancer, there are many reasons why workers from a particular group of mines might not be selected for study. Lung cancer often takes considerably more than 15 years to develop, and a valid study must allow not only for adequate duration of exposure but also for an adequate period of latency following exposure. Furthermore, many mines contain radioactive gases and/or

[44] In the proposed risk assessment, the studies identified as specifically investigating miners were Waxweiler et al. (1973) and Ahlman et al. (1991). At the Albuquerque public hearing, Mr. Bruce Watzman, representing the NMA, asked a member of the MSHA panel (Mr. Jon Kogut) to list six studies involving miners that he had cited earlier in the hearing and to identify those that were specific to miners. In both his response to Mr. Watzman, and in his earlier remarks, Mr. Kogut noted that the studies involving miners were listed in Tables III–4 and III–5. However, he inadvertently neglected to mention Ahlman et al. (op cit.) and Morabia et al. (1992). (The latter study addressed miners as a subgroup of a larger population.)

In his response to Mr. Watzman, Mr. Kogut cited Swanson et al. (1993) but not Burns and Swanson (1991), which he had mentioned earlier in the hearing in connection with the same study. These two reports are listed under a single entry in Table III–5 (Swanson et al.) because they both report findings based on the same body of data. Therefore, MSHA considers them to be two parts of the same study. The 5.03 odds ratio for mining machine operators mentioned by Mr. Kogut during the hearing was reported in Burns and Swanson (1991).

Only the six studies specified by Mr. Kogut in his response to Mr. Watzman were included in separate critiques by Dr. Peter Valberg and Dr. Jonathan Borak later submitted by the NMA and by MARG, respectively. Dr. Valberg did not address Burns and Swanson (1991), and he addressed a different report by Siemiatycki than the one listed in Table III–5 and cited during the hearing (i.e., Siemiatycki et al., 1988). Neither Dr. Valberg nor Dr. Borak addressed Ahlman et al. (op cit.) or Morabia et al. (op cit.). Also excluded were two additional miner-specific studies placed into the record on Feb. 12, 1999 (Fed Reg. 64:29 at 59258). Mr. Kogut did not include them in his response to Mr. Watzman, or in his prior remarks, because he was referring only to studies listed in Tables III–4 and III–5 of the published proposals. Mr. Kogut also did not include a study specific to German potash miners submitted by NIOSH at a subsequent public hearing, and this too was left out of both critiques. A published version of the study (Säverin et al., 1999) was placed into the record on June 30, 2000. All of the studies involving miners are in the public record and have been available for comment by interested parties throughout the posthearing comment periods.

[45] Some commenters suggested that MSHA ''overlooked'' a recently published study on NSW miners, Brown et al., 1997. This study evaluated the occurrence of forms of cancer other than lung cancer in the same cohort studied by Christie et al. (1995).

[46] This study was published in two separate reports on the same body of data: Burns and Swanson (1991) and Swanson et al. (1993). Both published reports are listed in Table III–5 under the entry for Swanson et al.

respirable silica dust, making it difficult to isolate the effects of a potential carcinogen.

Similarly, at the public hearing in Albuquerque on May 13, 1999, a representative of Getchell Gold stated that he thought comparing miners to rats was irrational and that ''there has not been a study on these miners as to what the effects are.'' To correct the impression that MSHA was basing its risk assessment primarily on laboratory animal studies, an MSHA panelist pointed out Tables III–4 and III–5 of the proposed preamble and identified six studies pertaining to miners that were listed in those tables. However, he placed no special weight on these studies and cited them only to illustrate the existence of epidemiologic studies reporting an elevated risk of lung cancer among miners.

With their post-hearing comments, the NMA and MARG submitted critiques by Dr. Peter Valberg and Dr. Jonathan Borak of six reports involving miners (see Footnote 42). Drs. Valberg and Borak both noted that the six studies reviewed lacked information on diesel exposure and were vulnerable to confounders and exposure misclassification. For these reasons, Dr. Valberg judged them ''particularly poor in identifying what specific role, if any, diesel exhaust plays in lung cancer for miners.'' He concluded that they do not ''implicate diesel exposure per se as strongly associated with lung cancer risk in miners.'' Similarly, Dr. Borak suggested that, since they do not relate adverse health effects in miners to any particular industrial exposure, ''the strongest conclusion that can be drawn from these six studies is that the miners in the studies had an increased risk of lung cancer.''

MSHA agrees with Drs. Valberg and Borak that none of the studies they reviewed provides direct evidence of a link between dpm exposure and the excess risk of lung cancer reported for miners. (A few disagreements on details of the individual studies will be discussed below). As MSHA said at the Albuquerque hearing, the lack of exposure information on miners in these studies led MSHA to rely more heavily on associations reported for other occupations. MSHA also noted the limitations of these studies in the proposed risk assessment. MSHA explicitly stated that other epidemiologic studies exist which, though not pertaining specifically to mining environments, contain better diesel exposure information and are less susceptible to confounding by extraneous risk factors.

Inconclusive as they may be on their own, however, even studies involving miners with only presumed or sporadic occupational diesel exposure can contribute something to the weight of evidence. They can do this by corroborating evidence of increased lung cancer risk for other occupations with likely diesel exposures and by providing results that are at least consistent with an increased risk of lung cancer among miners exposed to dpm. Moreover, two newer studies pertaining specifically to miners do contain dpm exposure assessments based on concurrent exposure measurements (Johnston *et al.,* op cit.; Säverin et al.,op cit.). The major limitations pointed out by Drs. Valberg and Borak with respect to other studies involving miners do not apply to these two studies.

Case-Control Studies

Five case-control studies, all of which adjusted for smoking, found elevated rates of lung cancer for miners, as shown in Table III–5. The results for miners in three of these studies (Benhamou *et al.,* 1988; Morabia *et al.,* 1992; Siemiatycki *et al.,* 1988) are given little weight, partly because of possible confounding by occupational exposure to radioactive gasses, asbestos, and silica dust. Also, Benhamou and Morabia did not verify occupational diesel exposure status for the miners. Siemiatycki performed a large number of multiple comparisons and reported that most of the miners ''were exposed to diesel exhaust for short periods of time,'' Lerchen *et al.* (1987) showed a marginally significant result for underground non-uranium miners, but cases and controls were not matched on date of birth or death, and the frequency of diesel exposure and exposure to known occupational carcinogens among these miners was not reported.

Burns and Swanson (1991) [47] reported elevated lung cancer risk for miners and especially mining machine operators, which the authors attributed to diesel exposure. Potential confounding by other carcinogens associated with mining make the results inconclusive, but the statistically significant odds ratio of 5.0 reported for mining machine operators is high enough to cause concern with respect to diesel exposures, especially in view of the significantly elevated risks reported in the same study for other diesel-exposed occupations. The authors noted that the ''occupation most likely to have high levels of continuous exposure to diesel exhaust and to experience that exposure in a confined area has the highest elevated risks: mining machine operators.''

Cohort Studies

As shown in Table III–4, MSHA identified six cohort studies reporting results for miners likely to have been exposed to dpm. An elevated risk of lung cancer was reported in five of these six studies. These results will be discussed chronologically.

Waxweiller (1973) investigated a cohort of underground and surface potash miners. The authors noted that potash ore ''is not embedded in siliceous rock'' and that the ''radon level in the air of potash mines is not significantly higher than in ambient air.'' Contrary to Dr. Valberg's review of this study, the number of lung cancer cases was reported to be slightly higher than expected, for both underground and surface miners, based on lung cancer rates in the general U.S. population (after adjustment for age, sex, race, and date of death). Although the excess was not statistically significant, the authors noted that lung cancer rates in the general population of New Mexico were about 25 percent lower than in the general U.S. population. They also noted that a higher than average percentage of the miners smoked and that this would ''tend to counterbalance'' the adjustment needed for geographic location. The authors did not, however, consider two other factors that would tend to obscure or deflate an excess risk of lung cancer, if it existed: (1) A healthy worker effect and (2) the absence of any occupational diesel exposure for a substantial percentage of the underground miners.

MSHA agrees with Dr. Valberg's conclusion that ''low statistical power and indeterminate diesel-exhaust exposure render this study inadequate for assessing the effect of diesel exhaust on lung-cancer risk in miners.'' However, given the lack of any adjustment for a healthy worker effect, and the likelihood that many of the underground miners were occupationally unexposed, MSHA views the slightly elevated risk reported in this study as consistent with other studies showing significantly greater increases in risk for exposed workers.

Boffetta et al. (1988) investigated mortality in a cohort of male volunteers who enrolled in a prospective study conducted by the American Cancer Society. Lung cancer mortality was analyzed in relation to self-reported diesel exhaust exposure and to employment in various occupations

[47] This report is listed in Table III–5 under Swanson *et al.* (1993), which provides further analysis of the same body of data.

identified with diesel exhaust exposure, including mining. After adjusting for smoking patterns,[48] there was a statistically significant excess of 167 percent (RR = 2.67) in lung cancers among 2034 workers ever employed as miners, compared to workers never employed in occupations associated with diesel exposure. No analysis by type of mining was reported. Other findings reported from this study are discussed in the next subsection.

Although an adjustment was made for smoking patterns, the relative risk reported for mining did not control for exposures to radioactive gasses, silica dust, and asbestos. These lung carcinogens are probably present to a greater extent in mining environments than in most of the occupational environments used for comparison. Self-reported exposures to asbestos and stone dusts were taken into account in other parts of the study, but not in the calculation of excess lung cancer risks associated with specific occupations, including mining.

Several commenters reiterated two caveats expressed by the study's authors and noted in Table III–4. These are (1) that the study is susceptible to selection biases because participants volunteered and because the age-adjusted mortality rates differed between those who provided exposure information and those who did not; and (2) that all exposure information was self-reported with no quantitative measurements. Since these caveats are not specific to mining and pertain to most of the study's findings, they will be addressed when this study's overall results are described in the next subsection.

One commenter, however (Mr. Mark Kaszniak of IMC Global), argued that selection bias due to unknown diesel exposure status played an especially important role in the RR calculated for miners. About 21 percent of all participants provided no diesel exposure information. Mr. Kaszniak noted that diesel exposure status was unknown for an even larger percentage of miners and suggested that the RR calculated for miners was, therefore, inflated. He presented the following argument:

In the miner category, this [unknown diesel exposure status] accounted for 44.2% of the study participants, higher than any other occupation studied. This is important as this group experienced a higher mortality for all causes as well as lung cancer than the analyzed remainder of the cohort. If these persons had been included in the ''no exposure to diesel exhaust group,'' their inclusion would have lowered any risk estimates from diesel exposure because of their higher lung cancer rates. [IMC Global post-hearing comments]

This argument, which was endorsed by MARG, was apparently based on a misunderstanding of how the comparison groups used to generate the RR for mining were defined.[49] Actually, persons with unknown diesel exposure status were included among the miners, but excluded from the reference population. Including sometime miners with unknown diesel exposure status in the ''miners'' category would tend to mask or reduce any strong association that might exist between highly exposed miners and an increased risk of lung cancer. Excluding persons with unknown exposure status from the reference population had an opposing effect, since they happened to experience a higher rate of lung cancer than cohort members who said they were unexposed. Therefore, removing ''unknowns'' from the ''miner'' group and adding them to the reference group could conceivably shift the calculated RR for miners in either direction. However, the RR reported for persons with unknown diesel exposure status, compared to unexposed persons, was 1.4 (ibid., p. 412)—which is smaller than the 2.67 reported for miners. Therefore, it appears more likely that the RR for mining was deflated than inflated on account of persons with unknown exposure status.

Although confounders and selection effects may have contributed to the 2.67 RR reported for mining, MSHA believes this result was high enough to support a dpm effect, especially since elevated lung cancer rates were also reported for the three other occupations associated with diesel exhaust exposure. Dr. Borak stated without justification that ''[the] association between dpm and lung cancer was confounded by age, smoking, and other occupational exposures * * *.'' He ignored the well-documented adjustments for age and smoking. Although it does not provide strong or direct evidence that dpm exposure was responsible for any of the increased risk of lung cancer observed among miners, the RR for miners is consistent with evidence provided by the rest of the study results.

Ahlman et al. (1991) studied cohorts of 597 surface miners and 338 surface workers employed at two sulfide ore mines using diesel powered front-end loaders and haulage equipment. Both of these mines (one copper and one zinc) were regularly monitored for alpha energy concentrations (i.e., due to radon progeny), which were at or below the Finish limit of 0.3 WL throughout the study period. The ore in both mines contained arsenic only as a trace element (less than 0.005 percent). Lung cancer rates in the two cohorts were compared to rates for males in the same province of Finland. Age-adjusted excess mortality was reported for both lung cancer and cardiovascular disease among the underground miners, but not among the surface workers. None of the underground miners who developed lung cancer had been occupationally exposed to asbestos, metal work, paper pulp, or organic dusts. Based on the alpha energy concentration measurements made for the two mines, the authors calculated that not all of the excess lung cancer for the underground miners was attributable to radon exposure. Based on a questionnaire, the authors found similar underground and surface age-specific smoking habits and alcohol consumption and determined that ''smoking alone cannot explain the difference in lung cancer mortality between the [underground] miners and surface workers. Due to the small size of the cohort, the excess lung cancer mortality for the underground miners was not statistically significant. However, the authors concluded that the portion of excess lung cancer not attributable to radon exposure could be explained by the combined effects of diesel exhaust and silica exposure. Three of the ten lung cancers reported for underground miners were experienced by conductors of diesel-powered ore trains.

Christie et al. (1994, 1995) studied mortality in a cohort of 23,630 male Australian (New South Wales, NSW)

[48] During the public hearing on May 25, 1999, Mr. Mark Kaszniak of IMC Global incorrectly asserted that ''smoking was treated in a simplistic way in this study by using three categories: smokers, ex-smokers, and non-smokers.'' The study actually used five categories, dividing smokers into separate categories for 1–20 cigarettes per day, 21 or more cigarettes per day, and exclusively pipe and/or cigar smoking.

[49] During the public hearing on May 25, 1999, Mr. Kaszniak stated his belief that, for miners, the ''relative risk calculation excluded that 44% of folks who did not respond to the questionnaire with regards to diesel exposure.'' Contrary to Mr. Kaszniak's belief, however, the ''miners'' on which the 2.67 RR was based included all 2034 cohort members who had ever been a miner, regardless of whether they had provided diesel exposure information (see Boffetta et al., 1988, p. 409).

Furthermore, the 44.2-percent nonrespondent figure is not pertinent to potential selection bias in the RR calculation reported for miners. The group of 2034 ''sometime'' miners used in that calculation was 65 percent larger than the group of 1233 ''mainly'' miners to which the 44-percent nonrespondent rate applies. The reference group used for comparison in the calculation consisted of all cohort members ''with occupation different from those listed [i.e., railroad workers, truck drivers, heavy equipment operators, and miners] and not exposed [to diesel exhaust].'' The overall nonrespondent rate for occupations in the reference group was about 21 percent (calculated by MSHA from Table VII of Boffetta et al., 1988).

coal mine workers who entered the industry after 1972. Although the majority of these workers were underground miners, most of whom were presumably exposed to diesel emissions, the cohort included office workers and surface (''open cut'') miners. The cohort was followed up through 1992. After adjusting for age, death rates were lower than those in the general male population for all major causes except accidents. This included the mortality rate for all cancers as a group (Christie et al., 1995, Table 1). Lower-than-normal incidence rates were also reported for cancers as a group and for lung cancer specifically (Christie et al., 1994, Table 10).

The investigators noted that the workers included in the cohort were all subject to pre-employment physical examinations. They concluded that ''it is likely that the well known 'healthy worker' effect * * * was operating'' and that, instead of comparing to a general population, ''a more appropriate comparison group is Australian petroleum industry workers.'' (Christie et al., 1995) In contrast to the comparison with the population of NSW, the all-cause standardized mortality ratio (SMR) for the cohort of coal miners was greater than for petroleum workers by a factor of over 20 percent—i.e., 0.76 vs. 0.63 (ibid., p. 20). However, the investigators did not compare the cohort to petroleum workers specifically with respect to lung cancer or other causes of death. Nor did they adjust for a healthy worker effect or make any attempt to compare mortality or lung cancer rates among workers with varying degrees of diesel exposure within the cohort.

Despite the elevated SMR relative to petroleum workers, several commenters cited this study as evidence that exposure to diesel emissions was not causally associated with an increased risk of lung cancer (or with adverse health effects associated with fine particulates). These commenters apparently ignored the investigators' explanation that the low SMRs they reported were likely due to a healthy worker effect. Furthermore, since the cohort exhibited lower-than-normal mortality rates due to heart disease and non-cancerous respiratory disease, as well as to cancer, there may well have been less tobacco smoking in the cohort than in the general population. Therefore, it is reasonably likely that the age-adjusted lung cancer rate would have been elevated, if it had been adjusted for smoking and for a healthy worker effect based on mortality from causes other than accidents or respiratory disease. In addition, the cohort SMR for accidents (other than motor vehicle accidents) was significantly above that of the general population. Since the coal miners experienced an elevated rate of accidental death, they had a lower-than-normal chance to die from other causes or to develop lung cancer. The investigators made no attempt to adjust for the competing, elevated risk of death due to occupational accidents.

Given the lack of any adjustment for smoking, healthy worker effect, or the competing risk of accidental death, the utility of this study in evaluating health consequences of Dpm exposure is severely limited by its lack of any internal comparisons or comparisons to a comparable group of unexposed workers. Furthermore, even if such adjustments or comparisons were made, several other attributes of this study limit its usefulness for evaluating whether exposure to diesel emissions is associated with an increased risk of lung cancer. First, the study was designed in such a way as to allow inadequate latency for a substantial portion of the cohort. Although the cohort was followed up only through 1992, it includes workers who entered the workforce at the end of 1992. Therefore, there is no minimum duration of occupational exposure for members of the cohort. Approximately 30 percent of the cohort was employed in the industry for less than 10 years, and the maximum duration of employment and latency combined was 20 years. Second, average age for members of the cohort was only 40 to 50 years (Christie et al., p. 7), and the rate of lung cancer was based on only 29 cases. The investigators acknowledged that ''it is a relatively young cohort'' and that ''this means a small number of cancers available for analysis, because cancer is more common with advancing age * * *.'' They further noted that ''* * * the number of cancers available for analysis is increasing very rapidly. As a consequence, every year that passes makes the cancer experience of the cohort more meaningful in statistical terms.'' (ibid., p. 27) Third, miners's work history was not tracked in detail, beyond identifying the first mine in which a worker was employed. Some of these workers may have been employed, for various lengths of time, in both underground and surface operations at very different levels of diesel exposure. Without detailed work histories, it is not possible to construct even semi-quantitative measures of diesel exposure for making internal comparisons within the cohort.

One commenter (MARG) claimed that this (NSW) study ''* * * reflects the latest and best scientific evidence, current technology, and the current health of miners'' and that it ''is not rational to predicate regulations for the year 2000 and beyond upon older scientific studies * * *.'' For the reasons stated above, MSHA believes, to the contrary, that the NSW study contributes little or no information on the potential health effects of long-term dpm exposures and that whatever information it does contribute does not extend to effects, such as cancer, expected in later life.

Furthermore, three even more recent studies are available that MSHA regards as far more informative for the purposes of the present risk assessment. Unlike the NSW study, these directly address Dpm exposure and the risk of lung cancer. Two of these studies (Johnston et al., 1997; Säverin et al., 1999), both incorporating a quantitative Dpm exposure assessment, were carried out specifically on mining cohorts and will be discussed next. The third (Brüske-Hohlfeld et al., 1999) is a case-control study not restricted to miners and will be discussed in the following subsection. In accordance with MARG's emphasis on the timeliness of scientific studies, MSHA places considerable weight on the fact that all three—the most recent epidemiologic studies available—reported an association between diesel exposure and an increased risk of lung cancer.

Johnston et al. (1997) studied a cohort of 18,166 coal miners employed in ten British coal mines over a 30-year period. Six of these coal mines used diesel locomotives, and the other four were used for comparison. Historical NO_X and respirable dust concentration measurements were available, having routinely been collected for monitoring purposes. Two separate approaches were taken to estimate dpm exposures, leading to two different sets of estimates. The first approach was based on NO_X measurements, combined with estimated ratios between dpm and NO_X. The second approach was based on complex calculations involving measurements of total respirable dust, ash content, and the ratio of quartz to dust for diesel locomotive drivers compared to the ratio for face workers (ibid., Figure 4.1 and pp 25–46). These calculations were used to estimate dpm exposure concentrations for the drivers, and the estimates were then combined with traveling times and dispersion rates to form estimates of dpm concentration levels for other occupational groups. In four of the six dieselized mines, the NO_X-based and dust-based estimates of dpm were in generally good agreement, and they

were combined to form time-independent estimates of shift average dpm concentration for individual seams and occupational groups within each mine. In the fifth mine, the PFR measurements were judged unreliable for reasons extensively discussed in the report, so the NO_X-based estimates were used. There was no NO_X exposure data for the sixth mine, so they used dust-based estimates of dpm exposure.

Final estimates of shift-average dpm concentrations ranged from 44 μg/m³ to 370 μg/m³ for locomotive drivers and from 1.6 μg/m³ to 40 μg/m³ for non-drivers at various mines and work locations (ibid.,Tables 8.3 and 8.6, respectively). These were combined with detailed work histories, obtained from employment records, to provide an individual estimate of cumulative dpm exposure for each miner in the cohort. Although most cohort members (including non-drivers) had estimated cumulative exposures less than 1 g-hr/m³, some members had cumulative exposures that ranged as high as 11.6 g-hr/m³ (ibid., Figure 9.1 and Table 9.1).

A statistical analysis (time-dependent proportional hazards regression) was performed to examine the relationship between lung cancer risk and each miner's estimated cumulative dpm exposure (unlagged and lagged by 15 years), attained age, smoking habit, mine, and cohort entry date. Smoking habit was represented by non-smoker, ex-smoker, and smoker categories, along with the average number of cigarettes smoked per day for the smokers. Pipe tobacco consumption was expressed by an equivalent number of cigarettes per day.

In their written comments, MARG and the NMA both mischaracterized the results of this study, apparently confusing it with a preliminary analysis of the same cohort. The preliminary analysis (one part of what Johnston et al. refer to as the ''wider mortality study'') was summarized in Section 1.2 (pp 3–5) of the 105-page report at issue, which may account for the confusion by MARG and the NMA.[50]

Contrary to the MARG and NMA characterization, Johnston et al. found a positive, quantitative relationship between cumulative dpm exposure (lagged by 15 years) and an excess risk of lung cancer, after controlling for age, smoking habit, and cohort entry date. For each incremental g-hr/m³ of cumulative occupational dpm exposure, the relative risk of lung cancer was estimated to increase by a factor of 22.7 percent. Adjusting for mine-to-mine differences that may account for a portion of the elevated risk reduced the estimated RR factor to 15.6 percent. Therefore, with the mine-specific adjustment, the estimated RR was 1.156 per g-hr/m³ of cumulative dpm exposure. It follows that, based on the mine-adjusted model, the estimated RR for a specified cumulative exposure is 1.156 raised to a power equal to that exposure. For example, RR = $(1.156)^{3.84}$ = 1.74 for a cumulative dpm exposure of 3.84 g-hr/m³, and RR = $(1.156)^{7.68}$ = 3.04 for a cumulative dpm exposure of 7.68 g-hr/m³.[51] Estimates of RR based on the mine-unadjusted model would substitute 1.227 for 1.156 in these calculations.

Two limitations of this study weaken the evidence it presents of an increasing exposure-response relationship. First, although the exposure assessment is quantitative and carefully done, it is indirect and depends heavily on assumptions linking surrogate measurements to dpm exposure levels. The authors, however, analyzed sources of inaccuracy in the exposure assessment and concluded that ''the similarity between the estimated * * * [dpm] exposure concentrations derived by the two different methods give some degree of confidence in the accuracy of the final values * * *.'' (ibid., pp. 71–75) Second, the highest estimated cumulative dpm exposures were clustered at a single coal mine, where the SMR was elevated relative to the regional norm. Therefore, as the authors pointed out, this one mine greatly influences the results and is a possible confounder in the study. The investigators also noted that this mine was ''* * * found to have generally the higher exposures to respirable quartz and low level radiation.'' Nevertheless, MSHA regards it likely that the relatively high dpm exposures at this mine were responsible for at least some of the excess mortality. There is no apparent way, however, to ascertain just how much of the excess mortality (including lung cancer) at this coal mine should be attributed to high occupational dpm exposures and how much to confounding factors distinguishing it (and the employees working there) from other mines in the study.

The RR estimates based on the mine-unadjusted model assume that the excess lung cancer observed in the cohort is entirely attributable to dpm exposures, smoking habits, and age distribution. If some of the excess lung cancer is attributed to other differences between mines, then the dpm effect is estimated by the lower RR based on the mine-adjusted model.

For purposes of comparison with the findings of Säverin et al.(1999), it will be useful to calculate the RR for a cumulative dpm exposure of 11.7 g-hr/m³ (i.e., the approximate equivalent of 4.9 mg-yr/m³ TC).[52] At this exposure level, the mine-unadjusted model produces an estimated RR = $(1.227)^{11.7}$ = 11, and the mine-adjusted model produces an estimated RR = $(1.156)^{11.7}$ = 5.5.

Säverin et al. (1999) studied a cohort of male potash miners in Germany who had worked underground for at least one year after 1969, when the mines involved began converting to diesel powered vehicles and loading equipment. Members of the cohort were selected based on company medical records, which also provided bi-annual information on work location for each miner and, routinely after 1982, the miner's smoking habits. After excluding miners whose workplace histories could not be reconstructed from the medical records (5.5 percent) and miners lost to follow-up (1.9 percent), 5,536 miners remained in the cohort. Within this full cohort, the authors defined a sub-cohort consisting of 3,258 miners who had ''worked underground for at least ten years, held one single job during at least 80% of their underground time, and held not more than three underground jobs in total.''

The authors divided workplaces into high, medium, and low diesel exposure categories, respectively corresponding

[50] Since MARG and the NMA both stressed the importance of a quantitative exposure assessment, it is puzzling that they focused on a crude SMR from the preliminary analysis and ignored the quantitative results from the subsequent analysis. Johnston et al. noted that SMRs from the preliminary analysis were consistent ''with other studies of occupational cohorts where a healthy worker effect is apparent.'' But even the preliminary analysis explored a possible surrogate exposure-response relationship, rather than simply relying on SMRs. Unlike the analysis by Johnston et al., the preliminary analysis used travel time as a surrogate measure of dpm exposure and made no attempt to further quantify dpm exposure concentrations. (ibid.,p.5)

[51] Assuming an average dpm concentration of 200 μg/m³ and 1920 work hours per year, 3.84 g-hr/m³ and 7.68 g-hr/m³ correspond to 10 and 20 years of occupational exposure, respectively.

[52] This value represents 20 years of cumulative exposure for the most highly exposed category of workers in the cohort studied by Säverin et al.

As explained elsewhere in this preamble, TC constitutes approximately 80 percent of total dpm. Therefore, the TC value of 4.9 mg-yr/m³ presented by Säverin et al. must first be divided by 0.8 to produce a corresponding dpm value of 6.12 mg-yr/m³. To convert this result to the units used by Johnston et al., it is then multiplied by 1920 work hours per year and divided by 1000 mg/g to yield 11.7 g-hr/m³. This is nearly identical to the maximum cumulative dpm exposure estimated for locomotive drivers in the study by Johnston et al. (See Johnston et al., op cit., Table 9.1.)

to production, maintenance, and workshop areas of the mine. Each of these three categories was assigned a representative respirable TC concentration, based on an average of measurements made in 1992. These averages were 390 μg/m³ for production, 230 μg/m³ for maintenance, and 120 μg/m³ for workshop. Some commenters expressed concern about using average exposures from 1992 to represent exposure throughout the study. The authors justified using these measurement averages to represent exposure levels throughout the study period because ''the mining technology and the type of machinery used did not change substantially after 1970.'' This assumption was based on interviews with local engineers and industrial hygienists.

Thirty-one percent of the cohort consented to be interviewed, and information from these interviews was used to validate the work history and smoking data reconstructed from the medical records. The TC concentration assigned to each work location was combined with each miner's individual work history to form an estimate of cumulative exposure for each member of the cohort. Mean duration of exposure was 15 years. As of the end of follow-up in 1994, average age was 49 years, average time since first exposure was 19 years, and average cumulative exposure was 2.70 mg-y/m³.

The authors performed an analysis (within each TC exposure category) of smoking patterns compared with cumulative TC exposure. They also analyzed smoking misclassification as estimated by comparing information from the interviews with medical records. From these analyses, the authors determined that the cohort was homogeneous with respect to smoking and that a smoking adjustment was neither necessary nor desirable for internal comparisons. However, they did not entirely rule out the possibility that smoking effects may have biased the results to some extent. On the other hand, the authors concluded that asbestos exposure was minor and restricted to jobs in the workshop category, with negligible effects. The miners were not occupationally exposed to radon progeny, as documented by routine measurement records.

As compared to the general male population of East Germany, the cohort SMR for all causes combined was less than 0.6 at a 95-percent confidence level. The authors interpreted this as demonstrating a healthy worker effect, noting that ''underground workers are heavily selected for health and sturdiness, making any surface control group incomparable.'' Accordingly, they performed internal comparisons within the cohort of underground miners. The RR reported for lung cancer among miners in the high-exposure production category, compared to those in the low-exposure workshop category, was 2.17. The corresponding RR was not elevated for other cancers or for diseases of the circulatory system.

Two statistical methods were used to investigate the relationship between lung cancer RR and each miner's age and cumulative TC exposure: Poisson regression and time-dependent proportional hazards regression. These two statistical methods were applied to both the full cohort and the subcohort, yielding four different estimates characterizing the exposure-response relationship. Although a high confidence level was not achieved, all four of these results indicated that the RR increased with increasing cumulative TC exposure. For each incremental mg-yr/m³ of occupational TC exposure, the relative risk of lung cancer was estimated to increase by the following multiplicative factor: [53]

Method	RR per mg-yr/m³	
	Full cohort	Sub-cohort
Poisson	1.030	1.139
Proportional Hazards	1.112	1.225

Based on these estimates, the RR for a specified cumulative TC exposure (X) can be calculated by raising the tabled value to a power equal to X. For example, using the proportional hazards analysis of the subcohort, the RR for X = 3.5 mg-yr/m³ is $(1.225)^{3.5} = 2.03$.[54] The authors calculated the RR expected for a cumulative TC exposure of 4.9 mg-yr/m³, which corresponds to 20 years of occupational exposure for miners in the production category of the cohort. These miners were exposed for five hours per 8-hour shift at an average TC concentration of 390 μg/m³. The resulting RR values were reported as follows:

Method	RR for 4.9 mg-yr/m³	
	Full cohort	Sub-cohort
Poisson	1.16	1.89
Proportional Hazards	1.68	2.70

This study has two important limitations that weaken the evidence it presents of a positive correlation between cumulative TC exposure and the risk of lung cancer. These are (1) potential confounding due to tobacco smoking and (2) a significant probability (i.e., greater than 10 percent) that a correlation of the magnitude found could have arisen simply by chance, given that it were based on a relatively small number of lung cancer cases.

Although data on smoking habits were compiled from medical records for approximately 80 percent of the cohort, these data were not incorporated into the statistical regression models. The authors justified their exclusion of smoking from these models by showing that the likelihood of smoking was essentially unrelated to the cumulative TC exposure for cohort members. Based on the portion of the cohort that was interviewed, they also determined that the average number of cigarettes smoked per day was the same for smokers in the high and low TC exposure categories (production and workshop, respectively). However, these same interviews led them to question the accuracy of the smoking data that had been compiled from medical records. Despite the cohort's apparent homogeneity with respect to smoking, the authors noted that smoking was potentially such a strong confounder that ''even small inaccuracies in smoking data could cause effects comparable in size to the weak carcinogenic effect of diesel exhaust.'' Therefore, they excluded the smoking data from the analysis and stated they could not entirely rule out the possibility of a smoking bias. MSHA agrees with the authors of this report and the HEI Expert Panel (op cit.) that even a high degree of cohort homogeneity does not rule out the possibility of a spurious correlation due to residual smoking effects. Nevertheless, because of the cohort's homogeneity, the authors concluded that ''the results are unlikely to be substantially biased by confounding,'' and MSHA accepts this conclusion.

The second limitation of this study is related to the fact that the results are based on a total of only 38 cases of lung cancer for the full cohort and 21 cases for the subcohort. In their description of this study at the May 27, 1999, public

[53] MSHA *determined* these values by calculating the antilog, to the base e, of each corresponding estimate of α reported by Säverin et al. (op cit.) in their Tables III and IV. The cumulative exposure unit of mg-yr/m³ refers to the average TC concentration experienced over a year's worth of 8-hour shifts.

[54] This is the estimated risk relative not to miners in the workshop category but to a theoretical age-adjusted baseline risk for cohort members accumulating zero occupational TC exposure.

hearing, NIOSH noted that the ''lack of [statistical] significance may be a result of the study having a small cohort (approximately 5,500 workers), a limited time from first exposure (average of 19 years), and a young population (average age of 49 years at the end of follow-up).'' More cases of lung cancer may be expected to occur within the cohort as its members grow older. The authors of the study addressed statistical significance as follows:

* * * the small number of lung cancer cases produced wide confidence intervals for all measures of effect and substantially limited the study power. We intend to extend the follow-up period in order to improve the statistical precision of the exposure-response relationship. [Säverin et al., op cit.]

Some commenters stated that due to these limitations, data from the Säverin et al. study should not be the basis of this rule. On the other hand, NIOSH commented that ''[d]espite the limitations discussed * * * the findings from the Säverin et al. (1999) study should be used as an alternative source of data for quantifying the possible lung cancer risks associated with Dpm exposures.'' As stated earlier, MSHA is not relying on any single study but, instead, basing its evaluation on the weight of evidence from all available data.

(iii) Best Available Epidemiologic Evidence

Based on the evaluation criteria described earlier, and after considering all the public comment that was submitted, MSHA has identified four cohort studies (including two from U.S.) and four case-control studies (including three from U.S.) that provide the best currently available epidemiologic evidence relating dpm exposure to an increased risk of lung cancer. Three of the 11 studies involving miners fall into this select group. MSHA considers the statistical significance of the combined evidence far more important than confidence levels for individual studies. Therefore, in choosing the eight most informative studies, MSHA placed less weight on statistical significance than on the other criteria. The basis for MSHA's selection of these eight studies is summarized as follows:

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STUDY	STATISTICAL SIGNIFICANCE (at 95% Conf.)	COMPARISON GROUPS	EXPOSURE ASSESSMENT	CONTROLS ON POTENTIAL CONFOUNDING
Boffetta et al. 1988 (cohort)	YES	Internal Comparison	Job history and self-reported duration of occupational diesel exposure.	Adjustments for age, smoking, and, in some analyses, for occupational exposures to asbestos, coal & stone dusts, coal tar & pitch, and gasoline exhaust.
Boffetta et al. 1990 (case-control)	NO	Matched within hospital on smoking, age, year of interview.	Job history and self-reported duration of occupational diesel exposure.	Adjustments for age, smoking habit and intensity, asbestos exposure, race, and education.
Brüske-Hohlfeld et al. 1999 (case-control)	YES	Matched on sex, age, and region of residence.	Total duration of occupational diesel exposure based on detailed job history.	Adjustments for current and past smoking patterns, cumulative amount smoked (packyears), and asbestos exposure.
Garshick et al. 1987 (case-control)	YES	Matched within cohort on dates of birth and death.	Semi-quantitative, based on job history and tenure combined with exposure status established later for each job.	Adjustments for lifetime smoking and asbestos exposure.
Garshick et al. 1988, 1991 (cohort)	YES	Internal Comparison	Semi-quantitative, based on job history and tenure combined with exposure status established later for each job.	Subjects with likely or possible asbestos exposure excluded from cohort. Cigarette smoking determined to be uncorrelated with diesel exposure within cohort.
Johnston et al. 1997 (cohort)	NO (marginal)	Internal Comparison	Quantitative, based on surrogate exposure measurements and detailed employment records.	Adjustments for age, smoking habit & intensity, mine site, and cohort entry date.
Säverin et al. 1999 (cohort)	NO	Internal Comparison	Quantitative, based on TC exposure measurements and detailed employment records.	Adjustment for age. Cigarette smoking determined to be uncorrelated with cumulative TC exposure within cohort.
Steenland et al. 1990, 1992, 1998 (case-control)	YES	Matched within cohort on date of death within 2 years.	Semi-quantitative, based on job history and subsequent EC measurements.	Adjustments for age, smoking, and asbestos exposure. Dietary covariates were tested and found not to confound the analysis.

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Six entirely negative studies were identified earlier in this risk assessment. Several commenters objected to MSHA's treatment of the negative studies, indicating that they had been discounted without sufficient justification. To put this in proper perspective, the six negative studies should be compared to those MSHA has identified as the best available epidemiologic evidence, with respect to the same evaluation criteria. (It should be noted that the statistical significance of a negative study is best represented by its power.) In accordance with those criteria, MSHA discounts the evidentiary significance of these six studies for the following reasons:

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STUDY	POWER	COMPARISON GROUPS	EXPOSURE ASSESSMENT	CONTROLS ON POTENTIAL CONFOUNDING
Bender et al. 1989 (cohort)	Relatively small cohort (N = 4849)	External comparison; No adjustment for healthy worker effect.	Job only: highway maintenance workers.	Disparate comparison groups with no smoking adjustment.
Christie et al. 1996 (cohort)	Inadequate latency allowance.	External comparison; No adjustment for healthy worker effect.	Industry only: combined all underground and surface workers at coal mines.	Disparate comparison groups with no smoking adjustment
DeCoufle et al. 1977 (case-control)	Inadequate latency allowance.	Cases not matched with controls.	Job only: (1) Combined bus, taxi, and truck drivers; (2) locomotive engineers.	Age differences not taken into account.
Edling et al. 1987 (cohort)	Small cohort (N = 694)	External comparison; No adjustment for healthy worker effect.	Job only: bus workers.	Disparate comparison groups with no smoking adjustment
Kaplan 1959 (cohort)	Inadequate latency allowance.	External comparison; No adjustment for healthy worker effect.	Jobs classified by diesel exposure. No attempt to differentiate between diesel and coal-fired locomotives.	Disparate comparison groups with no smoking adjustment
Waller 1981 (cohort)	Acceptable.	External comparison; No adjustment for healthy worker effect; Selection bias due to excluding retirees from cohort.	Job only: bus workers.	Disparate comparison groups with no smoking adjustment

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Other studies proposed as counter-evidence by some commenters will be addressed in the next subsection of this risk assessment.

The eight studies MSHA identified as representing the best available epidemiologic evidence all reported an elevated risk of lung cancer associated with diesel exposure. The results from these studies will now be reviewed, along with MSHA's response to public comments as appropriate.

Boffetta et al., 1988

The structure of this cohort study was summarized in the preceding subsection of this risk assessment. The following table contains the main results. The relative risks listed for duration of exposure were calculated with reference to all members of the cohort reporting no diesel exposure, regardless of occupation, and adjusted for age, smoking pattern, and other occupational exposures (asbestos, coal and stone dusts, coal tar and pitch, and gasoline exhausts). The relative risks listed for occupations were calculated for cohort members that ever worked in the occupation, compared to cohort members never working in any of the four occupations listed and reporting no diesel exposure. These four relative risks were adjusted for age and smoking pattern only. Smoking pattern was coded by 5 categories: never smoker; current 1–20 cigarettes per day; current 21 or more cigarettes per day; ex-smoker of cigarettes; current or past pipe and/or cigar smoker.

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Main results from Boffetta et al., 1988

(RRs by duration adjusted for age, smoking, and other occupational exposures;

Occupational RRs adjusted for age and smoking only)

Self-Reported Duration of Exposure to Diesel Exhaust (years)	Lung Cancer RR	95-Percent Confidence Interval
1 to 15	1.05	0.80 - 1.39
16 or more	1.21	0.94 - 1.56
Occupation		
Truck Drivers	1.24	0.93 - 1.66
Railroad Workers	1.59	0.94 - 2.69
Heavy Equipment Operators	2.60	1.12 - 6.06
Miners	2.67	1.63 - 4.37

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In addition to comments (addressed earlier) on the RR for miners in this study, IMC Global submitted several comments pertaining to the RR calculated for persons who explicitly stated that they had been occupationally exposed to diesel emissions. This RR was 1.18 for persons reporting any exposure (regardless of duration) compared to all subjects reporting no exposure. MSHA considers the most important issue raised by IMC Global to be that 20.6 percent of all cohort members did not answer the question about occupational diesel exhaust exposure during their lifetimes, and these subjects experienced a higher age-adjusted mortality rate than the others. As the authors of this study acknowledged, this ''could introduce a substantial bias in the estimate of the association.'' (Boffetta et al., 1988, p.412).

To show that the impact of this bias could indeed be substantial, the authors of the study addressed one extreme possibility, in which all ''unknowns'' were actually unexposed. Under this scenario, excluding the ''unknowns'' would have biased the calculated RR upward by a sufficient amount to explain the entire 18-percent excess in RR. This would not, however, explain the higher RR for persons reporting more than 16 years exposure, compared to the RR for persons reporting 1 to 15 years. Moreover, the authors did not discuss the opposite extreme: if all or most of the ''unknowns'' who experienced lung cancer were actually exposed, then excluding them would have biased the calculated RR downward. There is little basis for favoring one of these extremes over the other.

Another objection to this study raised by IMC Global was:

> All exposure information in the study was self-reported and not validated. The authors of the study have no quantitative data or measurements of actual diesel exhaust exposures.

MSHA agrees with IMC Global and other commenters that a lack of quantitative exposure measurements limits the strength of the evidence this study presents. MSHA believes, however, that the evidence presented is nevertheless substantial. The possibility of random classification errors due to self-reporting of exposures does not explain why persons reporting 16 or more years of exposure would experience a higher relative risk of lung cancer than persons reporting 1 to 15 years of exposure. This difference is not statistically significant, but random exposure misclassification would tend to make the effects of exposure less conspicuous. Nor can self-reporting explain why an elevated risk of lung cancer would be observed for four occupations commonly associated with diesel exposure.

Furthermore, the study's authors did perform a rough check on the accuracy of the cohort's exposure information. First, they confirmed that, after controlling for age, smoking, and other occupational exposures, a statistically significant relationship was found between excess lung cancer and the cohort's self-reported exposures to asbestos. Second they found no such association for self-reported exposure to pesticides and herbicides, which they considered unrelated to lung cancer (*ibid.,* pp. 410–411).

IMC Global also commented that the ''* * * study may suffer from volunteer bias in that the cohort was healthier and less likely to be exposed to important risk factors, such as smoking or alcohol.'' They noted that this possibility ''is supported by the U.S. EPA in their draft Health Assessment Document for Diesel Emissions.''

The study's authors noted that enrollment in the cohort was nonrandom and that participants tended to be healthier and less exposed to various risk factors than the general population. These differences, however, would tend to reduce any relative risk for the cohort calculated in comparison to the external, general population. The authors pointed out that external comparisons were, therefore, inappropriate; but ''the internal comparisons upon which the foregoing analyses are based are not affected strongly by selection biases.'' (ibid.)

Although the 1999 EPA draft notes potential volunteer bias, it concludes: ''Given the fact that all diesel exhaust exposure occupations * * * showed elevated lung cancer risk, this study is suggestive of a causal association.''[55] (EPA, 1999, p. 7–13) No objection to this conclusion was raised in the most recent CASAC review of the EPA draft (CASAC, 2000).

Boffetta et al., 1990

This case-control study was based on 2,584 male hospital patients with histologically confirmed lung cancer, matched with 5099 male patients with no tobacco-related diseases. Cases and controls were matched within each of 18 hospitals by age (within two years) and year of interview. Information on each patient, including medical and smoking history, occupation, and alcohol and coffee consumption, was obtained at the time of diagnosis in the hospital, using a structured questionnaire. For smokers, smoking data included the number of cigarettes per day. Prior to 1985, only the patient's usual job was recorded. In 1985, the questionnaire was expanded to include up to five other jobs and the length of time worked in each job. After 1985, information was also obtained on dietary habits, vitamin consumption, and exposure to 45 groups of chemicals, including diesel exhaust.

The authors categorized all occupations into three groups, representing low, possible, and probable diesel exhaust exposure. The ''low exposure'' group was used as the reference category for calculating odds ratios for the ''possible'' and ''probable'' job groups. These occupational comparisons were based on the full cohort of patients, enrolled both before and after 1985. A total of 35 cases and 49 controls (all enrolled after the questionnaire was expanded in 1985) reported a history of diesel exposure. The reference category for self-reported diesel exposure consisted of a corresponding subset of 442 cases and 897 controls reporting no diesel exposure on the expanded questionnaire. The authors made three comparisons to rule out bias due to self-reporting of exposure: (1) No difference was found between the average number of jobs reported by cases and controls; (2) the association between self-reported asbestos exposure was in agreement with previously published estimates; and (3) no association was found for two exposures (pesticides and fuel pumping) considered unrelated to lung cancer (*ibid.,* p. 584).

Stöber and Abel (1996) identified this study as being ''of eminent importance owing to the care taken in including the most influential confounding factors and analyses of dose-effect relationships.'' The main findings are presented in the following table. All of these results were obtained using logistic regression, factoring in the estimated effects of age, race, years of

[55] In his review of this study for the NMA, Dr. Peter Valberg stated: ''This last sentence reveals EPA's bias; the RRs for truck drivers and railroad workers were not statistically elevated.'' Contrary to Dr. Valberg's statement, the RRs were greater than 1.0 and, therefore, were ''statistically elevated.'' Although the elevation for these two occupations was not statistically significant at a 95-percent confidence level, the EPA made no claim that it was. Under a null hypothesis of no real association, the probability should be ½ that the RR would exceed 1.0 for an occupation associated with diesel exposure. Therefore, under the null hypothesis, the probability that the RR would exceed 1.0 for all four such occupations is $(1/2)^4 = 0.06$. This corresponds to a 94-percent confidence level for rejecting the null hypothesis.

education, number of cigarettes per day, and asbestos exposure (yes or no). An elevated risk of lung cancer was reported for workers with more than 30 years of either self-reported or ''probable'' diesel exposure. The authors repeated the occupational analysis using ''ever'' rather than ''usual'' employment in jobs classified as ''probable'' exposure, with ''remarkably similar'' results (*ibid.,* p. 584).

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Main results from Boffetta et al., 1990

(adjusted for age, race, education, smoking, and asbestos exposure)

Self-Reported Duration of Exposure to Diesel Exhaust (years)	Lung Cancer Odds Ratio	95-Percent Confidence Interval
1 to 15	0.90	0.40 - 1.99
16 to 30	1.04	0.44 - 2.48
31 or more	2.39	0.87 - 6.57
Likelihood of Exposure		
19 jobs with "possible" exposure	0.92	0.76 - 1.10
13 jobs with "probable" exposure	0.95	0.78 - 1.16
1 to 15 years in "probable" jobs	0.52	0.15 - 1.86
16 to 30 years in "probable" jobs	0.70	0.34 - 1.44
31 or more years in "probable" jobs	1.49	0.72 - 3.11

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The study's authors noted that most U.S. trucks did not have diesel engines until the late 1950s or early 1960s and that many smaller trucks are still powered by gasoline engines. Therefore, they performed a separate analysis of truck drivers cross-classified by self-reported diesel exposure ''to compare presumptive diesel truck drivers with nondiesel drivers.'' After adjusting for smoking, the resulting OR for diesel drivers was 1.25, with a 95-percent confidence interval of 0.85 to 2.76 (*ibid.,* p. 585).

Brüske-Hohlfeld et al., 1999

This was a pooled analysis of two case-control studies on lung cancer in Germany. The data pool consisted of 3,498 male cases with histologically or cytologically confirmed lung cancer and 3,541 male controls randomly drawn from the general population. Cases and controls were matched for age and region of residence. For the pooled analysis, information on demographic characteristics, smoking, and detailed job and job-task history was collected by personal interviews with the cases and controls, using a standardized questionnaire.

Over their occupational lifetimes, cases and controls were employed in an average of 2.9 and 2.7 different jobs, respectively. Jobs considered to have had potential exposure to diesel exhaust were divided into four groups: Professional drivers (including trucks, buses, and taxis), other ''traffic-related'' jobs (including switchmen and operators of diesel locomotives or diesel forklift trucks), full-time drivers of farm tractors, and heavy equipment operators. Within these four groups, each episode of work in a particular job was classified as being exposed or not exposed to diesel exhaust, based on the written description of job tasks obtained during the interview. This exposure assessment was done without knowledge of the subject's case or control status. Each subject's lifetime duration of occupational exposure was compiled using only the jobs determined to have been diesel-exposed. There were 264 cases and 138 controls who accumulated diesel exposure exceeding 20 years, with 116 cases and 64 controls accumulating more than 30 years of occupational exposure.

For each case and control, detailed smoking histories from the questionnaire were used to establish smoking habit, including consumption of other tobacco products, cumulative smoking exposure (expressed as pack-years), and years since quitting smoking. Cumulative asbestos exposure (expressed as the number of exposed working days) was assessed based on 17 job-specific questionnaires that supplemented the main questionnaire.

The main findings of this study, all adjusted for cumulative smoking and asbestos exposure, are presented in the following table. Although the odds ratio for West German professional drivers was a statistically significant 1.44, as shown, the odds ratio for East German professional drivers was not elevated. As a possible explanation, the authors noted that after 1960, the number of vehicles (cars, busses, and trucks) with diesel engines per unit area was about five times higher in West Germany than in East Germany. Also, the higher OR shown for professional drivers first exposed after 1955, compared to earlier years of first exposure, may have resulted from the higher density of diesel traffic in later years.

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Main results from Brüske-Hohlfeld et al., 1999

(controlled for age; adjusted for smoking and asbestos exposure)

Occupational Exposure to Diesel Exhaust	Lung Cancer Odds Ratio	95-Percent Confidence Interval
Any During Lifetime	1.43	1.23 - 1.67
West German Professional Drivers	*1.44*	*1.18 - 1.76*
First exposed before 1946	1.32	0.68 - 2.07
First exposed 1946 - 1955	1.49	0.96 - 1.88
First exposed after 1955	1.56	1.21 - 2.03
"Traffic-Related" Jobs other than Driving	*1.53*	*1.04-2.24*
4 to 10 years	1.18	0.6 - 2.4†
11 to 20 years	2.49	1.1 - 5.6†
More than 20 years	2.88	1.1 - 7.2†
Full-Time Drivers of Farm Tractors	*1.29*	*0.78 - 2.14*
11 to 20 years	1.51	0.4 - 3.8‡
21 to 30 years	3.67	1.0 - 13‡
More than 30 years	6.81	1.1 - 40‡
Heavy Equipment Operators	*2.31*	*1.44 - 3.70*
More than 20 years	4.30	statistically significant (interval not reported)

† Confidence limits estimated from Fig. 1 of Brüske-Hohlfeld et al. (1999).

‡ Confidence limits estimated from Fig. 2 of Brüske-Hohlfeld et al. (1999).

BILLING CODE 4510–43–C

As the authors noted, a strength of this study is the good statistical power resulting from having a significant number of workers exposed to diesel emissions for more than 30 years. Another strength is the statistical treatment of potential confounders, using quantitative measures of cumulative smoking and asbestos exposures.

Although they did not rely solely on job title, and differentiated between diesel-exposed and unexposed work periods, the authors identified limitations in the assessment of diesel exposure, ''under these circumstances leading to an odds ratio that is biased towards one and an underestimation of the true [relative] risk of lung cancer.'' A more quantitative assessment of diesel exposure would tend to remove this bias, thereby further elevating the relative risks. Therefore, the authors concluded that their study ''showed a statistically significant increase in lung cancer risk for workers occupationally exposed to [diesel exhaust] in Germany with the exception of professional drivers in East Germany.''

Garshick et al., 1987

This case-control study was based on 1,256 primary lung cancer deaths and 2,385 controls whose cause of death was not cancer, suicide, accident, or unknown. Cases and controls were drawn from records of the U.S. Railroad Retirement Board (RRB) and matched within 2.5 years of birth date and 31 days of death date. Selected jobs, with and without regular diesel exposure, were identified by a review of job titles and duties and classified as ''exposed'' or ''unexposed'' to diesel exhaust. For 39 jobs, this exposure classification was confirmed by personal sampling of current respirable dust concentrations, adjusted for cigarette smoke, at four different railroads. Jobs for which no personal sampling was available were classified based on similarities in location and activity to sampled jobs.

A detailed work history for each case and control was obtained from an annual report filed with the RRB. This was combined with the exposure classification for each job to estimate the lifetime total diesel exposure (expressed as ''diesel-years'') for each subject. Years spent not working for a railroad, or for which a job was not recorded, were considered to be unexposed. This amounted to 2.4% of the total worker-years from 1959 to death or retirement.

Because of the transition from steam to diesel locomotives in the 1950s, occupational lifetime exposures were accumulated beginning in 1959. Since many of the older workers retired not long after 1959 and received little or no diesel exposure, separate analyses were carried out for subjects above and below the age of 65 years at death. The group of younger workers was considered to be less susceptible to exposure misclassification.

Detailed smoking histories, including years smoked, cigarettes per day, and years between quitting and death, were obtained from next of kin. Based on job history, each case and control was also classified as having had regular, intermittent, or no occupational asbestos exposure.

The main results of this study, adjusted for smoking and asbestos exposure, are presented in the following table for workers aged less than 65 years at the time of their death. All of these results were obtained using logistic regression, conditioned on dates of birth and death. The odds ratio presented in the shaded cell for 20 years of unlagged exposure was derived from an analysis that modeled diesel-years as a continuous variable. All of the other odds ratios in the table were derived from analyses that modeled cumulative exposure categorically, using workers with less than five diesel-years of exposure as the reference group. Statistically significant elevations of lung cancer risk were reported for the younger workers with at least 20 diesel-years of exposure or at least 15 years accumulated five years prior to death. No elevated risk of lung cancer was observed for the older workers, who were 65 or more years old at the time of their death. The authors attributed this to the fact, mentioned above, that many of these older workers retired shortly after the transition to diesel-powered locomotives and, therefore, experienced little or no occupational diesel exposure. Based on the results for younger workers, they concluded that ''this study supports the hypothesis that occupational exposure to diesel exhaust increases lung cancer risk.''

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Main results from Garshick et al., 1987, for workers aged less than 65 years at death

(controlled for dates of birth and death; adjusted for cigarette smoking and asbestos exposure).

Diesel Exposure (no lag)	Lung Cancer Odds Ratio	95-Percent Confidence Interval
0 - 4 diesel-years	1	N/A (reference group)
5 - 19 diesel-years	1.02	0.72 - 1.45
20 diesel-years (diesel exposure modeled as continuous variable)	1.41	1.06 - 1.88
20 or more diesel-years	1.64	1.18 - 2.29
Diesel Exposure (accumulated at least 5 years before death)		
0 - 4 diesel-years	1	N/A (reference group)
5 - 14 diesel-years	1.07	0.69 - 1.66
15 or more diesel-years	1.43	1.06 - 1.94

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In its 1999 draft Health Assessment Document for Diesel Emissions, the U.S. EPA noted various limitations of this study but concluded that ''compared with previous studies [i.e., prior to 1987] * * *, [it] provides the most valid evidence that occupational diesel exhaust emission exposure increases the risk of lung cancer.'' (EPA, 1999, p. 7–33) No objection to this conclusion was raised in the most recent CASAC review of the EPA draft (CASAC, 2000).

The EMA objected to this study's determination of smoking frequency based on interviews with next of kin, stating that such determination ''generally results in an underestimate, as it has been shown that cigarette companies manufacture 60% more product than public surveys indicate are being smoked.''

A tendency to mischaracterize smoking frequency would have biased the study's reported results if the degree of under- or over-estimation varied systematically with diesel exposure. The EMA, however, submitted no evidence that the smoking under-estimate, if it existed at all, was in any way correlated with cumulative duration of diesel exposure. In the absence of such evidence, MSHA finds no reason to assume differential mis-reporting of smoking frequency.

Even more importantly, the EMA failed to distinguish between ''public surveys'' of the smokers themselves (who may be inclined to understate their habit) and interviews with next of kin. The investigators specifically addressed the accuracy of smoking data obtained from next of kin, citing two studies on the subject. Both studies reported a tendency for surrogate respondents to overestimate, rather than underestimate, cigarette consumption. The authors concluded that ''this could exaggerate the contribution of cigarette smoking to lung cancer risk if the next of kin of subjects dying of lung cancer were more likely to report smoking histories than were those of controls.'' (ibid, p.1246)

IMC Global, along with Cox (1997) objected to several methodological features of this study. MSHA's response to each of these criticisms appears immediately following a summary quotation from IMC Global's written comments:

(A) The regression models used to analyze the data assumed without justification that an excess risk at any exposure level implied an excess risk at all exposure levels.

The investigators did not extrapolate their regression models outside the range supported by the data. Furthermore, MSHA is using this study only for purposes of hazard identification at exposure levels at least as high as those experienced by workers in the study. Therefore, the possibility of a threshold effect at much lower levels is irrelevant.

(B) The regression model used did not specify that the exposure estimates were imperfect surrogates for true exposures. As a result, the regression coefficients do not bear any necessary relationship to the effects that they try to measure.

As noted by Cox (op cit.), random measurement errors for exposures in an univariate regression model will tend to bias results in the direction of no apparent association, thereby masking or reducing any apparent effects of exposure. The crux of Cox's criticism, however, is that, for statistical analysis

of the type employed in this study, random errors in a multivariate exposure (such as an interdependent combination of smoking, asbestos, and diesel exposure) can potentially bias results in either direction. This objection fails to consider the fact that a nearly identical regression result was obtained for the effect of diesel exposure when smoking and asbestos exposure were removed from the model: OR = 1.39 instead of 1.41. Furthermore, even with a multivariate exposure, measurement errors in the exposure being evaluated typically bias the estimate of relative risk downward toward a null result. Relative risk is biased upwards only when the various exposures are interrelated in a special way. No evidence was presented that the data of this study met the special conditions necessary for upward bias or that any such bias would be large enough to be of any practical significance.

C) The * * * analysis used regression models without presenting diagnostics to show whether the models were appropriate for the date.

MSHA agrees that regression diagnostics are a valuable tool in assuring the validity of a statistical regression analysis. There is nothing at all unusual, however, about their not having been mentioned in the published report of this study. Regression diagnostics are rarely, if ever, published in epidemiologic studies making use of regression analysis. This does not imply that such diagnostics were not considered in the course of identifying an appropriate model or checking how well the data conform to a given model's underlying assumptions. Evaluation of the validity of any statistical analysis is (or should be) part of the peer-review process prior to publication.

D) The * * * risk models assumed that 1959 was the effective year when DE exposure started for each worker. Thus, the analysis ignored the potentially large differences in pre-1959 exposures among workers. This modeling assumption makes it impossible to interpret the results of the study with confidence.

MSHA agrees that the lack of diesel exposure information on individual workers prior to 1959 represents an important limitation of this study. This limitation, along with a lack of quantitative exposure data even after 1959, may preclude using it to determine, with reasonable confidence, the shape or slope of a quantitative exposure-response relationship. Neither of these limitations, however, invalidates the study's finding of an elevated lung cancer risk for exposed workers. MSHA is not basing any quantitative risk assessment on this study and is relying on it, in conjunction with other evidence, only for purposes of hazard identification.

E) The risk regression models * * * assume, without apparent justification, that all exposed individuals have identical dose-response model parameters (despite the potentially large differences in their pre-1959 exposure histories). This assumption was not tested against reasonable alternatives, *e.g.,* that individuals born in different years have different susceptibilities * * *

Cases and controls were matched on date of birth to within 2.5 years, and separate analyses were carried out for the two groups of younger and older workers. Furthermore, it is not true that the investigators performed no tests of reasonable alternatives even to the assumption that younger workers shared the same model parameters. They explored and tested potential interactions between smoking intensity and diesel exposure, with negative results. The presence of such interactions would have meant that the response to diesel exposure differed among individuals, depending on their smoking intensity.

One other objection that Cox (op. cit.) raised specifically in connection with this study was apparently overlooked by IMC Global. To illustrate what he considered to be an improper evaluation of statistical significance when more than one hypothesis is tested in a study, Cox noted the finding that for workers aged less than 65 years at time of death, the odds ratio for lung cancer was significantly elevated at 20 diesel-years of exposure. He then asserted that this finding was merely

* * * an instance of a whole family of statements of the form ''Workers who were A years or younger at the time of death and who were exposed to diesel exhaust for Y years had a significantly increased relative odds ratios for lung cancer. The probability of at least one false positive occurring among the multiple hypotheses in this family corresponding to different combinations of A (*e.g.,* no more than 54, 59, 64, 69, 74, 79, etc. years old at death) and durations of exposure (*e.g.,* Y = 5, 10, 15, 20, 25, etc. years) is not limited to 5% when each combination of A and Y values is tested at a p = 5% significance level. For example, if 30 different (A, Y) combinations are considered, each independently having a 5% probability of a false positive (*i.e.,* a reported 5% significance level), then the probability of at least one false positive occurring in the study as a whole is $p = 1 - (1 - 0.05)\ 30 = 78\%$. This p-value for the whole study is more than 15 times greater than the reported significance level of 5%.

MSHA is evaluating the cumulative weight of evidence from many studies and is not relying on the level of statistical significance attached to any single finding or study viewed in isolation. Furthermore, Cox's analysis of the statistical impact of multiple comparisons or hypothesis tests is flawed on several counts, especially with regard to this study in particular. First, the analysis relies on a highly unrealistic assumption that when several hypotheses are tested within the same study, the probabilities of false positives are statistically independent. Second, Cox fails to distinguish between those hypotheses or comparisons suggested by exploration of the data and those motivated by prior considerations. Third, Cox ignores the fact that the result in question was based on a statistical regression analysis in which diesel exposure duration was modeled as a single continuous variable. Therefore, this particular result does not depend on multiple hypothesis-testing with respect to exposure duration. Fourth, and most importantly, Cox assumes that age and exposure duration were randomly picked for tested from a pool of interchangeable possibilities and that the only thing distinguishing the combination of ''65 years of age'' and ''20 diesel-years of exposure'' from other random combinations was that it happened to yield an apparently significant result. This is clearly not the case. The investigators divided workers into only two age groups and explained that this division was based on the history of dieselization in the railroad industry—not on the results of their data analysis. Similarly, the result for 20 diesel-years of exposure was not favored over shorter exposure times simply because 20 years yielded a significant result and the shorter times did not. Lengthy exposure and latency periods are required for the expression of increased lung cancer risks, and this justifies a focus on the longest exposure periods for which sufficient data are available.

Garshick et al., 1988; Garshick, 1991

In this study, the investigators assessed the risk of lung cancer in a cohort of 55,407 white male railroad workers, aged 40 to 64 years in 1959, who had begun railroad work between 1939 and 1949 and were employed in one of 39 jobs later surveyed for exposure. Workers whose job history indicated likely occupational exposure to asbestos were excluded. Based on the subsequent exposure survey, each of the 39 jobs represented in the cohort was classified as either exposed or unexposed to diesel emissions. The cohort was followed through 1980, and

1,694 cases of death due to lung cancer were identified.

As in the 1987 study by the same investigators, detailed railroad job histories from 1959 to date of death or retirement were obtained from RRB records and combined with the exposure classification for each job to provide the years of diesel exposure accumulated since 1959 for each worker in the cohort. Using workers classified as ''unexposed'' within the cohort to establish a baseline, time-dependent proportional hazards regression models were employed to evaluate the relative risk of lung cancer for exposed workers. Although the investigators believed they had excluded most workers with significant past asbestos exposures from the cohort, based on job codes, they considered it possible that some workers classified as hostlers or shop workers may have been included in the cohort even if occupationally exposed to asbestos. Therefore, they carried out statistical analyses with and without shop workers and hostlers included.

The main results of this study are presented in the following table. Statistically significant elevations of lung cancer risk were found regardless of whether or not shop workers and hostlers were included. The 1988 analysis adjusted for age in 1959, and the 1991 analysis adjusted, instead, for age at death or end of follow-up (i.e., end of 1980).[56] In the 1988 analysis, any work during a year counted as a diesel-year if the work was in a diesel-exposed job category, and the results from the 1991 analysis presented here are based on this same method of compiling exposure durations. Exposure durations excluded the year of death and the four prior years, thereby allowing for some latency in exposure effects. Results for the analysis excluding shop workers and hostlers were not presented in the 1991 report, but the report stated that ''similar results were obtained.'' Using either method of age adjustment, a statistically significant elevation of lung cancer risk was associated with each exposure duration category. Using ''attained age,'' however, there was no strong indication that risk increased with increasing exposure duration. The 1991 report concluded that ''there appears to be an effect of diesel exposure on lung cancer mortality'' but that ''because of weaknesses in exposure ascertainment * * *, the nature of the exposure-response relationship could not be found in this study.''

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Main results from Garshick et al., 1988 and Garshick, 1991.

Exposure Duration (diesel-years, last 5 years excluded)	Full Cohort		Shopworkers & Hostlers Excluded	
	Relative Risk	95% Conf. Int.	Relative Risk	95% Conf. Int.
1 - 4	1.20	1.01 - 1.44	1.34	1.08 - 1.65
	1.31	1.09 - 1.57	N.R.	N.R.
5 - 9	1.24	1.06 - 1.44	1.33	1.12 - 1.58
	1.28	1.09 - 1.49	N.R.	N.R.
10 - 14	1.32	1.13 - 1.56	1.33	1.10 - 1.60
	1.19	1.002 - 1.41	N.R.	N.R.
15 or more	1.72	1.27 - 2.33	1.82	1.30 - 2.55
	1.40	1.03 - 1.90	N.R.	N.R.

Top entry within each cell is from 1988 analysis, adjusted for age in 1959. Bottom entry is from 1991 analysis, adjusted for age at death or end of follow-up ("attained age"). N.R. means "not reported."

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Some commenters noted that removing the shop workers and hostlers from the analysis increased the relative risk estimates. Dr. Peter Valberg found this ''paradoxical,'' since workers in these categories had later been found to experience higher average levels of diesel exposure than other railroad workers.

This so-called paradox is likely to have resulted simply from exposure misclassification for a significant portion of the shop workers. The effect was explained by Garshick (1991) as follows:

[1] Also, the 1991 analysis excluded 12 members of the cohort due to discrepancies between work history and reported year of death, leaving 55,395 railroad workers included in the analysis.

> * * * shop workers who worked in the diesel repair shops shared job codes with workers in non-diesel shops where there was no diesel exhaust * * *. Apparent exposure as a shop worker based on the job code was then diluted with workers with the same job code but without true exposure, making it less likely to see an effect in the shop worker group. In addition, workers in the shop worker group of job codes tended to have less stable career paths * * * compared to the other diesel exposure categories.

So although many of the shopworkers may have been exposed to relatively high dpm concentrations, many others were among the lowest-exposed workers or were even unexposed because they spent their entire occupational lifetimes in unexposed locations. This could readily account for the increase in relative risks calculated when shop workers were excluded from the analysis.

Dr. Valberg also noted that, according to Crump 1999), mortality rates for cirrhosis of the liver and heart disease were significantly elevated for ''train riders,'' who were exposed to diesel emissions, as compared to other members of the cohort, who were less likely to be exposed. It is also the train riders who account, primarily, for the elevated risk of lung cancer associated with diesel exposure in the overall cohort. Dr. Valberg interpreted this as suggesting that ''lifestyle'' factors such as diet or smoking habits, rather than diesel exposure, were responsible for the increased risk of lung cancer observed among the diesel-exposed workers.

Dr. Valberg presented no evidence that, apart from diesel exposure, the train riders differed systematically from the other workers in their smoking habits or in other ways that would be expected to affect their risk of lung cancer. Therefore, MSHA views the suggestion of such a bias as speculative. Even if lifestyle factors associated with train ridership were responsible for an increased risk of cirrhosis of the liver or heart disease, this would not necessarily mean that the same factors were also responsible for the increased risk of lung cancer. Still, it is hypothetically possible that systematic differences, other than diesel exposure, between train riders and other railroad workers could account for some or even all of the increased lung cancer risk. That is why MSHA does not rely on this, or any other, single study in isolation.

Some commenters, including the NMA, objected to this study on grounds that it failed to control for potentially confounding factors, principally smoking. The NMA stated that this ''has rendered its utility questionable at best.'' As explained earlier, there is more than one way in which a study can control for smoking or other potential confounders. One of the ways is to make sure that groups being compared do not differ with respect to the potential confounder. In this study, workers with likely asbestos exposure were excluded from the cohort, stability of workers within job categories was well documented, and similar results were reported when job categories subject to asbestos exposure misclassification were excluded. In their 1988 report, the investigators provided the following reasons to believe that smoking did not seriously affect their findings:

> * * * the cohort was selected to include only blue-collar workers of similar socioeconomic class, a known correlate of cigarette smoking * * *, in our case-control study [Garshick et al.,1987], when cigarette smoking was considered, there was little difference in the crude or adjusted estimates of diesel exhaust effects. Finally, in the group of 517 current railroad workers surveyed by us in 1982 * * *, we found no difference in cigarette smoking prevalence between workers with and without potential diesel exhaust exposure. [Garshick et al.,1988]

Since relative risks were based on internal comparisons, and the cohort appears to have been fairly homogeneous, MSHA regards it as unlikely that the association of lung cancer with diesel exposure in this study resulted entirely from uncontrolled asbestos or smoking effects. Nevertheless, MSHA recognizes that differential smoking patterns may have affected, in either direction, the degree of association reported in each of the exposure duration categories.

Cox (1997) re-analyzed the data of this study using exploratory, nonparametric statistical techniques. As quoted by IMC Global, Cox concluded that ''these methods show that DE [i.e., dpm] concentration has no positive causal association with lung cancer mortality risk.'' MSHA believes this quotation (taken from the abstract of Cox's article) overstates the findings of his analysis. At most, Cox confirmed the conclusion by Garshick (1991) that these data do not support a positive exposure-response relationship. Specifically, Cox determined that inter-relationships among cumulative diesel exposure, age in 1959, and retirement year make it ''impossible to prove causation by eliminating plausible rival hypotheses based on this dataset.'' (Cox, 1997; p.826) Even if Cox's analysis were correct, it would not follow that there is no underlying causal connection between dpm exposure and lung cancer. It would merely mean that the data do not contain internal evidence implicating dpm exposure as the cause, rather than one or more of the variables with which exposure is correlated. Cox presented no evidence that any ''rival hypotheses'' were more plausible than causation by dpm exposure. Furthermore, it may simply be, as Garshick suggested, that an underlying exposure-response relationship is not evident ''because of weaknesses in exposure ascertainment.'' (Garshick, 1991, op cit.) None of this negates the fact that, after adjusting for either age in 1959 or ''attained'' age, lung cancer was significantly more prevalent among the exposed workers.

Along similar lines, many commenters pointed out that an HEI expert panel examined the data of this study (HEI, 1999) and found that it had very limited use for quantitative risk assessment (QRA). Several of these commenters mischaracterized the panel's findings. The NMA, for example, drew the following unjustified conclusion from the panel's report: ''In short, * * * the correct interpretation of the Garshick study is that any occupational increase in lung cancer among train workers was not due to diesel exposures.''

Contrary to the NMA's characterization, the HEI Expert Panel's report stated that the data are

> * * * consistent with findings of a weak association between death from lung cancer and occupational exposure to diesel exhaust. Although the secondary exposure-response analyses * * * are conflicting, the overall risk of lung cancer was elevated among diesel-exposed workers. [ibid., p.25]

The panel agreed with Garshick (1991) and Cox (1997) that the data of this study do not support a positive exposure-response relationship. Like Garshick and unlike Cox, however, the panel explicitly recognized that problems with the data could mask such a relationship and that this does not negate the statistically significant finding of elevated risk among exposed workers. Indeed, the panel even identified several factors, in addition to weak exposure assessment as suggested by Garshick, that could mask a positive relationship: unmeasured confounding variables such as cigarette smoking, previous occupational exposures, or other sources of pollution; a ''healthy worker survivor effect''; and differential misclassification or incomplete ascertainment of lung cancer deaths. (HEI, 1999; p.32)

Positive exposure-response relationships based on these data were reported by the California EPA (OEHHA, 1998). MSHA recognizes that those findings were sensitive to various assumptions and that other investigators

have obtained contrary results. The West Virginia Coal Association, paraphrasing Dr. Peter Valberg, concluded that although the two studies by Garshick et al. "* * * may represent the best in the field, they fail to firmly support the proposition that lung cancer risk in workers derives from exposure to dpm." At least one commenter (IMC Global) apparently reached a considerably stronger conclusion that they were of no value whatsoever, and urged MSHA to "discount their results and not consider them in this rulemaking." On the other hand, in response to the ANPRM, a consultant to the National Coal Association who was critical of all other studies available at the time acknowledged that these two:

* * * have successfully controlled for severally [sic] potentially important confounding factors * * * Smoking represents so strong a potential confounding variable that its control must be nearly perfect if an observed association between cancer and diesel exhaust is * * * [inferred to be causal]. In this regard, two observations are relevant. First, both case-control [Garshick et al., 1987] and cohort [Garshick et al., 1988] study designs revealed consistent results. Second, an examination of smoking related causes of death other than lung cancer seemed to account for only a fraction of the association observed between diesel exposure and lung cancer. A high degree of success was apparently achieved in controlling for smoking as a potentially confounding variable. [Robert A. Michaels, RAM TRAC Corporation, submitted by National Coal Association].

To a limited extent, MSHA agrees with Dr. Valberg and the West Virginia Coal Association: these two studies—like every real-life epidemiologic study—are not "firmly" conclusive when viewed in isolation. Nevertheless, MSHA believes that they provide important contributions to the overall body of evidence. Whether or not they can be used to quantify an exposure-response relationship, these studies—among the most comprehensive and carefully controlled currently available—do show statistically significant increases in the risk of lung cancer among diesel-exposed workers.

Johnston et al. (1997)

Since it focused on miners, this study has already been summarized and discussed in the previous subsection of this risk assessment. The main results are presented in the following table. The tabled relative risk estimates presented for cumulative exposures greater than 1000 mg-hr/m^3 (i.e., 1 g-hr/m^3) were calculated by MSHA based on the regression coefficients reported by the authors. The conversion from mg-hr/m^3 to mg-yr/m^3 assumes 1,920 occupational exposure hours per year. Although 6.1 mg-yr/m^3 Dpm roughly equals the cumulative exposure estimated for the most highly exposed locomotive drivers in the study, the relative risk associated with this exposure level is presented primarily for purposes of comparison with findings of Säverin et al. (1999).

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Main results from Johnston et al., 1997.

Cumulative dpm exposure	Mine-adjusted Model (15-yr lag)		Mine-unadjusted Model (15-yr lag)	
	Relative Risk	95% Conf. Interval	Relative Risk	95% Conf. Interval
1000 mg-hr/m^3 (≈ 0.521 mg-yr/m^3)	1.156	0.90 - 1.49	1.227	1.00 - 1.50
1920 mg-hr/m^3 (≈ 1 mg-yr/m^3)	1.321	Not Reported	1.479	Not Reported
11,700 mg-hr/m^3 (≈ 6.1 mg-yr/m^3)	5.5	Not Reported	11.0	Not Reported

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In its post-hearing comments, MARG acknowledged that this study "found a 'weak association' between lung cancer and respiratory diesel particulate exposure" but failed to note that the estimated relative risk increased with increasing exposure. MARG also stated that the association was "deemed non-significant by the researchers" and that "no association was found among men with different exposures working in the same mines." Although the mine-adjusted model did not support 95-percent confidence for an increasing exposure-response relationship, the mine-unadjusted model yielded a statistically significant positive slope at this confidence level. Furthermore, since the mine-adjusted model adjusts for differences in lung cancer rates between mines, the fact that relative risk increased with increasing exposure under this model indicates (though not at a 95-percent confidence level) that the risk of lung cancer increased with exposure among men with different exposures working in the same mines.

Säverin et al. (1999)

Since this study, like the one by Johnston et al., was carried out on a cohort of miners, it too was summarized and discussed in the previous subsection of this risk assessment. The main results are presented in the following table. The relative risk estimates and confidence intervals at the mean exposure level of 2.7 mg-yr/m^3 TC (total carbon) were calculated by MSHA, based on values of α and corresponding confidence intervals presented in Tables III and IV of the

published report (ibid., p.420). The approximate equivalency between 4.9 mg-yr/m^3 TC and 6.1 mg-yr/m^3 dpm assumes that, on average, TC comprises 80 percent of dpm.

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Main results from Säverin et al., 1999.

	Relative Risk	95% Confidence Interval
Highest Compared to Least Exposed Worker Category	2.17	0.79 - 5.99

Cumulative Total Carbon Exposure	Proportional Hazards (Cox) Model*		Poisson Model*	
	Relative Risk	95% Conf. Interval	Relative Risk	95% Conf. Interval
2.7 mg-yr/m^3 TC (i.e., cohort mean)	1.33 1.73	0.67 - 2.64 0.70 - 4.30	1.08 1.42	0.59 - 1.99 0.65 - 3.92
4.9 mg-yr/m^3 TC (≈ 6.1 mg-yr/m^3 Dpm)	1.68 2.70	0.49 - 5.8 0.52 - 14.1	1.16 1.89	0.38 - 3.3 0.46 - 11.9

* Top entry in each cell is based on full cohort; bottom entry is based on subcohort, which was restricted to miners who worked underground at least ten years, with at least 80 percent of employment in same job, etc.

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These results are not statistically significant at the conventional 95-percent confidence level. However, the authors noted that the relative risk calculated for the subcohort was consistently higher than that calculated for the full cohort. They also considered the subcohort to have a superior exposure assessment and a better latency allowance than the full cohort. According to the authors, these factors provide ''some assurance that the observed risk elevation was not entirely due to chance since improving the exposure assessment and allowing for latency effects should, in general, enhance exposure effects.''

Steenland et al., (1990, 1992, 1998)

The basis for the analyses in this series was a case-control study comparing the risk of lung cancer for diesel-exposed and unexposed workers who had belonged to the Teamsters Union for at least twenty years (Steenland et al., 1990). Drawing from union records, 996 cases of lung cancer were identified among more than 10,000 deaths in 1982 and 1983. For comparison to these cases, a total of 1,085 controls was selected (presumably at random) from the remaining deaths, restricted to those who died from causes other than lung cancer, bladder cancer, or motor vehicle accident. Information on work history, duration and intensity of cigarette smoking, diet, and asbestos exposure was obtained from next of kin. Detailed work histories were also obtained from pension applications on file with the Teamsters Union.

Both data sources were used to classify cases and controls according to a job category in which they had worked the longest. Based on the data obtained from next of kin, the job categories were diesel truck drivers, gasoline truck drivers, drivers of both truck types, truck mechanics, and dock workers. Based on the pension applications, the principal job categories were long-haul drivers, short-haul or city drivers, truck mechanics, and dock workers. Of the workers identified by next of kin as primarily diesel truck drivers, 90 percent were classified as long-haul drivers according to the Teamster data. The corresponding proportions were 82 percent for mechanics and 81 percent for dock workers. According to the investigators, most Teamsters had worked in only one exposed job category. However, because of the differences in job category definitions, and also because the next of kin data covered lifetimes whereas the pension applications covered only time in the Teamsters Union, the investigators found it problematic to fully evaluate the concordance between the two data sources.

In the 1990 report, separate analyses were conducted for each source of data used to compile work histories. The investigators noted that ''many trucking companies (where most study subjects worked) had completed most of the dieselization of their fleets by 1960, while independent drivers and nontrucking firms may have obtained diesel trucks later. * * *'' Therefore, they specifically checked for associations between increased risk of lung cancer and occupational exposure after 1959 and, separately, after 1964. In the 1992 report, the investigators presented, for the Union's occupational categories used in the study, dpm exposure estimates based on subsequent measurements of submicrometer elemental carbon (EC) as reported by Zaebst et al. (1991). In the 1998 report, cumulative dpm exposure estimates for individual workers were compiled by combining the individual work histories obtained from the Union's records with the subsequently measured occupational exposure levels, along with an evaluation of historical changes in diesel engine emissions and patterns of diesel usage. Three alternative sets of cumulative exposure estimates were considered, based on alternative assumptions about the extent of

improvement in diesel engine emissions between 1970 and 1990. A variety of statistical models and techniques were then employed to investigate the relationship between estimated cumulative dpm exposure (expressed as EC) and the risk of lung cancer. The authors pointed out that the results of these statistical analyses depended heavily on ''very broad assumptions'' used to generate the estimates of cumulative dpm exposure. While acknowledging this limitation, however, they also evaluated the sensitivity of their results to various changes in their assumptions and found these changes to have little impact on the results.

The investigators also identified and addressed several other limitations of this study as follows:

(1) possible misclassification smoking habits by next of kin, (2) misclassification of exposure by next of kin, (3) a relatively small non-exposed group (n = 120) which by chance may have had a low lung cancer risk, and (4) lack of sufficient latency (time since first exposure) to observe a lung cancer excess. On the other hand, next-of-kin data on smoking have been shown to be reasonably accurate, non-differential misclassification of exposure * * * would only bias our findings toward * * * no association, and the trends of increased risk with increased duration of employment in certain jobs would persist even if the non-exposed group had a higher lung cancer risk. Finally, the lack of potential latency would only make any positive results more striking. (Steenland et al., 1990)

The main results from the three reports covering this study are summarized in the following table. All of the analyses were controlled for age, race, smoking (five categories), diet, and asbestos exposure as reported by next of kin. Odds ratios for the occupations listed were calculated relative to the odds of lung cancer for occupations other than truck driver (all types), mechanic, dock worker, or other potentially diesel exposed jobs (Steenland et al., 1990, Appendix A). The exposure-response analyses were carried out using logistic regression. Although the investigators performed analyses under three different assumptions for the rate of engine emissions (gm/mile) in 1970, they considered the intermediate value of 4.5 gm/mile to be their best estimate, and this is the value on which the results shown here are based. Under this assumption, cumulative occupational EC exposure for all workers in the study was estimated to range from 0.45 to 2,440 μg-yr/m^3, with a median value of 373 μg-yr/m^3. The estimates of relative risk (expressed as odds ratios) presented for EC exposures of 373 μg-yr/m^3, 1000 μg-yr/m^3, and 2450 μ-yr/m^3 were calculated by MSHA based on the regression coefficients reported by the authors for five-year lagged exposures (Steenland et al. 1998, Table II).

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Main results from Steenland et al., (1990, 1992, 1998)

Principal Occupation	Mean 1990 EC Concentration (μg/m³)	Duration of Employment	Lung Cancer Odds Ratio	95-percent Conf. Interval
Diesel truck driver	N.A.	35 or more years*	1.89	1.04 - 3.42
Short-haul driver	5.4	18 or more years after 1959	1.79	0.94 - 3.42
Long-haul driver	5.1	18 or more years after 1959	1.55	0.97 - 2.47
		13 or more years after 1964	1.64	1.05 - 2.57
Truck mechanic	26.6	18 or more years after 1959	1.50	0.59 - 3.40

Cumulative Occupational Exposure (μg-yr/m³, lagged 5 years)**			Lung Cancer Odds Ratio	95-percent Conf. Interval
EC	TC ≈ 2•EC	Dpm ≈ TC/0.8 ≈ 2.5•EC		
0 - 169	0 - 338	0 - 422	1.08	0.72 - 1.63
169 - 257	338 - 514	422 - 642	1.10	0.74 - 1.65
257 - 331	514 - 662	642 - 827	1.36	0.90 - 2.04
more than 331	more than 662	more than 827	1.64	1.09 - 2.49
			Lung Cancer Odds Ratio‡	
		Logistic regression model →	Simple Cum. Exposure	Log of Cum. Exposure
373	746	932	1.16	1.41
1,000	2,000	2,500	1.48	1.66
2,450	4,900	6,100	2.59	1.93

*Although primary occupation was driving diesel trucks, employment duration includes years driving any type of truck.

**Conversions between EC, TC, and Dpm assume that, on average, TC ≈ 2•EC and TC ≈ 0.8•DPM.

‡ Calculated by MSHA from regression coefficients presented by Steenland et al. (1990), Table II. Statistically significant regression coefficients reported for both models (95% Conf. level). Tabled results for Log(Cum. exposure) model have been adjusted for lifetime background exposure of 65 μg-yr/m³ assumed in regression analysis.

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Under the assumption of a 4.5 gm/mile emissions rate in 1970, the cumulative EC exposure of 2450 μg–yr/m³ (≈ 6.1 mg–yr/m³ Dpm) shown in the table closely corresponds to the upper limit of the range of data on which the regression analyses were based (Steenland et al., 1998, p. 224). However, the relative risks (i.e., odds ratios) calculated for this level of occupational exposure are presented primarily for purposes of comparison with the findings of Johnston et al. (1997) and Säverin et al. (1999). At a cumulative Dpm exposure of approximately 6.1 mg—yr/m³, it is evident that the Johnston models predict a far greater elevation in lung cancer risk than either the Säverin or Steenland models. A possible explanation for this is that the Johnston data included exposures of up to 30 years in duration, and the statistical models showing an exposure-response relationship allowed for a 15-year lag in exposure effects. The other two studies were based on generally shorter diesel exposures and allowed less time for latent effects. In Subsection 3.b.ii(3) of this risk assessment, the quantitative results of these three studies will be further compared with respect to exposure levels found in underground mines.

Several commenters noted that the HEI Expert Panel (HEI, 1999) had identified uncertainties in the diesel exposure assessment as an important limitation of the exposure-response analyses by Steenland et al. (1998) and had recommended further investigation before the quantitative results of this study were accepted as conclusive. In addition, Navistar International Transportation (NITC) raised a number of objections to the methods by which diesel exposures were estimated for the period between 1949 and 1990 (NITC, 1999). In general, the thrust of these objections was that exposures to diesel engine emissions had been overestimated, while potentially relevant exposures to gasoline engine emissions had been underestimated and/or unduly discounted.[57]

As mentioned above, the investigators recognized that these analyses rely on ''broad assumptions rather than actual [concurrent] measurements,'' and they proposed that the ''results should be regarded with appropriate caution.'' While agreeing with both the investigators and the HEI Expert Panel that these results should be interpreted with appropriate caution, MSHA also agrees with the Panel ''* * * that regulatory decisions need to be made in spite of the limitations and uncertainties of the few studies with quantitative data currently available.'' (HEI, 1999, p. 39) In this context, MSHA considers it appropriate to regard the 1998 exposure-response analyses as contributing to the weight of evidence that dpm exposure increases the risk of lung cancer, even if the results are not conclusive when viewed in isolation.

Some commenters also noted that the HEI Expert Panel raised the possibility that the method for selecting controls in this study could potentially have biased the results in an unpredictable direction. Such bias could have occurred because deaths among some of the controls were likely due to diseases (such as cardiovascular disease) that shared some of the same risk factors (such as tobacco smoking) with lung cancer. The Panel presented hypothetical examples of how this might bias results in either direction. Although the possibility of such bias further demonstrates why the results of this study should be regarded with ''appropriate caution,'' it is important to distinguish between the mere possibility of a control-selection bias, evidence that such a bias actually exists in this particular study, and the further evidence required to show that such bias not only exists but is of sufficient magnitude to have produced seriously misleading results. Unlike the commenters who cited the HEI Expert Panel on this issue, the Panel itself clearly drew this distinction, stating that ''no direct evidence of such bias is apparent'' and emphasizing that ''even though these examples [presented in HEI (1999), Appendix D] could produce misleading results, it is important to note that they are only hypothetical examples. Whether or not such bias is present will require further examination.'' (HEI, 1999, pp. 37–38) As the HEI showed in its examples, such bias (if it exists) could lead to underestimating the association between lung cancer and dpm exposure, as well as to overestimating it. Therefore, in the absence of evidence that control-selection bias actually distorted the results of this study one way or the other, MSHA considers it prudent to accept the study's finding of an association at face value.

One commenter (MARG) noted that information on cigarette smoking, asbestos exposure, and diet in the trucking industry study was obtained from next of kin and stated that such information was ''likely to be unreliable.'' By increasing random variability in the data, such errors could widen the confidence intervals around an estimated odds ratio or reduce the confidence level at which a positive exposure-response relationship might be established. However, unless such errors were correlated with diesel exposure or lung cancer in such a way as to bias the results, they would not, on average, inflate the estimated degree of association between diesel exposure and an increased risk of lung cancer. The commenter provided no reason to suspect that errors with respect to these factors were in any way correlated with diesel exposure or with the development of lung cancer.

Some commenters pointed out that EC concentrations measured in 1990 for truck mechanics were higher, on average, than for truck drivers, but the mechanics, unlike the drivers, showed no evidence of increasing lung cancer risk with increasing duration of employment. NITC referred to this as a ''discrepancy'' in the data, assuming that ''cumulative exposure increases with duration of employment such that mechanics who have been employed for 18 or more years would have greater cumulative exposure than workers who have been employed for 1–11 years.'' (NITC, 1999)

Mechanics were included in the logistic regression analyses (Steenland et al., 1998) showing an increase in lung cancer risk with increasing cumulative exposure. These analyses pooled the data for all occupations by estimating exposure for each worker based on the worker's occupation and the particular years in which the worker was employed. There are at least three reasons why, for mechanics viewed as a separate group, an increase in lung cancer risk with increasing dpm exposure may not have been reflected by increasing duration of employment.

First, relatively few truck mechanics were available for analyzing the relationship between length of employment and the risk of lung cancer. Based on the union records, 50 cases and 37 controls were so classified; based on the next-of-kin data, 43 cases and 41 controls were more specifically classified as diesel truck mechanics

[57] Many of the issues NITC raised in its critique of this study depend on a peculiar identification of Dpm exclusively with elemental carbon. For example, NITC argued that ''more than 65 percent of the total carbon to which road drivers (and mechanics) were exposed consisted of organic (i.e., non-diesel) carbon, further suggesting that some other etiology caused or contributed to excess lung cancer mortality in these workers.'' (NITC, 1999, p. 16) Such lines of argument, which depend on identifying organic carbon as ''non-diesel,'' ignore the fact that Dpm contains a large measure of organic carbon compounds (and also some sulfates), as well as elemental carbon. Any adverse health effects due to the organic carbon or sulfate constituents of Dpm would nonetheless be due to Dpm exposures.

(Steenland et al., 1990). In contrast, 609 cases and 604 controls were classified as long-haul drivers (union records). This was both the largest occupational category and the only one showing statistically significant evidence of increasing risk with increasing employment duration. The number of mechanics included in the study population may simply not have been sufficient to detect a pattern of increasing risk with increasing length of employment, even if such a pattern existed.

The second part of the explanation as to why mechanics did not exhibit a pattern similar to truck drivers could be that the data on mechanics were more subject to confounding. After noting that ''the risk for mechanics did not appear to increase consistently with duration of employment,'' Steenland et al. (1990) further noted that the mechanics may have been exposed to asbestos when working on brakes. The data used to adjust for asbestos exposure may have been inadequate to control for variability in asbestos exposure among the mechanics.

Third, as noted by NITC, the lung cancer risk for mechanics (adjusted for age, race, tobacco smoking, asbestos exposure, and diet) would be expected to increase with increasing duration of employment only if the mechanics' cumulative dpm exposure corresponded to the length of their employment. None of the commenters raising this issue, however, provided any support for this assumption, which fails to consider the particular calendar years in which mechanics included in the study were employed. In compiling cumulative exposure for an individual worker, the investigators took into account historical changes in both diesel emissions and the proportion of trucks with diesel engines—so the exposure level assigned to each occupational category was not the same in each year. In general, workers included in the study neither began nor ended their employment in the same year. Consequently, workers with the same duration of employment in the same occupational category could be assigned different cumulative exposures, depending on when they were employed. Similarly, workers in the same occupational category who were assigned the same cumulative exposure may not have worked the same length of time in that occupation. Therefore, it should not be assumed that duration of employment corresponds very well to the cumulative exposure estimated for workers within any of the occupational categories. Furthermore, in the case of mechanics, there is an additional historical variable that is especially relevant to actual cumulative exposure but was not considered in formulating exposure estimates: the degree of ventilation or other means of protection within repair shops. Historical changes in shop design and work practices, as well as differences between shops, may have caused more exposure misclassification among mechanics than among long-haul or diesel truck drivers. Such misclassification would tend to further obscure any relationship between mechanics' risk of lung cancer and either duration of employment or cumulative exposure.

(iv) Counter-Evidence

Several commenters stated that, in the proposal, MSHA had dismissed or not adequately addressed epidemiology studies showing no association between lung cancer and exposures to diesel exhaust. For example, the EMA wrote:

> MSHA's discussion of the negative studies generally consists of arguments to explain why those studies should be dismissed. For example, MSHA states that, ''All of the studies showing negative or statistically insignificant positive associations * * * lacked good information about dpm exposure * * *'' or showed similar shortcomings. 63 Fed. Reg. at 17533. The statement about exposure information is only partially true, for, in fact, very few of any of the cited studies (the ''positive'' studies as well) included any exposure measurements, and none included concurrent exposures.

It should, first of all, be noted that the statement in question on dpm exposure referred to the issue of any diesel exposure—not to quantitative exposure measurements, which MSHA acknowledges are lacking in most of the available studies. In the absence of quantitative measurements, however, studies comparing workers known to have been occupationally exposed to unexposed workers are preferable to studies not containing such comparisons. Furthermore, two of the studies now available (and discussed above) utilize essentially concurrent exposure measurements, and both show a positive association (Johnston et al., 1997; Säverin et al., 1999).

MSHA did not entirely ''dismiss'' the negative studies. They were included in both MSHA's tabulation (see Tables III–4 and III–5) and (if they met the inclusion criteria) in the two meta-analyses cited both here and in the proposal (Lipsett and Campleman, 1999, and Bhatia et al., 1998). As noted by the commenter, MSHA presented reasons (such as an inadequate latency allowance) for why negative studies may have failed to detect an association. Similarly MSHA gave reasons for giving less weight to some of the positive studies, such as Benhamou et al. (1988), Morabia et al. (1992), and Siemiatycki et al., 1988. Additional reasons for giving less weight to the six entirely negative studies have been tabulated above, under the heading of ''Best Available Epidemiologic Evidence.'' The most recent of these negative studies (Christie et al., 1994, 1995) is discussed in detail under the heading of ''Studies Involving Miners.''

One commenter (IMC Global) listed the following studies (all of which MSHA had considered in the proposed risk assessment) as ''examples of studies that reported negative associations between [dpm] exposure and lung cancer risk'':

- Waller (1981). This is one of the six negative studies discussed earlier. Results were likely to have been biased by excluding lung cancers occurring after retirement or resignation from employment with the London Transit Authority. Comparison was to a general population, and there was no adjustment for a healthy worker effect. Comparison groups were disparate, and there was no adjustment for possible differences in smoking frequency or intensity.
- Howe et al. (1983). Contrary to the commenter's characterization of this study, the investigators reported statistically significant elevations of lung cancer risk for workers classified as ''possibly exposed'' or ''probably exposed'' to diesel exhaust. MSHA recognizes that these results may have been confounded by asbestos and coal dust exposures.
- Wong et al. (1985). The investigators reported a statistically insignificant deficit for lung cancer in the entire cohort and a statistically significant deficit for lung cancer in the less than 5-year duration group. However, since comparisons were to a general population, these deficits may be the result of a healthy worker effect, for which there was no adjustment. Because of the latency required for development of lung cancer, the result for ''less than 5-year duration'' is far less informative than the results for longer durations of employment and greater latency allowances. Contrary to the commenter's characterization of this study, the investigators reported statistically significant elevations of lung cancer risks for ''normal'' retirees (SMR = 1.30) and for ''high exposure'' dozer operators with 15–19 years of union membership and a latency allowance of at least 20 years (SMR = 3.43).
- Edling et al. (1987). This is one of the six negative studies discussed

earlier. The cohort consisted of only 694 bus workers and, therefore, lacked statistical power. Furthermore, comparison was to a general, external population with no adjustment for a healthy worker effect.

• Garshick (1988). The reason the commenter (IMC Global) gave for characterizing this study as negative was: ''That the sign of the association in this data set changes based on the models used suggests that the effect is not robust. It apparently reflects modeling assumptions more than data.'' Contrary to the commenter's characterization, however, the finding of increased lung cancer risk for workers classified as diesel-exposed did not change when different methods were used to analyze the data. What changed, depending on modeling assumptions, was the shape and direction of the exposure-response relationship among exposed workers (Cal-EPA, 1998; Stayner et al., 1998; Crump, 1999; HEI, 1999). MSHA agrees that the various exposure-response relationships that have been derived from this study are highly sensitive to data modeling assumptions. This includes assumptions about historical patterns of exposure, as well as assumptions related to technical aspects of the statistical analysis. However, as noted by the HEI Expert Panel, the study provides evidence of a positive association between exposure and lung cancer despite the conflicting exposure-response analyses. Even though different assumptions and methods of analysis have led to different conclusions about the utility of this study for quantifying an exposure-response relationship, ''the overall risk of lung cancer was elevated among diesel-exposed workers'' (HEI, 1999, p. 25).

Another commenter (MARG) cited a number of studies (all of which had already been placed in the public record by MSHA) that, according to the commenter, ''reflect either negative health effects trends among miners or else failed to demonstrate a statistically significant positive trend correlated with dpm exposure.'' It should be noted that, as explained earlier, failure of an individual study to achieve statistical significance (i.e., a high confidence level for its results) does not necessarily prevent a study from contributing important information to a larger body of evidence. An epidemiologic study may fail to achieve statistical significance simply because it did not involve a sufficient number of subjects or because it did not allow for an adequate latency period. In addition to this general point, the following responses apply to the specific studies cited by the commenter.

• Ahlman et al. (1991). This study is discussed above, under the heading of ''Studies Involving Miners.'' MSHA agrees with the commenter that this study did not ''establish'' a relationship between diesel exposure and the excess risk of lung cancer reported among the miners involved. Contrary to the commenter's characterization, however, the evidence presented by this study does incrementally point in the direction of such a relationship. As mentioned earlier, none of the underground miners who developed lung cancer had been occupationally exposed to asbestos, metal work, paper pulp, or organic dusts. Based on measurements of the alpha energy concentration at the mines, and a comparison of smoking habits between underground and surface miners, the authors concluded that not all of the excess lung cancer for the underground miners was attributable to radon daughter exposures and/or smoking. A stronger conclusion may have been possible if the cohort had been larger.

• Ames et al. (1984). MSHA has taken account of this study, which made no attempt to evaluate cancer effects, under the heading of ''Chronic Effects other than Cancer.'' The commenter repeated MSHA's statement (in the proposed risk assessment) that the investigators had not detected any association of chronic respiratory effects with diesel exposure, but ignored MSHA's observation that the analysis had failed to consider baseline differences in lung function or symptom prevalence. Furthermore, as acknowledged by the investigators, diesel exposure levels in the study population were low.

• Ames et al. (1983). As discussed later in this risk assessment, under the heading of ''Mechanisms of Toxicity,'' this study was among nine (out of 17) that did not find evidence of a relationship between exposure to respirable coal mine dust and an increased risk of lung cancer. Unlike the Australian mines studied by Christie et al. (1995), the coal mines included in this study were not extensively dieselized, and the investigators did not relate their findings to diesel exposures.

• Ames et al. (1982). As noted earlier under the heading of ''Acute Health Effects,'' this study, which did not attempt to evaluate cancer or other chronic health effects, detected no statistically significant relationship between diesel exposure and pulmonary function. However, the authors noted that this might have been due to the low concentrations of diesel emissions involved.

• Armstrong et al. (1979). As discussed later in this risk assessment, this study was among nine (out of 17) that did not find evidence of a relationship between exposure to respirable coal mine dust and an increased risk of lung cancer. As pointed out by the commenter, comparisons were to a general population. Therefore, they were subject to a healthy worker effect for which no adjustment was made. The commenter further stated that ''diesel emissions were not found to be related to increased health risks.'' However, diesel emissions were not mentioned in the report, and the investigators did not attempt to compare lung cancer rates in exposed and unexposed miners.

• Attfield et al. (1982). MSHA has taken the results of this study into account, under the heading of ''Chronic Effects other than Cancer.''

• Attfield (1979). MSHA has taken account of this study, which did not attempt to evaluate cancer effects, under the heading of ''Chronic Effects other than Cancer.'' Although the results were not conclusive at a high confidence level, miners occupationally exposed to diesel exhaust for five or more years exhibited an increase in various respiratory symptoms, as compared to miners exposed for less than five years.

• Boffetta et al. (1988). This study is discussed in two places above, under the headings ''Studies Involving Miners'' and ''Best Available Epidemiologic Evidence.'' The commenter stated that ''the study obviously does not demonstrate risks from dpm exposure.'' If the word ''demonstrate'' is taken to mean ''conclusively prove,'' then MSHA would agree that the study, viewed in isolation, does not do this. As explained in the earlier discussion, however, MSHA considers this study to contribute to the weight of evidence that dpm exposure increases the risk of lung cancer.

• Costello *et al.* (1974). As discussed later in this risk assessment, this study was among nine (out of 17) that did not find evidence of a relationship between exposure to respirable coal mine dust and an increased risk of lung cancer. Since comparisons were to a general population, they were subject to a healthy worker effect for which no adjustment was made. Diesel emissions were not mentioned in the report.

• Gamble and Jones (1983). MSHA has taken account of this study, which did not attempt to evaluate cancer effects, under the heading of ''Chronic Effects other than Cancer.'' The commenter did not address MSHA's observation that the method of

statistical analysis used by the investigators may have masked an association of respiratory symptoms with diesel exposure.

• Glenn *et al.* (1983). As summarized by the commenter, this report reviewed NIOSH medical surveillance on miners exposed to dpm and found that ''* * * neither consistent nor obvious trends implicating diesel exhaust in the mining atmosphere were revealed.'' The authors noted that ''results were rather mixed,'' but also noted that ''levels of diesel exhaust contaminants were generally low,'' and that ''overall tenure in these diesel equipped mines was fairly short.'' MSHA acknowledges the commenter's emphasis on the report's 1983 conclusion: ''further research on this subject is needed.'' However, the authors also pointed out that ''all four of the chronic effects analyses revealed an excess of cough and phlegm among the diesel exposed group. In the potash, salt and trona groups, these excesses were substantial.'' The miners included in the studies summarized by this report would not have been exposed to Dpm for sufficient time to exhibit a possible increase in the risk of lung cancer.

• Johnston *et al.* (1997). This study is discussed in two places above, under the headings ''Studies Involving Miners'' and ''Best Available Epidemiologic Evidence.'' MSHA disagrees with the commenter's assertion that ''the study does not support a health risk from dpm.'' This was not the conclusion drawn by the authors of the study. As explained in the earlier discussion, this study, one of the few containing quantitative estimates of cumulative dpm exposures, provides evidence of increasing lung cancer risk with increasing exposure.

• Jörgenson and Svensson (1970). MSHA discussed this study, which did not attempt to evaluate cancer effects, under the heading of ''Chronic Effects other than Cancer.'' Contrary to the commenter's characterization, the investigators reported higher rates of chronic productive bronchitis, for both smokers and nonsmokers, among the underground iron ore miners exposed to diesel exhaust as compared to surface workers at the same mine.

• Kuempel (1995); Lidell (1973); Miller and Jacobsen (1985). As discussed later in this risk assessment, under the heading of ''Mechanisms of Toxicity,'' these three studies were among the nine (out of 17) that did not find evidence of a relationship between exposure to respirable coal mine dust and an increased risk of lung cancer. The extent, if any, to which workers involved in these studies were occupationally exposed to diesel emissions was not documented, and diesel emissions were not mentioned in any of these reports.

• Morfeld *et al.* (1997). The commenter's summary of this study distorted the investigators' conclusions. Contrary to the commenter's characterization, this is one of eight studies that showed an increased risk of lung cancer for coal miners, as discussed later in this risk assessment under the heading of ''Mechanisms of Toxicity.'' For lung cancer, the relative SMR, which adjusts for the healthy worker effect, was 1.11. (The value of 0.70 cited by the commenter was the unadjusted SMR.) The authors acknowledged that the relative SMR obtained by the ''standard analysis'' (*i.e.,* 1.11) was not statistically significant. However, the main object of the report was to demonstrate that the ''standard analysis'' is insufficient. The investigators presented evidence that the 1.11 value was biased downward by a ''healthy-worker-survivor-effect,'' thereby masking the actual exposure effects in these workers. They found that ''all the evidence points to the conclusion that a standard analysis suffers from a severe underestimate of the exposure effect on overall mortality, cancer mortality and lung cancer mortality.'' (Morfeld *et al.,* 1997, p. 350)

• Reger (1982). MSHA has taken account of this study, which made no attempt to evaluate cancer effects, under the heading of ''Chronic Effects other than Cancer.'' As summarized by the commenter, ''diesel-exposed miners were found to have more cough and phlegm, and lower pulmonary function,'' but the author found that ''the evidence would not allow for the rejection of the hypothesis of health equality between exposed and non-exposed miners.'' The commenter failed to note, however, that miners in the dieselized mines, had worked underground for less than 5 years on average.

• Rockette (1977). This is one of eight studies, discussed under ''Mechanisms of Toxicity,'' showing an increased risk of lung cancer for coal miners. As described by the commenter, the author reported SMRs of 1.12 for respiratory cancers and 1.40 for stomach cancer. MSHA agrees with the commenter that ''the study does not establish a dpm-related health risk,'' but notes that dpm effects were not under investigation. Diesel emissions were not mentioned in the report, and, given the study period, the miners involved may not have been occupationally exposed to diesel exhaust.

• Waxweiler (1972). MSHA's discussion of this study appears earlier in this risk assessment, under ''Studies Involving Miners.'' As noted by the commenter, the slight excess in lung cancer, relative to the general population of New Mexico, was not statistically significant. The commenter failed to note, however, that no adjustment was made for a healthy worker effect and that a substantial percentage of the underground miners were not occupationally exposed to diesel emissions.

(v) Summation

Limitations identified in both positive and negative studies include: lack of sufficient power, inappropriate comparison groups, exposure misclassification, statistically insignificant results, and potential confounders. As explained earlier, under ''Evaluation Criteria,'' weaknesses of the first three of these types can reasonably be expected, for the most part, to artificially decrease the apparent strength of any observed association between diesel exposure and increased risk of lung cancer. Statistical insignificance and potential confounders may, in the absence of evidence to the contrary, be regarded as neutral on average. The weaknesses that have been identified in these studies are not unique to epidemiologic studies involving lung cancer and diesel exhaust. They are sources of uncertainty in virtually all epidemiologic research.

Even when there is a strong possibility that the results of a study have been affected by confounding variables, it does not follow that the effect has been to inflate rather than deflate the results or that the study cannot contribute to the weight of evidence supporting a putative association. As cogently stated by Stöber and Abel (op cit., p. 4), ''* * * associations found in epidemiologic studies can always be, at least in part, attributed to confounding.'' Therefore, an objection grounded on potential confounding can always be raised against any epidemiologic study. It is well known that this same objection was, in the past, raised against epidemiologic studies linking lung cancer and radon exposure, lung cancer and asbestos dust exposure, and even lung cancer and tobacco smoking.

Some commenters have now proposed that virtually every existing epidemiologic study relating lung cancer to dpm exposure be summarily discredited because of susceptibility to confounding or other perceived weaknesses. Given the practical difficulties of designing and executing an epidemiologic study, this is not so much an objection to any specific study

as it is an attack on applied epidemiology in general. Indeed, in their review of these studies, Stöber and Abel (1996) conclude that.

> In this field * * * epidemiology faces its limits (Taubes, 1995). * * * Many of these studies were doomed to failure from the very beginning.

For important ethical reasons, however, tightly controlled lung cancer experiments cannot be performed on humans. Therefore, despite their inherent limitations, MSHA must rely on the weight of evidence from epidemiologic studies, placing greatest weight on the most carefully designed and executed studies available.

(b) Bladder Cancer

With respect to cancers other than lung cancer, MSHA's review of the literature identified only bladder cancer as a possible candidate for a causal link to dpm. Cohen and Higgins (1995) identified and reviewed 14 epidemiologic case-control studies containing information related to dpm exposure and bladder cancer. All but one of these studies found elevated risks of bladder cancer among workers in jobs frequently associated with dpm exposure. Findings were statistically significant in at least four of the studies (statistical significance was not evaluated in three).

These studies point quite consistently toward an excess risk of bladder cancer among truck or bus drivers, railroad workers, and vehicle mechanics. However, the four available cohort studies do not support a conclusion that exposure to dpm is responsible for the excess risk of bladder cancer associated with these occupations. Furthermore, most of the case-control studies did not distinguish between exposure to diesel-powered equipment and exposure to gasoline-powered equipment for workers having the same occupation. When such a distinction was drawn, there was no evidence that the prevalence of bladder cancer was higher for workers exposed to the diesel-powered equipment.

This, along with the lack of corroboration from existing cohort studies, suggests that the excessive rates of bladder cancer observed may be a consequence of factors other than dpm exposure that are also associated with these occupations. For example, truck and bus drivers are subjected to vibrations while driving and may tend to have different dietary and sleeping habits than the general population. For these reasons, MSHA does not find that convincing evidence currently exists for a causal relationship between dpm exposure and bladder cancer. MSHA received no public comments objecting to this conclusion.

ii. Studies Based on Exposures to $PM_{2.5}$ in Ambient Air

Prior to 1990, the relationship between mortality and long-term exposure to particulate matter was generally investigated by means of cross-sectional studies, but unaddressed spatial confounders and other methodological problems inherent in such studies limited their usefulness (EPA, 1996).[58] Two more recent prospective cohort studies provide better evidence of a link between excess mortality rates and exposure to fine particulate, although some of the uncertainties here are greater than with the short-term studies conducted in single communities. The two studies are the ''Six Cities'' study (Dockery et al., 1993), and the American Cancer Society (ACS) study (Pope et al., 1995).[59] The first study followed about 8,000 adults in six U.S. cities over 14 years; the second looked at survival data for half a million adults in 151 U.S. cities for 7 years. After adjusting for potential confounders, including smoking habits, the studies considered differences in mortality rates between the most polluted and least polluted cities.

Both the Six Cities study and the ACS study found a significant association between chronically higher concentrations of $PM_{2.5}$ (which includes dpm) and age-adjusted total mortality.[60] The authors of the Six Cities Study concluded that the results suggest that exposures to fine particulate air pollution ''contributes to excess mortality in certain U.S. cities.'' The ACS study, which not only controlled for smoking habits and various occupational exposures, but also, to some extent, for passive exposure to tobacco smoke, found results qualitatively consistent with those of the Six Cities Study.[61] In the ACS study, however, the estimated increase in mortality associated with a given increase in fine particulate exposure was lower, though still statistically significant. In both studies, the largest increase observed was for cardiopulmonary mortality.

Both studies also showed an increased risk of lung cancer associated with increased exposure to fine particulate. Although the lung cancer results were not statistically significant, they are consistent with reports of an increased risk of lung cancer among workers occupationally exposed to diesel emissions (discussed above).

The few studies on associations between chronic $PM_{2.5}$ exposure and morbidity in adults show effects that are difficult to separate from measures of PM_{10} and measures of acid aerosols. The available studies, however, show positive associations between particulate air pollution and adverse health effects for those with pre-existing respiratory or cardiovascular disease. This is significant for miners occupationally exposed to fine particulates such as dpm because, as mentioned earlier, there is a large body of evidence showing that respiratory diseases classified as COPD are significantly more prevalent among miners than in the general population. It also appears that PM exposure may exacerbate existing respiratory infections and asthma, increasing the risk of severe outcomes in individuals who have such conditions (EPA, 1996).

d. Mechanisms of Toxicity

Four topics will be addressed in this section of the risk assessment: (i) the agent of toxicity, (ii) clearance and deposition of dpm, (iii) effects other than cancer, and (iv) lung cancer. The section on lung cancer will include discussions of the evidence from (1) genotoxicity studies (including bioavailability of genotoxins) and (2) animal studies.

i. Agent of Toxicity

As described in Part II of this preamble, the particulate fraction of diesel exhaust is made up of aggregated soot particles, vapor phase hydrocarbons, and sulfates. Each soot particle consists of an insoluble, elemental carbon core and an adsorbed, surface coating of relatively soluble organic compounds, such as polycyclic aromatic hydrocarbons (PAHs). Many of these organic carbon compounds are

[58] Unlike *longitudinal studies,* which examine responses at given locations to changes in conditions over time, *cross-sectional studies* compare results from locations with different conditions at a given point in time.

[59] A third such study, the California Seventh Day Adventist study (Abbey et al., 1991), investigated only TSP, rather than fine particulate. It did not find significant excess mortality associated with chronic TSP exposures.

[60] The Six Cities study also found such relationships at elevated levels of PM_{10} and sulfates. The ACS study was designed to follow up on the fine particle results of the Six Cities Study, and also investigated sulfates separately. As explained earlier in this preamble, sulfates may be a significant constituent of dpm, depending on the type of diesel fuel used.

[61] The Six Cities study did not find a statistically significant increase in risk among non-smokers, suggesting that non-smokers might be less sensitive than smokers to adverse health effects from fine particulate exposures; however, the ACS study, with more statistical power, did find significantly increased risk even for non-smokers.

suspected or known mutagens and/or carcinogens. For example, nitrated PAHs, which are present in dpm, are potent mutagens in microbial and human cell systems, and some are known to be carcinogenic to animals (IPCS, 1996, pp. 100–105).

When released into an atmosphere, the soot particles formed during combustion tend to aggregate into larger particles. The total organic and elemental carbon in these soot particles accounts for approximately 80 percent of the dpm mass. The remaining 20 percent consists mainly of sulfates, such as H_2SO_4 (sulfuric acid).

Several laboratory animal studies have been performed to ascertain whether the effects of diesel exhaust are attributable specifically to the particulate fraction. (Heinrich *et al.,* 1986, 1995; Iwai *et al.,* 1986; Brightwell *et al.,* 1986). These studies compare the effects of chronic exposure to whole diesel exhaust with the effects of filtered exhaust containing no particles. The studies demonstrate that when the exhaust is sufficiently diluted to nullify the effects of gaseous irritants (NO_2 and SO_2), irritant vapors (aldehydes), CO, and other systemic toxicants, diesel particles are the prime etiologic agents of noncancer health effects. Exposure to dpm produced changes in the lung that were much more prominent than those evoked by the gaseous fraction alone. Marked differences in the effects of whole and filtered diesel exhaust were also evident from general toxicological indices, such as body weight, lung weight, and pulmonary histopathology.

These studies show that, when the exhaust is sufficiently diluted, it is the particles that are primarily responsible for the toxicity observed. However, the available studies do not completely settle the question of whether the particles might act additively or synergistically with the gases in diesel exhaust. Possible additivity or interaction effects with the gaseous portion of diesel exhaust cannot be completely ruled out.

One commenter (MARG) raised an issue with regard to the agent of toxicity in diesel exhaust as follows:

> MSHA has not attempted to regulate exposure to suspected carcinogens contained in dpm, but has opted instead, in metal/nonmetal mines, to regulate total carbon (''TC'') as a surrogate for diesel exhaust, without any evidence of adverse health effects from TC exposure. * * * Nor does the mere presence of suspected carcinogens, in minute quantities, in diesel exhaust require a 95 percent reduction of total diesel exhaust [sic] in coal mines. If there are small amounts of carcinogenic substances of concern in diesel exhaust, those substances, not TC, should be regulated directly on the basis of the risks (if any) posed by those substances in the quantities actually present in underground mines. [MARG]

First, it should be noted that the ''suspected carcinogens'' in diesel exhaust to which the commenter referred are part of the organic fraction of the total carbon. Therefore, limiting the concentration of airborne total carbon attributable to dpm, or removing the soot particles from the diesel exhaust by filtration, are both ways of effectively limiting exposures to these suspected carcinogens. Second, the commenter seems to have assumed that cancer is the only adverse health effect of concern and that the only agents in dpm that could cause cancer are the ''suspected carcinogens'' in the organic fraction. This not only ignores non-cancer health effects associated with exposures to dpm and other fine particles, but also the possibility (discussed below) that, with sufficient deposition and retention, soot particles themselves could promote or otherwise increase the risk of lung cancer—either directly or by stimulating the body's natural defenses against foreign substances.

The same commenter [MARG] also stated that ''* * * airborne carbon has not been shown to be harmful at levels currently established in MSHA's dust rules. If the problem is dpm, as MSHA asserts, then it is not rationally addressed by regulating airborne carbon.'' MSHA's intent is to limit dpm exposures in M/NM mines by regulating the submicrometer carbon from diesel emissions—not any and all airborne carbon. MSHA considers its approach a rational means of limiting dpm exposures because most of the dpm consists of carbon (approximately 80 percent by weight), and because using low sulfur diesel fuel will effectively reduce the sulfates comprising most of the remaining portion. The commenter offered no practical suggestion of a more direct, effective, and rational way of limiting airborne dpm concentrations in M/NM mines. Furthermore, direct evidence exists that the risk of lung cancer increases with increasing cumulative occupational exposure to dpm as measured by total carbon (Säverin *et al.,* 1999, discussed earlier in this risk assessment).

ii. Deposition, Clearance, and Retention

As suggested by Figure II–1 of this preamble, most of the aggregated particles making up dpm are no larger than one micrometer in diameter. Particles this small are able to penetrate into the deepest regions of the lungs, called *alveoli.* In the alveoli, the particles can mix with and be dispersed by a substance called *surfactant,* which is secreted by cells lining the alveolar surfaces.

The literature on deposition of fine particles in the respiratory tract was reviewed in Green and Watson (1995) and U.S. EPA (1996). The mechanisms responsible for the broad range of potential particle-related health effects varies depending on the site of deposition. Once deposited, the particles may be cleared from the lung, translocated into the interstitium, sequestered in the lymph nodes, metabolized, or be otherwise chemically or physically changed by various mechanisms. Clearance of dpm from the alveoli is important in the long-term effects of the particles on cells, since it may be more than two orders of magnitude slower than mucociliary clearance (IPCS, 1996).

IARC (1989) and IPCS (1996) reviewed factors affecting the deposition and clearance of dpm in the respiratory tracts of experimental animals. Inhaled PAHs adhering to the carbon core of dpm are cleared from the lung at a significantly slower rate than unattached PAHs. Furthermore, there is evidence that inhalation of whole dpm may increase the retention of subsequently inhaled PAHs. IARC (op cit.) suggested that this can happen when newly introduced PAHs bind to dpm particles that have been retained in the lung.

The evidence points to significant differences in deposition and clearance for different animal species (IPCS, 1996). Under equivalent exposure regimens, hamsters exhibited lower levels of retained Dpm in their lungs than rats or mice and consequently less pulmonary function impairment and pulmonary pathology. These differences may result from a lower intake rate of Dpm, lower deposition rate and/or more rapid clearance rate, or lung tissue that is less susceptible to the cytotoxicity of Dpm. Observations of a decreased respiration in hamsters when exposed by inhalation favor lower intake and deposition rates.

Retardation of lung clearance, called ''overload'' is not specific to dpm and may be caused by inhaling, at a sufficiently high rate, dpm in combination with other respirable particles, such as mineral dusts typical of mining environments. The effect is characterized by (1) an overwhelming of normal clearance processes, (2) disproportionately high retention and loading of the lung with particles, compared to what occurs at lower particle inhalation rates, (3) various pathological responses; generally including chronic inflammation,

epithelial hyperplasia and metaplasia, and pulmonary fibrosis; and sometimes including lung tumors.

In the proposed risk assessment, MSHA requested additional information, not already covered in the sources cited above, on fine particle deposition in the respiratory tract, especially as it might pertain to lung loading in miners exposed to a combination of diesel particulate and other dusts. In response to this request, NIOSH submitted a study that investigated rat lung responses to chronic inhalation of a combination of coal dust and diesel exhaust, compared to coal dust or dpm alone (Castranova et al., 1985). Although this report did not directly address deposition or clearance, the investigators reported that another phase of the study had shown that ''particulate clearance, as determined by particulate accumulation in the lung, is inhibited after two years of exposure to diesel exhaust but is not inhibited by exposure to coal dust.''

iii. Effects Other Than Cancer

A number of controlled animal studies have been undertaken to ascertain the toxic effects of exposure to diesel exhaust and its components. Watson and Green (1995) reviewed approximately 50 reports describing noncancerous effects in animals resulting from the inhalation of diesel exhaust. While most of the studies were conducted with rats or hamsters, some information was also available from studies conducted using cats, guinea pigs, and monkeys. The authors also correlated reported effects with different descriptors of dose, including both gravimetric and non-gravimetric (*e.g.,* particle surface area or volume) measures. From their review of these studies, Watson and Green concluded that:

(a) Animals exposed to diesel exhaust exhibit a number of noncancerous pulmonary effects, including chronic inflammation, epithelial cell hyperplasia, metaplasia, alterations in connective tissue, pulmonary fibrosis, and compromised pulmonary function.

(b) Cumulative weekly exposure to diesel exhaust of 70 to 80 mg·hr/m^3 or greater are associated with the presence of chronic inflammation, epithelial cell proliferation, and depressed alveolar clearance in chronically exposed rats.

(c) The extrapolation of responses in animals to noncancer endpoints in humans is uncertain. Rats were the most sensitive animal species studied.

Subsequent to the review by Watson and Green, there have been a number of animal studies on allergic immune responses to dpm. Takano et al. (1997) investigated the effects of dpm injected into mice through an intratracheal tube and found manifestations of allergic asthma, including enhanced antigen-induced airway inflammation, increased local expression of cytokine proteins, and increased production of antigen-specific immunoglobulins. The authors concluded that the study demonstrated dpm's enhancing effects on allergic asthma and that the results suggest that dpm is ''implicated in the increasing prevalence of allergic asthma in recent years.'' Similarly, Ichinose et al. (1997a) found that five different strains of mice injected intratracheally with dpm exhibited manifestations of allergic asthma, as expressed by enhanced airway inflammation, which were correlated with an increased production of antigen-specific immunoglobulin due to the dpm. The authors concluded that dpm enhances manifestations of allergic airway inflammation and that '' * * * the cause of individual differences in humans at the onset of allergic asthma may be related to differences in antigen-induced immune responses * * *.''

The mechanisms that may lead to adverse health effects in humans from inhaling fine particulates are not fully understood, but potential mechanisms that have been hypothesized for non-cancerous outcomes are summarized in Table III–6. A comprehensive review of the toxicity literature is provided in U.S. EPA (1996).

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Table III-6. — Hypothesized mechanisms of particulate toxicity†

Response	Description
Increased Airflow Obstruction	PM exposure may aggravate existing respiratory symptoms which feature airway obstruction. PM-induced airway narrowing or airway obstruction from increased mucous secretion may increase abnormal ventilation/perfusion ratios in the lung and create hypoxia. Hypoxia may lead to cardiac arrhythmias and other cardiac electrophysiologic responses that in turn may lead to ventricular fibrillation and ultimately cardiac arrest. For those experiencing airflow obstruction, increased airflow into non-obstructed areas of the lung may lead to increased particle deposition and subsequent deleterious effects on remaining lung tissue, further exacerbating existing disease processes. More frequent and severe symptoms may be present or more rapid loss of function.
Impaired Clearance	PM exposure may impair clearance by promoting hypersecretion of mucus which in turn results in plugging of airways. Alterations in clearance may also extend the time that particles or potentially harmful biogenic aerosols reside in the tracheobronchial region of the lung. Consequently alterations in clearance from either disturbance of the mucociliary escalator or of macrophage function may increase susceptibility to infection, produce an inflammatory response, or amplify the response to increased burdens of PM. Acid aerosols impair mucociliary clearance.
Altered Host Defense	Responses to an immunological challenge (e.g., infection), may enhance the subsequent response to inhalation of nonspecific material (e.g., PM). PM exposure may also act directly on macrophage function which may not only affect clearance of particles but also increase susceptibility and severity of infection by altering their immunological function. Therefore, depression or over-activation of the immune system, caused by exposure to PM, may be involved in the pathogenesis of lung disease. Decreased respiratory defense may result in increased risk of mortality from pneumonia and increased morbidity (e.g., infection).
Cardiovascular Perturbation	Pulmonary responses to PM exposure may include hypoxia, bronchoconstriction, apnea, impaired diffusion, and production of inflammatory mediators that can contribute to cardiovascular perturbation. Inhaled particles could act at the level of the pulmonary vasculature by increasing pulmonary vascular resistance and further increase ventilation/perfusion abnormalities and hypoxia. Generalized hypoxia could result in pulmonary hypertension and interstitial edema that would impose further workload on the heart. In addition, mediators released during an inflammatory response could cause release of factors in the clotting cascade that may lead to increased risk of thrombus formation in the vascular system. Finally, direct stimulation by PM of respiratory receptors found throughout the respiratory tract may have direct cardiovascular effects (e.g., bradycardia, hypertension, arrhythmia, apnea and cardiac arrest).
Epithelial Lining Changes	PM or its pathophysiological reaction products may act at the alveolar capillary membrane by increasing the diffusion distances across the respiratory membrane (by increasing its thickness) and causing abnormal ventilation/perfusion ratios. Inflammation caused by PM may increase "leakiness" in pulmonary capillaries leading eventually to increased fluid transudation and possibly to interstitial edema in susceptible individuals. PM induced changes in the surfactant layer leading to increased surface tension would have the same effect.
Inflammatory Response	Diseases which increase susceptibility to PM toxicity involve inflammatory response (e.g., asthma, COPD, and infection). PM may induce or enhance inflammatory responses in the lung which may lead to increased permeability, diffusion abnormality, or increased risk of thrombus formation in vascular system. Inflammation from PM exposure may also decrease phagocytosis by alveolar macrophages and therefore reduce particle clearance. (See discussions above for other inflammatory effects from PM exposure.)

† This table was derived from information in EPA (1996) 11:179-185; 13:67-72; and Appendix D of EPA staff report.

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Deposition of particulates in the human respiratory tract may initiate events leading to increased airflow obstruction, impaired clearance, impaired host defenses, or increased epithelial permeability. Airflow obstruction can result from laryngeal constriction or bronchoconstriction secondary to stimulation of receptors in extrathoracic or intrathoracic airways. In addition to reflex airway narrowing, reflex or local stimulation of mucus secretion can lead to mucus hypersecretion and, eventually, to mucus plugging in small airways.

Pulmonary changes that contribute to cardiovascular responses include a variety of mechanisms that can lead to hypoxemia, including bronchoconstriction, apnea, impaired diffusion, and production of inflammatory mediators. Hypoxia can lead to cardiac arrhythmias and other cardiac electrophysiologic responses that, in turn, may lead to ventricular fibrillation and ultimately cardiac arrest. Furthermore, many respiratory receptors have direct cardiovascular effects. For example, stimulation of C-fibers leads to bradycardia and hypertension, and stimulation of laryngeal receptors can result in hypertension, cardiac arrhythmia, bradycardia, apnea, and even cardiac arrest. Nasal receptor or pulmonary J-receptor stimulation can lead to vagally-mediated bradycardia and hypertension (Widdicombe, 1988).

Some commenters mistakenly attributed the sensory irritant effects of diesel exhaust entirely to its gaseous components. The mechanism by which constituents of dpm can cause sensory irritations in humans is much better understood than the mechanisms for other adverse health effects due to fine particulates. In essence, sensory irritants are ''scrubbed'' from air entering the upper respiratory tract, thereby preventing a portion from penetrating more deeply into the lower respiratory tract. However, the sensory irritants stimulate trigeminal nerve endings, which are located very close to the oro-nasal mucosa and also to the watery surfaces of the eye (cornea). This produces a burning, painful sensation. The intensity of the sensory irritant response is related to the irritant concentration and duration of exposure. Differences in relative potency are observed with different sensory irritants. Acrolein and formaldehyde are examples of highly potent sensory irritants which, along with others having low molecular weights (acids, aldehydes), are often found in the organic fraction of dpm (Nauss et al., 1995). They may be adsorbed onto the carbon-based core or released in a vapor phase. Thus, mixtures of sensory irritants in dpm may impinge upon the eyes and respiratory tract of miners and produce adverse health effects.

It is also important to note that mixtures of sensory irritants in dpm may produce responses that are not predicted solely on the basis of the individual chemical constituents. Instead, these irritants may interact at receptor sites to produce additive, synergistic, or antagonistic effects. For example, because of synergism, dpm containing a mixture of sensory irritants at relatively low concentrations may produce intense sensory responses (i.e., responses far above those expected for the individual irritants). Therefore, the irritant effects of whole dpm cannot properly be evaluated by simply adding together the known effects of its individual components.

As part of its public comments on the proposed preamble, NIOSH submitted a study (Hahon et al., 1985) on the effects of diesel emissions on mice infected with influenza virus. The object of this study was to determine if exposure to diesel emissions (either alone or in combination with coal dust) could affect resistance to pulmonary infections. The investigators exposed groups of mice to either coal dust, diesel emissions, a combination of both, or filtered air (control group) for various durations, after which they were infected with influenza. Although not reflected by excess mortality, the severity of influenza infection was found to be more pronounced in mice previously exposed to diesel emissions than in control animals. The effect was not intensified by inhalation of coal dust in combination with those emissions.

In addition to possible acute toxicity of particles in the respiratory tract, chronic exposure to particles that deposit in the lung may induce inflammation. Inflammatory responses can lead to increased permeability and possibly diffusion abnormality. Furthermore, mediators released during an inflammatory response could cause release of factors in the clotting cascade that may lead to an increased risk of thrombus formation in the vascular system (Seaton, 1995). Persistent inflammation, or repeated cycles of acute lung injury and healing, can induce chronic lung injury. Retention of the particles may be associated with the initiation and/or progression of COPD.

Takenaka et al. (1995) investigated mechanisms by which dpm may act to cause allergenic effects in human cell cultures. The investigators reported that application of organic dpm extracts over a period of 10 to 14 days increased IgE production from the cells by a factor of up to 360 percent. They concluded that enhanced IgE production in the human airway resulting from the organic fraction of dpm may be an important factor in the increasing incidence of allergic airway disease. Similarly, Tsien et al. (1997) investigated the effects of the organic fraction of dpm on IgE production in human cell cultures and found that application of the organic extract doubled IgE production after three days in cells already producing IgE.

Sagai et al. (1996) investigated the potential role of dpm-induced oxygen radicals in causing pulmonary injuries. Repeated intratracheal instillation of dpm in mice caused marked infiltration of inflammatory cells, proliferation of goblet cells, increased mucus secretion, respiratory resistance, and airway constriction. The results indicated that oxygen radicals, induced by intratracheally instilled dpm, can cause responses characteristic of bronchial asthma.

Lovik et al (1997) investigated inflammatory and systemic IgE responses to dpm, alone and in combination with the model allergen ovalbumin (OA), in mice. To determine whether it was the elemental carbon core or substances in the organic fraction of dpm that were responsible for observed allergenic effects, they compared the effects of whole dpm with those of carbon black (CB) particles of comparable size and specific surface area. Although the effects were slightly greater for dpm, both dpm and CB were found to cause significant, synergistic increases in allergenic responses to the OA, as expressed by inflammatory responses of the local lymph node and OA-specific IgE production. The investigators concluded that both dpm and CB synergistically enhance and prolong inflammatory responses in the lymph nodes that drain the site of allergen deposition. They further concluded that the elemental carbon core contributes substantially to the adjuvant activity of dpm.

Diaz-Sanchez et al. (1994, 1996, 1997) conducted a series of experiments on human subjects to investigate the effects of dpm on allergic inflammation as measured by IgE production. The studies by Takenaka et al. (op cit.) and Tsien et al. (op cit.) were also part of this series but were based on human cell cultures rather than live human volunteers. A principal objective of these experiments was to investigate the pathways and mechanisms by which dpm induces allergic inflammation. The investigators found that the organic fraction of dpm can enhance IgE production, but that the major

polyaromatic hydrocarbon in this fraction (phenanthrene) can enhance IgE without causing inflammation. On the other hand, when human volunteers were sprayed intranasally with carbon particles lacking the organic compounds, the investigators found a large influx of cells in the nasal mucosa but no increase in IgE. These results suggest that while the organic portion of dpm is not necessary for causing irritation and local inflammation, it is the organic compounds that act on the immune system to promote an allergic response.

Salvi et al. (1999) investigated the impact of diesel exhaust on human airways and peripheral blood by exposing healthy volunteers to diesel exhaust at a concentration of 300 $\mu g/m^3$ for one hour with intermittent exercise. Following exposure, they found significant evidence of acute inflammatory responses in airway lavage and also in the peripheral blood. Some commenters expressed a belief that the gaseous, rather than particulate, components of diesel exhaust caused these effects. The investigators noted that the inflammatory responses observed could not be attributed to NO_2 in the diesel exhaust because previous studies they had conducted, using a similar experimental protocol, had revealed no such responses in the airway tissues of volunteers exposed to a higher concentration of NO_2, for a longer duration, in the absence of dpm. They concluded that ''[i]t therefore seems more likely that the particulate component of DE is responsible.''

iv. Lung Cancer

(1) Genotoxicity Studies

Many studies have shown that diesel soot, or its organic component, can increase the likelihood of genetic mutations during the biological process of cell division and replication. A survey of the applicable scientific literature is provided in Shirnamé-Moré (1995). What makes this body of research relevant to the risk of lung cancer is that mutations in critical genes can sometimes initiate, promote, or advance a process of carcinogenesis.

The determination of genotoxicity has frequently been made by treating diesel soot with organic solvents such as dichloromethane and dimethyl sulfoxide. The solvent removes the organic compounds from the carbon core. After the solvent evaporates, the mutagenic potential of the extracted organic material is tested by applying it to bacterial, mammalian, or human cells propagated in a laboratory culture. In general, the results of these studies have shown that various components of the organic material can induce mutations and chromosomal aberrations.

One commenter (MARG) pointed out that ''even assuming diesel exhaust contains particular genotoxic substances, the bioavailability of these genotoxins has been questioned.'' As acknowledged in the proposed risk assessment, a critical issue is whether whole diesel particulate is mutagenic when dispersed by substances present in the lung. Since the laboratory procedure for extracting organic material with solvents bears little resemblance to the physiological environment of the lung, it is important to establish whether dpm as a whole is genotoxic, without solvent extraction. Early research indicated that this was not the case and, therefore, that the active genotoxic materials adhering to the carbon core of diesel particles might not be biologically damaging or even available to cells in the lung (Brooks et al., 1980; King et al., 1981; Siak et al., 1981). A number of more recent research papers, however, have shown that dpm, without solvent extraction, can cause DNA damage when the soot is dispersed in the pulmonary surfactant that coats the surface of the alveoli (Wallace et al., 1987; Keane et al., 1991; Gu et al., 1991; Gu et al., 1992). From these studies, NIOSH concluded in 1992 that:

> * * * the solvent extract of diesel soot and the surfactant dispersion of diesel soot particles were found to be active in procaryotic cell and eukaryotic cell *in vitro* genotoxicity assays. The cited data indicate that respired diesel soot particles on the surface of the lung alveoli and respiratory bronchioles can be dispersed in the surfactant-rich aqueous phase lining the surfaces, and that genotoxic material associated with such dispersed soot particles is biologically available and genotoxically active. Therefore, this research demonstrates the biological availability of active genotoxic materials without organic solvent interaction. [Cover letter to NIOSH response to ANPRM, 1992].

If this conclusion is correct, it follows that dpm itself, and not only its organic extract, can cause genetic mutations when dispersed by a substance present in the lung.

One commenter (IMC Global) noted that Wallace et al. (1987) used aged dpm samples from scrapings inside an exhaust pipe and contended that this was not a realistic representation of dpm. The commenter further argued that the two studies cited by Gu et al. involved ''direct application of an unusually high concentration gradient'' that does not replicate normal conditions of dpm exposure.

MSHA agrees with this commenter's general point that conditions set up in such experiments do not duplicate actual exposure conditions. However, as a follow-up to the Wallace study, Keane *et al.* (op cit) demonstrated similar results with both exhaust pipe soot and particles obtained directly from an exhaust stream. With regard to the two Gu studies, MSHA recognizes that any well-controlled experiment serves only a limited purpose. Despite their limitations, however, these experiments provided valuable information. They avoided solvent extraction. By showing that solvent extraction is not a necessary condition of dpm mutagenicity, these studies provided incremental support to the hypothesis of bioavailability under more realistic conditions. This possibility was subsequently tested by a variety of other experiments, including experiments on live animals and humans.

For example, Sagai et al. (1996) showed that whole dpm produced active oxygen radicals in the trachea of live mice, but that dpm stripped of organic compounds did not. Whole dpm caused significant damage to the lungs and also high mortality at low doses. According to the investigators, most of the toxicity observed appeared to be due to the oxygen radicals, which can also have genotoxic effects. Subsequently, Ichinose *et al.* (1997b) examined the relationship between tumor response and the formation of oxygen radicals in the lungs of mice injected with dpm. The mice were treated with sufficiently high doses of dpm to produce tumors after 12 months. As in the earlier study, the investigators found that the dpm generated oxygen radicals, even in the absence of biologically activating systems (such as macrophages), and that these oxygen radicals were implicated in the lung toxicity of the dpm. The authors concluded that ''oxidative DNA damage induced by the repeated DEP [*i.e.*, dpm] treatment could be an important factor in enhancing the mutation rate leading to lung cancer.''

The formation of DNA adducts is an important indicator of genotoxicity and potential carcinogenicity. Adduct formation occurs when molecules, such as those in dpm, attach to the cellular DNA. These adducts can negatively affect DNA transcription and/or cellular duplication. If DNA adducts are not repaired, then a mutation or chromosomal aberration can occur during normal mitosis (*i.e.*, cell replication) eventually leading to cancer cell formation. IPCS (1996) contains a survey of animal experiments showing DNA adduct induction in the lungs of experimental animals exposed to diesel

exhaust.[62] MSHA recognizes that such studies provide limited information regarding the bioavailability of organics, since positive results may well have been related to factors associated with lung particle overload. However, the bioavailability of genotoxic dpm components is also supported by human studies showing genotoxic effects of exposure to whole dpm. DNA adduct formation and/or mutations in blood cells following exposure to dpm, especially at levels insufficient to induce lung overload, can be presumed to result from organics diffusing into the blood.

Hemminki *et al.* (1994) found that DNA adducts were significantly elevated in lymphocytes of nonsmoking bus maintenance and truck terminal workers, as compared to a control group of hospital mechanics, with the highest adduct levels found among garage and forklift workers. Hou et al. (1995) reported significantly elevated levels of DNA adducts in lymphocytes of non-smoking diesel bus maintenance workers compared to a control group of unexposed workers. Similarly, Nielsen *et al.* (1996) found that DNA adducts were significantly increased in the blood and urine of bus garage workers and mechanics exposed to dpm as compared to a control group.

One commenter (IMC Global) acknowledged that ''the studies conducted by Hemminiki [Hemminiki et al, 1994] showed elevations in lymphocyte DNA adducts in garage workers, bus maintenance workers and diesel forklift drivers'' but argued that ''these elevations were at the borderline of statistical significance.'' Although results at a higher level of confidence would have been more persuasive, this does not negate the value of the evidence as it stands. Furthermore, statistical significance in an individual study becomes less of an issue when, as in this case, the results are corroborated by other studies.

IMC Global also acknowledged that the Nielsen study found significant differences in DNA adduct formation between diesel-exposed workers and controls but argued that ''the real source of genotoxins was unclear, and other sources of exposure, such as skin contact with lubricating oils could not be excluded.'' As is generally the case with studies involving human subjects, this study did not completely control for potential confounders. For this reason, MSHA considers it important that several human studies—not all subject to confounding by the same variables—found elevated adduct levels in diesel-exposed workers.

IMC Global cited another human study (Qu *et al.,* 1997) as casting doubt on the genotoxic effects of diesel exposure, even though this study (conducted on Australian coal miners) reported significant increases in DNA adducts immediately after a period of intense diesel exposure during a longwall move. As noted by the commenter, adduct levels of exposed miners and drivers were, prior to the longwall move, approximately 50% higher than for the unexposed control group; but differences by exposure category were not statistically significant. A more informative part of the study, however, consisted of comparing adducts in the same workers before and after a longwall move, which involved ''intensive use of heavy equipment, diesel powered in these mines, over a 2–3 week period.'' MSHA emphasizes that the comparison was made on the same workers, because doing so largely controlled for potentially confounding variables, such as smoking habits, that may be a factor when making comparisons between different persons. After the period of ''intensive'' exposure, statistically significant increases were observed in both total and individual adducts. Contrary to the commenter's characterization of this study, the investigators stated that their analysis ''provides results in which the authors have a high level of confidence.'' They concluded that ''given the * * * apparent increase in adducts during a period of intense DEE [*i.e.*, diesel exhaust emissions] exposures it would be prudent to pay particular attention to keeping exposures as low as possible, especially during LWCO [*i.e.*, ''longwall change out''] operations.'' Although the commenter submitted this study as counter-evidence, it actually provides significant, positive evidence that high dpm exposures in a mining environment can produce genotoxic effects.

The West Virginia Coal Association submitted an analysis by Dr. Peter Valberg, purporting to show that ''* * * the quantity of particle-bound mutagens that could potentially contact lung cells under human exposure scenarios is very small.'' According to Dr. Valberg's calculations, the dose of organic mutagens deposited in the lungs of a worker occupationally exposed (40 hours per week) to 500 μg/m^3 of dpm would be equivalent in potency to smoking about one cigarette per month.[63] Dr. Valberg indicated that a person smoking at this level would generally be classified a nonsmoker, but he made no attempt to quantify the carcinogenic effects. Nor did he compare this exposure level with levels of exposures to environmental tobacco smoke that have been linked to lung cancer.

Since the commenter did not provide details of Dr. Valberg's calculation, MSHA was unable to verify its accuracy or evaluate the plausibility of key assumptions. However, even if the equivalence is approximately correct, using it to discount the possibility that dpm increases the risk of lung cancer relies on several questionable assumptions. Although their precise role in the analysis is unclear because it was not presented in detail, these assumptions apparently include:

(1) That there is a good correlation between genotoxicity dose-response and carcinogenicity dose-response. Although genotoxicity data can be very useful for identifying a carcinogenic hazard, carcinogenesis is a highly complex process that may involve the interaction of many mutagenic, physiological, and biochemical responses. Therefore, the shape and slope of a carcinogenic dose-response relationship cannot be readily predicted from a genotoxic dose-response relationship.

(2) That only the organic fraction of dpm contributes to carcinogenesis. This contradicts the findings reported by Ichinose et al. (1997b) and does not take into account the contribution that inflammation and active oxygen radicals induced by the inorganic carbon core of dpm may have in promoting lung cancers. Multiple routes of carcinogenesis may operate in human lungs—some requiring only the various organic mutagens in dpm and others involving induction of free radicals by the elemental carbon core, either alone or in combination with the organics.

(3) That the only mutagens in dpm are those that have been identified as mutagenic to bacteria and that the

[62] Some of these studies will be discussed in the next subsection of this risk assessment.

[63] The only details provided for this calculation pertained to ajusting 8-hour occupational exposures. Dr. Valberg adjusted the 500 μg/m^3 concentration for an 8-hour occupational exposure to a supposedly equivalent 24-hour continuous concentration of 92 μg/m^3. This adjustment ignored differences in breathing rates between periods of sleep, leisure activities, and heavy work. Even under the unrealistic assumption of homogeneous breathing rates, the calculation appears to be erroneous, since (500 μg/m^3) × (40 hours/week) is nearly 30 percent greater than (92 μg/m^3) × (168 hours/week). Also, Dr. Valberg stated that the calculation assumed a deposition fraction of 20 percent for dpm but did not state what deposition fraction was being assumed for the particles in cigarette smoke.

mutagenic constituents of dpm have all been identified. One of the most potent of all known mutagens (3-nitrobenzanthrone) was only recently isolated and identified in dpm (Enya et al., 1997).

(4) That the mutagenic components of dpm have the same combined potency as those in cigarette smoke. This ignores the relative potency and amounts of the various mutagenic constituents. If the calculation did not take into account the relative amounts and potencies of all the individual mutagens in dpm and cigarette smoke, then it oversimplified the task of making such a comparison.

In sum, unlike the experimental findings of dpm genotoxicity discussed above, the analysis by Dr. Valberg is not based on empirical evidence from dpm experiments, and it appears to rely heavily on questionable assumptions. Moreover, the contention that active components of dpm are not available in sufficient quantities to cause significant mutagenic damage in humans appears to be directly contradicted by the empirical evidence of elevated DNA adduct levels in exposed workers (Hemminki et al., 1994; Hou et al., 1995; Nielsen et al., 1996; Qu et al., 1997).

(2) Animal Inhalation Studies

When dpm is inhaled, a number of adverse effects that may contribute to carcinogenesis are discernable by microscopic and biochemical analysis. For a comprehensive review of these effects, see Watson and Green (1995). In brief, these effects begin with phagocytosis, which is essentially an attack on the diesel particles by cells called alveolar macrophages. The macrophages engulf and ingest the diesel particles, subjecting them to detoxifying enzymes. Although this is a normal physiological response to the inhalation of foreign substances, the process can produce various chemical byproducts injurious to normal cells. In attacking the diesel particles, the activated macrophages release chemical agents that attract neutrophils (a type of white blood cell that destroys microorganisms) and additional alveolar macrophages. As the lung burden of diesel particles increases, aggregations of particle-laden macrophages form in alveoli adjacent to terminal bronchioles, the number of Type II cells lining particle-laden alveoli increases, and particles lodge within alveolar and peribronchial tissues and associated lymph nodes. The neutrophils and macrophages release mediators of inflammation and oxygen radicals, which have been implicated in causing various forms of chromosomal damage, genetic mutations, and malignant transformation of cells (Weitzman and Gordon, 1990). Eventually, the particle-laden macrophages are functionally altered, resulting in decreased viability and impaired phagocytosis and clearance of particles. This series of events may result in pulmonary inflammatory, fibrotic, or emphysematous lesions that can ultimately develop into cancerous tumors.

IARC (1989), Mauderly (1992), Busby and Newberne (1995), IPCS (1996), Cal-EPA (1998), and US EPA (1999) reviewed the scientific literature relating to excess lung cancers observed among laboratory animals chronically exposed to filtered and unfiltered diesel exhaust. The experimental data demonstrate that chronic exposure to whole diesel exhaust increases the risk of lung cancer in rats and that dpm is the causative agent. This carcinogenic effect has been confirmed in two strains of rats and in at least five laboratories. Experimental results for animal species other than the rat, however, are either inconclusive or, in the case of Syrian hamsters, suggestive of no carcinogenic effect. In two of three mouse studies reviewed by IARC (1989), lung tumor formation (including adenocarcinomas) was increased in the exposed animals as compared to concurrent controls; in the third study, the total incidence of lung tumors was not elevated compared to historical controls. Two more recent mouse studies (Heinrich et al., 1995; Mauderly et al., 1996) have both reported no statistically significant increase in lung cancer rates among exposed mice, as compared to contemporaneous controls. Monkeys exposed to diesel exhaust for two years did not develop lung tumors, but the short duration of exposure was judged inadequate for evaluating carcinogenicity in primates.

Bond et al. (1990a) investigated differences in peripheral lung DNA adduct formation among rats, hamsters, mice, and monkeys exposed to dpm at a concentration of 8100 $\mu g/m^3$ for 12 weeks. Mice and hamsters showed no increase of DNA adducts in their peripheral lung tissue, whereas rats and monkeys showed a 60 to 80-percent increase. The increased prevalence of lung DNA adducts in monkeys suggests that, with respect to DNA adduct formation, the human lungs' response to dpm inhalation may more closely resemble that of rats than that of hamsters or mice.

The conflicting carcinogenic effects of chronic dpm inhalation reported in studies of rats, mice, and hamsters may be due to non-equivalent delivered doses or to differences in response among species. Indeed, monkey lungs have been reported to respond quite differently than rat lungs to both diesel exhaust and coal dust (Nikula, 1997). Therefore, the results from rat experiments do not, by themselves, establish that there is any excess risk due to dpm exposure for humans. However, the human epidemiologic and genotoxicity (DNA adduct) data indicate that humans comprise a species that, like rats, do suffer a carcinogenic response to dpm exposure. This would be consistent with the observation, mentioned above, that lung DNA adduct formation is increased among exposed rats but not among exposed hamsters or mice. Therefore, although MSHA recognizes that there are important differences between rats and humans (as there are also between rats and hamsters or mice), MSHA considers the rat studies relevant to an evaluation of human health risks.

Reactions similar to those observed in rats inhaling dpm have also been observed in rats inhaling fine particles with no organic component (Mauderly et al., 1994; Heinrich et al., 1994, 1995; Nikula et al., 1995). Rats exposed to titanium dioxide (TiO_2) or pure carbon (''carbon black'') particles, which are not considered to be genotoxic, exhibited similar pathological responses and developed lung cancers at about the same rate as rats exposed to whole diesel exhaust. Carbon black particles were used in these experiments because they are physically similar to the inorganic carbon core of dpm but have negligible amounts of organic compounds adsorbed to their surface. Therefore, at least in some species, it appears that the lung cancer toxicity of dpm may result largely from a biochemical response to the core particle itself rather than from specific, genotoxic effects of the adsorbed organic compounds.[64]

One commenter stated that, in the proposed risk assessment, MSHA had neglected three additional studies suggesting that lung cancer risks in animals inhaling diesel exhaust are unrelated to genotoxic mechanisms. One of these studies (Mauderly et al.,

[64] NIOSH commented as follows: ''Data cited by MSHA in support of this statement are not comparable. Rats were exposed to dpm at 4 mg/m^3 for 2 years (Mauderly et al. 1987; Brightwell et al. 1989), in contrast to rats exposed to $Ti0_2$ at 250 mg/m^3 for two years [reference to article (Lee et al. 1985) not cited by MSHA]. It is not apparent that the overload mechanism that is proposed to be responsible for tumors in the $Ti0_2$ exposed rats could also have been responsible for the tumors seen in the dpm exposed rats at 62-fold lower exposure concentrations.'' In the reports cited by MSHA, levels of $Ti0_2$ and/or carbon black were commensurate with dpm levels.

1996) did not pertain to questions of genotoxicity but has been cited in the discussion of mouse studies above. The other two studies (Randerath et al., 1995 and Belinsky et al., 1995) were conducted as part of the cancer bioassay described in the 1994 article by Mauderly et al. (cited in the preceding paragraph). In the Randerath study, the investigators found that no DNA adducts specific to either diesel exhaust or carbon black were induced in the lungs of rats exposed to the corresponding substance. However, after three months of exposure, the total level of DNA adducts and the levels of some individual adducts were significantly higher in the diesel-exposed rats than in the controls. In contrast, multiple DNA adducts thought to be specific to diesel exhaust formed in the skin and lungs of mice treated topically with organic dpm extract. These results are consistent with the findings of Mauderly et al. (1994, op cit.). They imply that although the organic compounds of diesel exhaust are capable of damaging cellular DNA, they did not inflict such damage under the conditions of the inhalation experiment performed. The report noted that these results do not rule out the possibility of DNA damage by inhaled organics in ''other species or * * * [in] exposure situations in which the concentrations of diesel exhaust particles are much lower.'' In the Belinsky study, the investigators measured mutations in selected genes in the tumors of those rats that had developed lung cancer. This study did not succeed in elucidating the mechanisms by which dpm and carbon black cause lung tumors in rats. The authors concluded that ''until some of the genes involved in the carcinogenicity of diesel exhaust and carbon black are identified, a role for the organic compounds in tumor development cannot be excluded.''

The carbon-black and TiO_2 studies discussed above indicate that lung cancers in rats exposed to dpm may be induced by a mechanism that does not require the bioavailability of genotoxic organic compounds adsorbed on the elemental carbon particles. Some researchers have interpreted these studies as also suggesting that (1) the carcinogenic mechanism in rats depends on massive overloading of the lung and (2) that this may provide a mechanism of carcinogenesis involving a threshold effect specific to rats, which has not been observed in other rodents or in humans (Oberdorster, 1994; Watson and Valberg, 1996). Some commenters on the ANPRM cited the lack of a link between lung cancer and coal dust or carbon black exposure as evidence that carbon particles, by themselves, are not carcinogenic in humans. Coal mine dust, however, consists almost entirely of particles larger than those forming the carbon core of dpm or used in the carbon black and $Ti0_2$ rat studies. Furthermore, although there have been nine studies reporting no excess risk of lung cancer among coal miners (Liddell, 1973; Costello et al., 1974; Armstrong et al., 1979; Rooke et al., 1979; Ames et al., 1983; Atuhaire et al., 1985; Miller and Jacobsen, 1985; Kuempel et al., 1995; Christie et al., 1995), eight studies have reported an elevated risk of lung cancer for those exposed to coal dust (Enterline, 1972; Rockette, 1977; Howe et al., 1983; Correa et al., 1984; Levin et al., 1988; Morabia et al., 1992; Swanson et al., 1993; Morfeld et al., 1997). The positive results in five of these studies (Enterline, 1972; Rockette, 1977; Howe et al., 1983; Morabia et al., 1992; Swanson et al., 1993) were statistically significant. Morabia et al. (op cit.) reported increased risk associated with duration of exposure, after adjusting for cigarette smoking, asbestos exposure, and geographic area. Furthermore, excess lung cancers have been reported among carbon black production workers (Hodgson and Jones, 1985; Siemiatycki, 1991; Parent et al., 1996). After a comprehensive evaluation of the available scientific evidence, the World Health Organization's International Agency for Research on Cancer concluded: ''Carbon black is possibly carcinogenic to humans (Group 2B).'' (IARC, 1996)

The carbon black and TiO_2 animal studies cited above do not prove there is a threshold below which dpm exposure poses no risk of causing lung cancer in humans. They also do not prove that dpm exposure has no incremental, genotoxic effects. Even if the genotoxic organic compounds in dpm were biologically unavailable and played no role in human carcinogenesis, this would not rule out the possibility of a genotoxic route to lung cancer (even for rats) due to the presence of the particles themselves. For example, as a byproduct of the biochemical response to the presence of particles in the alveoli, free oxidant radicals may be released as macrophages attempt to digest the particles. There is evidence that dpm can both induce production of reactive oxygen agents and also depress the activity of naturally occurring antioxidant enzymes (Mori, 1996; Ichinose et al., 1997; Sagai et al., 1996). Oxidants can induce carcinogenesis either by reacting directly with DNA, or by stimulating cell replication, or both (Weitzman and Gordon, 1990). Salvi et al. (1999) reported acute inflammatory responses in the airways of human exposed to dpm for one hour at a concentration of 300 $\mu g/m^3$. Such inflammation is associated with the production of free radicals and could provide routes to lung cancer with even when normal lung clearance is occurring. It could also give rise to a ''quasi-threshold,'' or surge in response, corresponding to the exposure level at which the normal clearance rate becomes overwhelmed (lung overload).

Oxidant activity is not the only mechanism by which dpm could exert carcinogenic effects in the absence of mutagenic activity by its organic fraction. In its commentary on the Randerath study discussed above, the HEI's Health Review Committee suggested that dpm could both cause genetic damage by inducing free oxygen radicals and also enhance cell division by inducing cytokines or growth hormones:

> It is possible that diesel exhaust exerts its carcinogenic effects through a mechanism that does not involve direct genotoxicity (that is, formation of DNA adducts) but involves proliferative responses such as chronic inflammation and hyperplasia arising from high concentrations of particles deposited in the lungs of the exposed rats. * * * Phagocytes (macrophages and neutrophils) released during inflammatory reactions ''produce reactive oxygen species that can damage DNA. * * * Particles (with or without adsorbed PAHs) may thus induce oxidative DNA damage via oxygen free radicals. * * * Alternatively, activated phagocytes may release cytokines or growth factors that are known to increase cell division. Increased cell division has been implicated in cancer causation. * * * Thus, in addition to oxidative DNA damage, increased cell proliferation may be an important mechanism by which diesel exhaust and other insoluble particles induce pulmonary carcinogenesis in the rat. [Randerath et al., 1995, p.55]

Even if lung overload were the primary or sole route by which dpm induced lung cancer, this would not mean that the high dpm concentrations observed in some mines are without hazard. It is noteworthy, moreover, that dpm exposure levels recorded in some mines have been almost as high as laboratory exposures administered to rats showing a clearly positive response. Intermittent, occupational exposure levels greater than about 500 $\mu g/m^3$ dpm may overwhelm the human lung clearance mechanism (Nauss et al., 1995). Therefore, concentrations at the even higher levels currently observed in some mines could be expected to cause overload in some humans, possibly

inducing lung cancer by a mechanism similar to what occurs in rats. In addition, a proportion of exposed individuals can always be expected to be more susceptible than normal to clearance impairments and lung overload. Inhalation at even moderate levels may significantly impair clearance, especially in susceptible individuals. Exposures to cigarette smoke and respirable mineral dusts may further depress clearance mechanisms and reduce the threshold for overload. Consequently, even at dpm concentrations far lower than 500 $\mu g/m^3$ dpm, impaired clearance due to dpm inhalation may provide an important route to lung cancer in humans, especially if they are also inhaling cigarette smoke and other fine dusts simultaneously. (Hattis and Silver, 1992, Figures 9, 10, 11)

Furthermore, as suggested above, lung overload is not necessarily the only route to carcinogenesis in humans. Therefore, dpm concentrations too low to cause overload still may present a hazard. In humans exposed over a working lifetime to doses insufficient to cause overload, carcinogenic mechanisms unrelated to overload may operate, as indicated by the human epidemiologic studies and the data on human DNA adducts cited in the preceding subsection of this risk assessment. It is possible that overload provides the dominant route to lung cancer at high concentrations of fine particulate, while other mechanisms emerge as more relevant for humans under lower-level exposure conditions.

The NMA noted that, in 1998, the US EPA's Clean Air Scientific Advisory Committee (CASAC) concluded that there is ''no evidence that the organic fraction of soot played a role in rat tumorigenesis at any exposure level, and considerable evidence that it did not.'' According to the NMA, this showed ''* * * it is the rat data—not the hamster data—that lacks relevance for human health assessment.''

It must first be noted that, in MSHA's view, all of the experimental animal data on health effects has relevance for human health risk assessment—whether the evidence is positive or negative and even if the positive results cannot be used to quantify human risk. The finding that different mammalian species exhibit important differences in response is itself relevant for human risk assessment. Second, the passage quoted from CASAC pertains to the route for tumorigenesis in rats and does not discuss whether this does or does not have relevance to humans exposed at high levels. The context for the CASAC deliberations was ambient exposure conditions in the general environment, rather than the higher occupational exposures that might impair clearance rates in susceptible individuals. Third, the comment assumes that only a finding of tumorigenesis attributable to the organic portion of dpm would elucidate mechanisms of potential health effects in humans. This ignores the possibility that a mechanism promoting tumors, but not involving the organics, could operate in both rats and humans. Induction of free oxygen radicals is an example. Fourth, although there may be little or no evidence that organics contributed to rat tumorigenesis in the studies performed, there is evidence that the organics contributed to increases in DNA adduct formation. This kind of activity could have tumorigenic consequences in humans who may be exposed for periods far longer than a rat's 3-year lifetime and who, as a consequence, have more time to accumulate genetic damage from a variety of sources.

Bond et al. (1990b) and Wolff et al. (1990) investigated adduct formation in rats exposed to various concentrations of either dpm or carbon black for 12 weeks. At the highest concentration (10 mg/m^3), DNA adduct levels in the lung were increased by exposure to either dpm or carbon black; but levels in the rats exposed to dpm were approximately 30 percent higher. Gallagher et al. (1994) exposed different groups of rats to diesel exhaust, carbon black, or TiO_2 and detected no significant difference in DNA adduct levels in the lung. However, the level of one type of adduct, thought to be derived from a PAH, was elevated in the dpm-exposed rats but not found in the control group or in rats exposed to carbon black or TiO_2.

These studies indicate that the inorganic carbon core of dpm is not the only possible agent of genetic damage in rats inhaling dpm. After a review of these and other studies involving DNA adducts, IPCS (1996) concluded that ''Taken together, the studies of DNA adducts suggest that some organic chemicals in diesel exhaust can form DNA adducts in lung tissue and may play a role in the carcinogenic effects. * * * however, DNA adducts alone cannot explain the carcinogenicity of diesel exhaust, and other factors, such as chronic inflammation and cell proliferation, are also important.''

Nauss et al. (1995, pp. 35–38) judged that the results observed in the carbon black and TiO2 inhalation studies on rats do not preclude the possibility that the organic component of dpm has important genotoxic effects in humans. More generally, they also do not prove that lung overload is necessary for dpm-induced lung cancer. Because of the relatively high doses administered in some of the rat studies, it is conceivable that an overload phenomenon masked or even inhibited other potential cancer mechanisms. At dpm concentrations insufficient to impair clearance, carcinogenesis may have followed other routes, some possibly involving the organic compounds. At these lower concentrations, or among rats for which overload did not occur, tumor rates for dpm, carbon black, and TiO_2 may all have been too low to make statistically meaningful comparisons.

The NMA argued that ''MSHA's contention that lung overload might ''mask'' tumor production by lower doses of Dpm has been convincingly rebutted by recognized experts in the field,'' but provided no convincing explanation of why such masking could not occur. The NMA went on to say:

> The [CASAC] Panel viewed the premises that: a) a small tumor response at low exposure was overlooked due to statistical power; and b) soot-associated organic mutagens had a greater effect at low than at high exposure levels to be without foundation. In the absence of supporting evidence, the Panel did not view derivation of a quantitative estimate of human lung cancer risk from the low-level rat data as appropriate.

MSHA is not attempting to ''derive a quantitative estimate of human lung cancer risk from the low-level rat data.''

Dr. Peter Valberg, writing for the West Virginia Coal Association, provided the following argument for discounting the possibility of other carcinogenic mechanisms being masked by overload in the rat studies:

> Some regulatory agencies express concern about the mutagens bound to dpm. They hypothesize that, at high exposure levels, genotoxic mechanisms are overwhelmed (masked) by particle-overload conditions. However, they argue that at low-exposure concentrations, these organic compounds could represent a lung cancer risk. Tumor induction by mutagenic compounds would be characterized by a linear dose-response and should be detectable, given enough exposed rats. By using a ''meta-analysis'' type of approach and combining data from eight long-term rat inhalation studies, the lung tumor response can be analyzed. When all dpm-exposed rats from lifetime-exposure studies are combined, a threshold of response (noted above) occurs at approximately 600 $\mu g/m^3$ continuous lifetime exposure (approximately 2,500 $\mu g/m^3$ of occupational exposure). Additional statistical analysis of only those rats exposed to low concentrations of dpm confirms the absence of a tumorigenic effect below that threshold. Thus, even data in rats (the most sensitive laboratory species) do not support the hypothesis that particle-bound organics cause tumors.

MSHA finds that this analysis relies on several questionable and unsupported assumptions and that, for the following reasons, the possibility remains that organic compounds in inhaled dpm may, under the right exposure conditions, contribute to its carcinogenic effects:

(1) The absence of evidence for an organic carbon effect is not equivalent to evidence of the absence of such an effect. Dr. Valberg did not demonstrate that enough rats were exposed, at levels insufficient to cause overload, to ensure detection of a 30- to 40-percent increase in the risk of lung cancer. Also, the normal lifespan of a rat whose lung is not overloaded with particles may, because of the lower concentrations involved, provide insufficient time for the organic compounds to express carcinogenic effects. Furthermore, low bioavailability of the organics could further reduce the likelihood that a carcinogenic sequence of mutations would occur within a rat's relatively short lifespan (i.e., at particle concentrations too low to cause overload).

(2) If the primary mechanism for carcinogenesis requires a reduced clearance rate (due to overload), then acute exposures are important, and it may not be appropriate to represent equivalent hazards by spreading an 8-hour occupational exposures over a 24-hour period. For example, eight hours at 600 $\mu g/m^3$ would have different implications for lung clearance than 24 hours at 200 $\mu g/m^3$.

(3) Granting that the rat data cannot be used to extrapolate risk for humans, these data should also not be used to rule out mechanisms of carcinogenesis that may operate in humans but not in rats. Clearance, for example, may operate differently in humans than in rats, and there may be a gradual rather than abrupt change in human overload conditions with increasing exposure. Also, at least some of the organic compounds in dpm may be more biologically available to the human lung than to that of the rat.

(4) For experimental purposes, laboratory rats are deliberately bred to be homogeneous. This is done, in part, to deliberately minimize differences in response between individuals. Therefore, individual differences in the threshold for lung overload would tend to be masked in experiments on laboratory rats. It is likely that human populations would exhibit, to a far greater extent than laboratory rats, a range of susceptibilities to lung overload. Also some humans, unlike the laboratory rats in these experiments, place additional burdens on their lung clearance by smoking.

One commenter (MARG) concluded that ''[t]here is * * * no basis for extrapolating the rat results to human beings; the animal studies, taken together, do not justify MSHA's proposals.''

MSHA is neither extrapolating the rat results to make quantitative risk estimates for humans nor using them, in isolation, as a justification for these regulations. MSHA does regard it as significant, however, that the evidence for an increased risk of lung cancer due to chronic dpm inhalation comes from both human and animal studies. MSHA agrees that the quantitative results observed for rats in existing studies should not be extrapolated to humans. Nevertheless, the fact that high dpm exposures for two or three years can induce lung cancer in rats enhances the epidemiologic evidence that much longer exposures to miners, at concentrations of the same order of magnitude, could also induce lung cancers.

3. Characterization of Risk

After reviewing the evidence of adverse health effects associated with exposure to dpm, MSHA evaluated that evidence to ascertain whether exposure levels currently existing in mines warrant regulatory action pursuant to the Mine Act. The criteria for this evaluation are established by the Mine Act and related court decisions. Section 101(a)(6)(A) provides that:

> The Secretary, in promulgating mandatory standards dealing with toxic materials or harmful physical agents under this subsection, shall set standards which most adequately assure on the basis of the best available evidence that no miner will suffer material impairment of health or functional capacity even if such miner has regular exposure to the hazards dealt with by such standard for the period of his working life.

Based on court interpretations of similar language under the Occupational Safety and Health Act, there are three questions that need to be addressed: (a) Whether health effects associated with dpm exposure constitute a ''material impairment'' to miner health or functional capacity; (b) whether exposed miners are at significant excess risk of incurring any of these material impairments; and (c) whether the rule will substantially reduce such risks.

Some commenters argued that the link between dpm exposure and material health impairments is questionable, and that MSHA should wait until additional scientific evidence becomes available before concluding that there are health risks due to such exposure warranting regulatory action. For example, MARG asserted that ''[c]ontrary to the suggestions in the [proposed] preamble, a link between dpm exposure and serious illness has never been established by reliable scientific evidence.'' [65] MARG continued as follows:

> Precisely because the scientific evidence * * * is inconclusive at best, NIOSH and NCI are now conducting a * * * [study] to determine whether diesel exhaust is linked to illness, and if so, at what level of exposure. * * * MARG is also funding an independent parallel study.
>
> * * * Until data from the NIOSH/NCI study, and the parallel MARG study, are available, the answers to these important questions will not be known. Without credible answers to these and other questions, MSHA's regulatory proposals * * * are premature * * *.''

For reasons explained below, MSHA does not agree that the collective weight of scientific evidence is ''inconclusive at best.'' Furthermore, the criteria for evaluating the health effects evidence do not require scientific certainty. As noted by Justice Stevens in an important case on risk involving the Occupational Safety and Health Administration, the need to evaluate risk does not mean an agency is placed into a ''mathematical straitjacket.'' [*Industrial Union Department, AFL–CIO* v. *American Petroleum Institute*, 448 U.S. 607, 100 S.Ct. 2844 (1980), hereinafter designated the ''Benzene'' case]. The Court recognized that regulation may be necessary even when scientific knowledge is not complete; and—

> so long as they are supported by a body of reputable scientific thought, the Agency is free to use conservative assumptions in interpreting the data * * * risking error on the side of overprotection rather than underprotection. [Id. at 656].

[65] MARG supported this assertion by claiming that ''[t]he EPA reports which MSHA references in its preamble were found 'not scientifically adequate for making regulatory decisions concerning the use of diesel-powered engines' by EPA's Clean Air Scientific Advisory Committee. [reference to CASAC (1998)]'' Contrary to MARG's claim, CASAC (1998) did not review any of the 20 EPA documents MSHA cited in the proposed preamble. Instead, the document reviewed by CASAC (1998) was an unpublished draft of a health risk assessment on diesel exhaust (EPA, 1998), to which MSHA made no reference. Since MSHA has not relied in any way on this 1998 draft document, its ''scientific adequacy'' is entirely irrelevant to this rulemaking.

In response to the 1998 CASAC review, EPA modified its draft risk assessment (EPA, 1999), and CASAC subsequently reviewed the 1999 draft (CASAC, 2000). CASAC found the revised draft much improved over the previous version and agreed that even environmental exposure to diesel emissions is likely to increase the risk of lung cancer (CASAC, 2000). CASAC endorsed this conclusion for dpm concentrations in ambient air, which are lower, by a factor of more than 100, than the levels observed in some mines (see Fig. III–4).

Moreover, the statutory criteria for evaluating health effects do not require MSHA to wait for incontrovertible evidence. In fact, MSHA is required to set standards based on the ''best *available* evidence'' (emphasis added).

a. Material Impairments to Miners' Health or Functional Capacity

MSHA recognizes that there is considerable disagreement, among knowledgeable parties, in the interpretation of the overall body of scientific research and medical evidence related to human health effects of dpm exposures. One commenter for example, interpreted the collective evidence as follows:

> * * * the best available scientific evidence shows that diesel particulate exposure is associated with serious material impairment of health. * * * there is *clear* evidence that diesel particulate exposure can cause lung cancer (as well as other serious non-malignant diseases) among workers in a variety of occupational settings. While no body of scientific evidence is ever completely definitive, the evidence regarding diesel particulate is particularly strong * * *. [Michael Silverstein, MD, State of Washington Dept. of Labor and Industries]

Other commenters, including several national and regional organizations representing the mining industry, sharply disagreed with this interpretation. For example, one commenter stated that ''[i]n our opinion, the best available evidence does not provide substantial or credible support for the proposal.'' Several commenters argued that evidence from within the mining industry itself was especially weak.[66] A representative of one mining company that had been using diesel equipment for many years commented: ''[t]o date, the medical history of our employees does not indicate a single case of lung cancer, chronic illness, or material impairment of health due to exposure to diesel exhaust. This appears to be the established norm throughout the U.S. coal mining industry.'' This commenter, however, submitted no evidence comparing the rate of lung cancer or other material impairment among exposed miners to the rate for unexposed miners (or comparable workers) of similar age, smoking habits, and geographic location.

With due consideration to all oral and written testimony, comments, and evidence submitted during the rulemaking proceedings, MSHA conducted a review of the scientific literature cited in Part III.2. Based on the combined weight of the best available evidence, MSHA has concluded that underground miners exposed to current levels of dpm are at excess risk of incurring the following three kinds of material impairment: (i) Sensory irritations and respiratory symptoms (including allergenic responses); (ii) premature death from cardiovascular, cardiopulmonary, or respiratory causes; and (iii) lung cancer. The next three subsections will respectively explain MSHA's basis for linking these effects with dpm exposure.

i. Sensory Irritations and Respiratory Symptoms (Including Allergenic Responses)

Kahn et al. (1988), Battigelli (1965), Gamble et al. (1987a), and Rudell et al. (1996) identified a number of debilitating acute responses to diesel exhaust exposure. These responses included irritation of the eyes, nose and throat; headaches, nausea, and vomiting; chest tightness and wheeze. These symptoms were also reported by miners at the 1995 workshops and the public hearings held on these proceedings in 1998. In addition, Ulfvarson et al. (1987, 1990) reported evidence of reduced lung function in workers exposed to dpm for a single shift. The latter study supports attributing a portion of the reduction to the dpm in diesel exhaust. After reviewing this body of literature, Morgan et al. (1997) concluded ''it is apparent that exposure to diesel fumes in sufficient concentrations may lead to [transient] eye and nasal irritation'' and ''a transient decline of ventilatory capacity has been noted following such exposures.''

One commenter (Nevada Mining Association) acknowledged there was evidence that miners exposed to diesel exhaust experienced, as a possible consequence of their exposure, ''acute, short-term or 'transitory' irritation, such as watering eyes, in susceptible individuals * * *''; but asserted that ''[a]ddressing any such transient irritant effects does not require the Agency's sweeping, stringent PEL approach [in M/NM mines].''

Although there is evidence that such symptoms subside within one to three days of no occupational exposure, a miner who must be exposed to dpm day after day in order to earn a living may not have time to recover from such effects. Hence, the opportunity for a so-called ''reversible'' health effect to reverse itself may not be present for many miners. Furthermore, effects such as stinging, itching and burning of the eyes, tearing, wheezing, and other types of sensory irritation can cause severe discomfort and can, in some cases, be seriously disabling. Also, workers experiencing sufficiently severe sensory irritations can be incapacitated or distracted as a result of their symptoms, thereby endangering themselves and other workers and increasing the risk of accidents. For these reasons, MSHA considers such irritations to constitute ''material impairments'' of health or functional capacity within the meaning of the Act, regardless of whether or not they are reversible. Further discussion of why MSHA believes reversible effects can constitute material impairments can be found above, in Subsection 2.a.2 of this risk assessment.

The best available evidence also points to more severe respiratory consequences of exposure to dpm. Significant statistical associations have been detected between acute environmental exposures to fine particulates and debilitating respiratory impairments in adults, as measured by lost work days, hospital admissions, and emergency room visits (see Table III–3). Short-term exposures to fine particulates, or to particulate air pollution in general, have been associated with significant increases in the risk of hospitalization for both pneumonia and COPD (EPA, 1996).

The risk of severe respiratory effects is exemplified by specific cases of persistent asthma linked to diesel exposure (Wade and Newman, 1993). Glenn et al. (1983) summarized results of NIOSH health evaluations among coal, salt, trona, and potash miners and reported that ''all four of the chronic effects analyses revealed an excess of cough and phlegm among the diesel exposed group.'' There is persuasive evidence for a causal connection between dpm exposure and increased manifestations of allergic asthma and other allergic respiratory diseases, coming from recent experiments on animals and human cells (Takenaka et al., 1995; Lovik et al., 1997; Takano et al., 1997; Ichinose et al., 1997a). Based on controlled experiments on healthy human volunteers, Diaz-Sanchez et al. (1994, 1996, 1997), Peterson and Saxon (1996), and Salvi et al. (1999) reported significant increases in various markers of allergic response resulting from exposure to dpm.

Peterson and Saxon (1996) reviewed the scientific literature on the

[66] At the public hearing on May 11, 1999, a commenter representing MARG suggested there is evidence that miners exposed to dpm experience adverse health effects at lower-than-normal rates. According to this commenter, ''[s]ignificantly, the human studies conducted in the mining industry reveal a negative propensity for diesel particulate matter-related health effects.'' These studies drew comparisons against an external reference population and failed to adjust for the ''healthy worker effect.'' (See MSHA's discussion of this effect, especially as manifested in the study by Christie et al., 1995, in Subsection 2.c.i(2)(a) of this risk assessment.)

relationship between PAHs and other products of fossil fuel combustion found in dpm and trends in allergic respiratory disease. They found that the prevalences of allergic rhinitis (''hay fever'') and allergic asthma have significantly increased with the historical increase in fossil fuel combustion and that laboratory data support the hypothesis that certain organic compounds found in dpm ''* * * are an important factor in the long-term increases in the prevalence in allergic airway disease.'' Similarly, much of the research on allergenic responses to dpm was reviewed by Diaz-Sanchez (1997), who concluded that dpm pollution in the ambient environment ''may play an important role in the increased incidence of allergic airway disease.'' Morgan et al. (1997) noted that dpm ''* * * may be partly responsible for some of the exacerbations of asthma'' and that ''* * * it would be wise to err on the side of caution.'' Such health outcomes are clearly ''material impairments'' of health or functional capacity within the meaning of the Act.

ii. Premature Death from Cardiovascular, Cardiopulmonary, or Respiratory Causes

The evidence from air pollution studies identifies death, largely from cardiovascular, cardiopulmonary, or respiratory causes, as an endpoint significantly associated with acute exposures to fine particulates ($PM_{2.5}$—see Table III–3). The weight of epidemiologic evidence indicates that short-term ambient exposure to particulate air pollution contributes to an increased risk of daily mortality (EPA, 1996). Time-series analyses strongly suggest a positive effect on daily mortality across the entire range of ambient particulate pollution levels. Relative risk estimates for daily mortality in relation to daily ambient particulate concentration are consistently positive and statistically significant across a variety of statistical modeling approaches and methods of adjustment for effects of relevant covariates such as season, weather, and co-pollutants. The mortality effects of acute exposures appear to be primarily attributable to combustion-related particles in $PM_{2.5}$ (such as dpm) and are especially pronounced for death due to pneumonia, COPD, and IHD (Schwartz et al., 1996). After thoroughly reviewing this body of evidence, the U.S. Environmental Protection Agency (EPA) concluded:

> It is extremely unlikely that study designs not yet employed, covariates not yet identified, or statistical techniques not yet developed could wholly negate the large and consistent body of epidemiologic evidence * * *. [EPA, 1996]

There is also substantial evidence of a relationship between chronic exposure to fine particulates ($PM_{2.5}$) and an excess (age-adjusted) risk of mortality, especially from cardiopulmonary diseases. The Six Cities and ACS studies of ambient air particulates both found a significant association between chronic exposure to fine particles and excess mortality. In some of the areas studied, $PM_{2.5}$ is composed primarily of dpm; and significant mortality and morbidity effects were also noted in those areas. In both studies, after adjusting for smoking habits, a statistically significant excess risk of cardiopulmonary mortality was found in the city with the highest average concentration of $PM_{2.5}$ as compared to the city with the lowest. Both studies also found excess deaths due to lung cancer in the cities with the higher average level of $PM_{2.5}$, but these results were not statistically significant (EPA, 1996). The EPA concluded that—

> * * * the chronic exposure studies, taken together, suggest there may be increases in mortality in disease categories that are consistent with long-term exposure to airborne particles and that at least some fraction of these deaths reflect cumulative PM impacts above and beyond those exerted by acute exposure events * * *. There tends to be an increasing correlation of long-term mortality with PM indicators as they become more reflective of fine particle levels. [EPA, 1996]

Whether associated with acute or chronic exposures, the excess risk of death that has been linked to pollution of the air with fine particles like dpm is clearly a ''material impairment'' of health or functional capacity within the meaning of the Act.

In a review, submitted by MARG, of MSHA's proposed risk assessment, Dr. Jonathan Borak asserted that ''MSHA appears to regard all particulates smaller than 2.5 $\mu g/m^3$ as equivalent.'' He argued that ''dpm and other ultra-fine particulates represents only a small proportion of ambient particulate samples,'' that ''chronic cough, chronic phlegm, and chronic wheezing reflect mainly tracheobronchial effects,'' and that tracheobronchial deposition is highly dependent on particle size distribution.

No part of Dr. Borak's argument is directly relevant to MSHA's identification of the risk of death from cardiovascular, cardiopulmonary, or respiratory causes faced by miners exposed to high concentrations of dpm. First, MSHA does not regard all fine particulates as equivalent. However, dpm is a major constituent of $PM_{2.5}$ in many of the locations where increased mortality has been linked to $PM_{2.5}$ levels. MSHA regards dpm as presenting a risk by virtue of its comprising a type of $PM_{2.5}$. Second, the studies MSHA used to support the existence of this risk specifically implicate fine particles (*i.e.,* $PM_{2.5}$), so the percentage of dpm in ''total suspended particulate emissions'' (which includes particles even larger than PM_{10}) is not relevant. Third, the chronic respiratory symptoms listed by Dr. Borak are not among the material impairments that MSHA has identified from the $PM_{2.5}$ studies. Much of the evidence pertaining to excess mortality is based on acute—not chronic—ambient exposures of relatively high intensity. In the preceding subsection of this risk assessment, MSHA identified various respiratory symptoms, including allergenic responses, but the evidence for these comes largely from studies on diesel emissions.

As discussed in Section 2.a.iii of this risk assessment, many miners smoke tobacco, and miners experience COPD at a significantly higher rate than the general population. This places many miners in two of the groups that EPA (1996) identified as being at greatest risk of premature mortality due to particulate exposures.

iii. Lung Cancer

It is clear that lung cancer constitutes a ''material impairment'' of health or functional capacity within the meaning of the Act. Therefore, the issue to be addressed in this section is whether there is sufficient evidence (*i.e.,* enough to warrant regulatory action) that occupational exposure to dpm causes the risk of lung cancer to increase.

In the proposed risk assessment, MSHA noted that various national and international institutions and governmental agencies had already classified diesel exhaust or particulate as a probable human carcinogen. Considerable weight was also placed on two comprehensive meta-analyses of the epidemiologic literature, which had both found that the combined evidence supported a causal link. MSHA also acknowledged, however, that some reviewers of the evidence disagreed with MSHA's conclusion that, collectively, it strongly supports a causal connection. As examples of the opposing viewpoint, MSHA cited Stöber and Abel (1996), Watson and Valberg (1996), Cox (1997), Morgan *et al.* (1997), and Silverman (1998). As stated in the proposed risk assessment, MSHA considered the opinions of these reviewers and agreed that no individual study was perfect: Even the strongest of

the studies had limitations when viewed in isolation. MSHA nevertheless concluded (in the proposal) that the best available epidemiologic studies, supported by experimental data showing toxicity, collectively provide strong evidence that chronic dpm exposure (at occupational levels) actually does increase the risk of lung cancer in humans.

Although miners and labor representatives generally agreed with MSHA's interpretation of the collective evidence, many commenters representing the mining industry strongly objected to MSHA's conclusion. Some of these commenters also expressed dissatisfaction with MSHA's treatment, in the proposed risk assessment, of opposing interpretations of the collective evidence—saying that MSHA had dismissed these opposing views without sufficient explanation. Some commenters also submitted new critiques of the existing evidence and of the meta-analyses on which MSHA had relied. These commenters also emphasized the importance of two reports (CASAC, 1998 and HEI, 1999) that both became available after MSHA completed its proposed risk assessment.

MSHA has re-evaluated the scientific evidence relating lung cancer to diesel emissions in light of the comments, suggestions, and detailed critiques submitted during these proceedings. Although MSHA has not changed its conclusion that occupational dpm exposure increases the risk of lung cancer, MSHA believes that the public comments were extremely helpful in identifying areas of MSHA's discussion of lung cancer needing clarification, amplification, and/or additional supportive evidence.

Accordingly MSHA has re-organized this section of the risk assessment into five subsections. The first of these provides MSHA's summary of the collective epidemiologic evidence. Second is a description of results and conclusions from the only two existing peer-reviewed and published statistical meta-analyses of the epidemiologic studies: Bhatia *et al.* (1998) and Lipsett and Campleman (1999). The third subsection contains a discussion of potential systematic biases that might tend to shift all study results in the same direction. The fourth evaluates the overall weight of evidence for causality, considering not only the collective epidemiologic evidence but also the results of toxicity experiments. Within each of these first four subsections, MSHA will respond to the relevant issues and criticisms raised by commenters in these proceedings, as well as by other outside reviewers. The final subsection will describe general conclusions reached by other reviewers of this evidence, and present some responses by MSHA about opposing interpretations of the collective evidence.

(1) Summary of Collective Epidemiologic Evidence

As mentioned in Section III.2.c.i(2)(a) and listed in Tables III–4 and III–5, MSHA reviewed a total of 47 epidemiologic studies involving lung cancer and diesel exposure. Some degree of association between occupational dpm exposure and an excess rate of lung cancer was reported in 41 of these studies: 22 of the 27 cohort studies and 19 of the 20 case-control studies. Section III.2.c.1(2)(a) explains MSHA's criteria for evaluating these studies, summarizes those on which MSHA places greatest weight, and explains why MSHA places little weight on the six studies reporting no increased risk of lung cancer for exposed workers. It also contains summaries of the studies involving miners, addresses criticisms of individual studies by commenters and reviewers, and discusses studies that, according to some commenters, suggest that dpm exposure does not increase the risk of lung cancer.

Here, as in the earlier, proposed version of the risk assessment, MSHA was careful to note and consider limitations of the individual studies. Several commenters interpreted this as demonstrating a corresponding weakness in the overall body of epidemiologic evidence. For example, one commenter [Energy West] observed that ''* * * by its own admission in the preamble * * * most of the evidence in [the epidemiologic] studies is relatively weak'' and argued that MSHA's conclusion was, therefore, unjustified.

It should first be noted that the three most recent epidemiologic studies became available too late for inclusion in the risk assessment as originally written. These three (Johnston et al., 1997; Säverin et al., 1999; Brüske-Hohlfeld, 1999) rank among the strongest eight studies available (see Section III.2.c.1(2)(a)) and do not have the same limitations identified in many of the other studies. Even so, MSHA recognizes that no single one of the existing epidemiologic studies, viewed in isolation, provides conclusive evidence of a causal connection between dpm exposure and an elevated risk of lung cancer in humans. Consistency and coherency of results, however, do provide such evidence. An appropriate analogy for the collective epidemiologic evidence is a braided steel cable, which is far stronger than any of the individual strands of wire making it up. Even the thinnest strands can contribute to the strength of the cable.

(a) Consistency of Epidemiologic Results

Although no epidemiologic study is flawless, studies of both cohort and case-control design have quite consistently shown that chronic exposure to diesel exhaust, in a variety of occupational circumstances, is associated with an increased risk of lung cancer. Furthermore, as explained earlier in this risk assessment, limitations such as small sample size, short latency, and (usually) exposure misclassification reduce the power of a study. These limitations make it more difficult to detect a relationship even when one exists. Therefore, the sheer number of studies showing a positive association readily distinguishes those studies criticized by Taubes (1995), where weak evidence is available from only a single study. With only rare exceptions, involving too few workers and/or observation periods too short to have a good chance of detecting excess cancer risk, the human studies have shown a greater risk of lung cancer among exposed workers than among comparable unexposed workers.

Moreover, the fact that 41 out of 47 studies showed an excess risk of lung cancer for exposed workers may itself be a significant result, even if the evidence in most of those 41 studies is relatively weak. Getting ''heads'' on a single flip of a coin, or two ''heads'' out of three flips, does not provide strong evidence that there is anything special about the coin. However, getting 41 ''heads'' in 47 flips would normally lead one to suspect that the coin was weighted in favor of heads. Similarly, results reported in the epidemiologic literature lead one to suspect that the underlying relationship between diesel exposure and an increased risk of lung cancer is indeed positive.

More formally, as MSHA pointed out in the earlier version of this risk assessment, the high proportion of positive studies is statistically significant according to the 2-tailed sign test. Under the ''null hypothesis'' that there is no systematic bias in one direction or the other, and assuming that the studies are independent, the probability of 41 or more out of 47 studies being either positive or negative is less than one per ten million. Therefore, the sign test rejects, at a very high confidence level, the null hypothesis that each study is equally likely to be positive or negative. This

means that the collective results, showing increased risk for exposed workers, are statistically significant at a very high confidence level—regardless of the statistical significance of any individual study.

MSHA received no comments directly disputing its attribution of statistical significance to the collective epidemiologic evidence based the sign test. However, several commenters objected to the concept that a number of inconclusive studies can, when viewed collectively, provide stronger evidence than the studies considered in isolation. For example, the Engine Manufacturers Association (EMA) asserted that—

> [j]ust because a number of studies reach the same conclusion does not make the collective sum of those studies stronger or more conclusive, particularly where the associations are admittedly weak and scientific difficulties exist in each. [EMA]

Similarly, IMC Global stated that—

> * * * IMC Global does not consider cancer studies with a relative risk of less than 2.0 as showing evidence of a casual relationship between Dpm exposure and lung cancer.* * * Thus while MSHA states [in the proposed risk assessment; now updated to 41 out of 47] that 38 of 43 epidemiologic studies show some degree of association between occupational Dpm exposures and lung cancer and considers that fact significant, IMC Global does not. [IMC Global]

Although MSHA agrees that even statistically significant consistency of epidemiologic results is not sufficient to establish causality, MSHA believes that consistency is an important part of establishing that a suspected association is causal.[67] Many of the commenters objecting to MSHA's emphasis on the collective evidence failed to distinguish the strength of evidence in each individual study from the strength of evidence in total.

Furthermore, weak evidence (from just one study) should not be confused with a weak effect. As Dr. James Weeks pointed out at the public hearing on Nov. 19, 1998, a 40-percent increase in lung cancer is a strong effect, even if it may be difficult to detect in an epidemiologic study.

Explicable differences, or heterogeneity, in the magnitudes of relative risk reported from different studies should not be confused with inconsistency of evidence. For example, as described by Silverman (1998), one of the available meta-analyses (Bhatia et al., 1998) ''examined the primary sources of heterogeneity among studies and found that a main source of heterogeneity is the variation in diesel exhaust exposure across different occupational groups.'' Figures III–9 and III–10, taken from Cohen and Higgins (1995), respectively show relative risks reported for the two occupations on which the most studies are available: railroad workers and truck drivers.

Each of these two charts compares results from studies that adjusted for smoking to results from studies that did not make such an adjustment. For each study, the point plotted is the estimated relative risk or odds ratio, and the horizontal line surrounding it represents a 95-percent confidence interval. If the left endpoint of a confidence interval exceeds 1.0, then the corresponding result is statistically significant at a 95-percent confidence level.

The two charts show that the risk of lung cancer has consistently been elevated for exposed workers and that the results are not significantly different within each occupational category. Differences in the magnitude and statistical significance of results within occupation are not surprising, since the groups studied differed in size, average exposure intensity and duration, and the time allotted for latent effects.

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[67] With respect to IMC Global's blanket rejection of studies showing a relative risk less than 2.0, please see also the related discussions in Subsection 2.c.i(2)(a) above, under the heading of ''Potential Confounders,'' and in Subsection 3.a.iii(3) below, entitled ''Potential Systematic Biases.''

Figure III-5

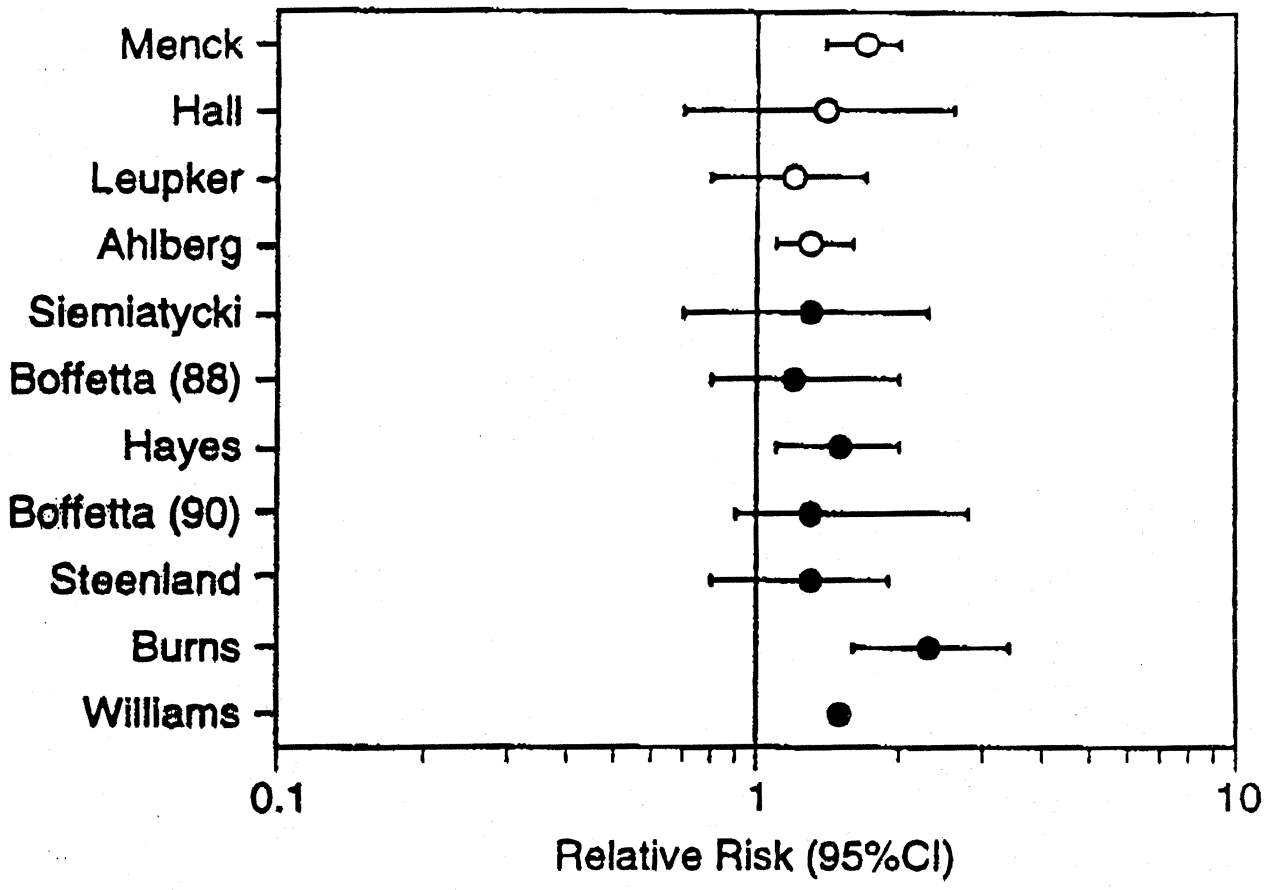

Figure , Lung cancer and exposure to diesel exhaust in truck drivers. ● = RR adjusted for cigarette smoking; O = RR not adjusted for cigarette smoking. For the study by Williams, CIs were not reported and could not be calculated. For the Steenland study, the data were gathered from union reports of long-haul truckers; for the Boffetta (1988) study, the data were self-reported by diesel truck drivers; and for the Siemiatycki study, they were self-reported by heavy-duty truck drivers (personal communication).

Figure III–6

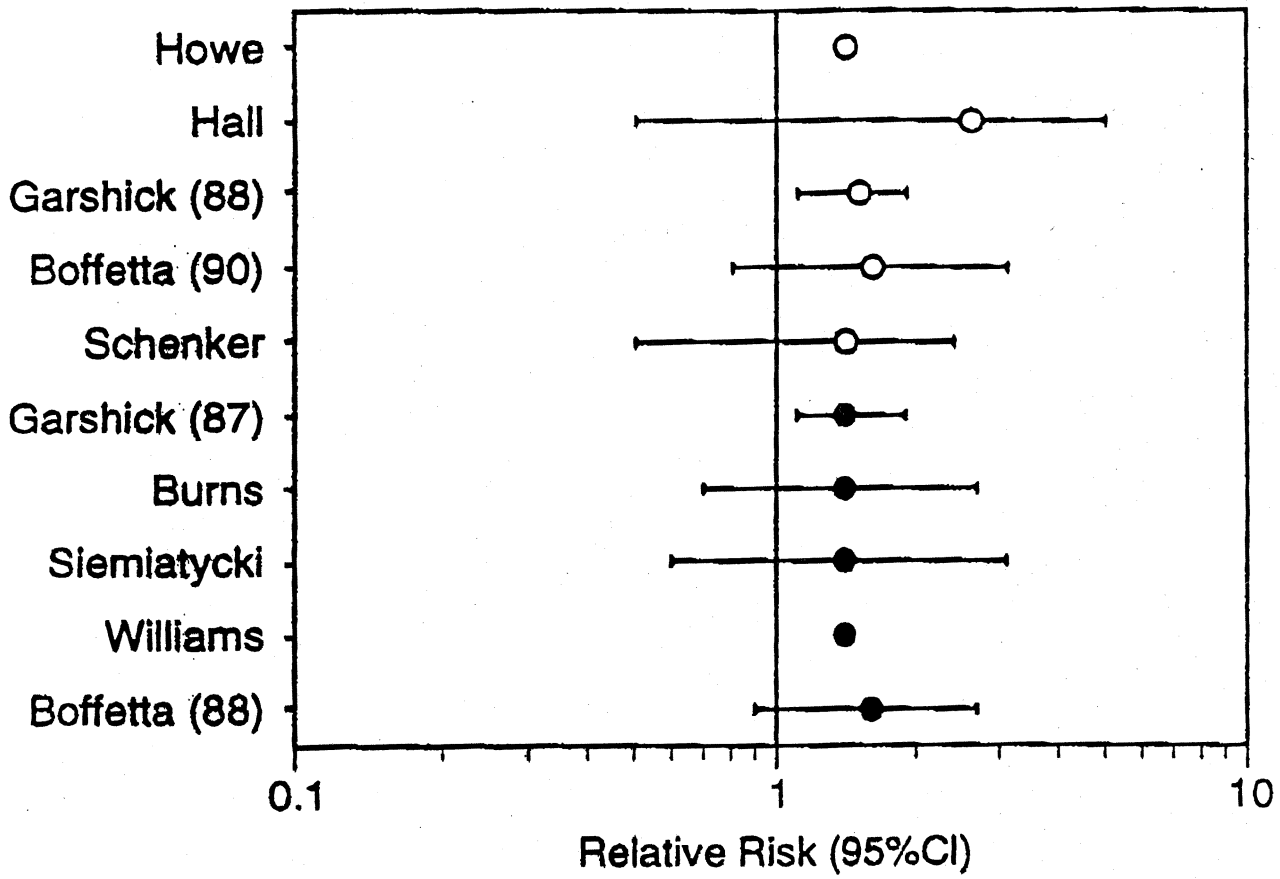

Figure . Lung cancer and exposure to diesel exhaust in railroad workers. ● = RR adjusted for cigarette smoking; O = RR not adjusted for cigarette smoking. For the two studies by Howe and Williams, CIs were not reported and could not be calculated.

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As documented in Subsection 2.c.i(2)(a) of risk assessment, all of the studies showing negative associations were either based on relatively short observation or follow-up periods, lacked good information about dpm exposure, involved low duration or intensity of dpm exposure, or, because of inadequate sample size or latency allowance, lacked the power to detect effects of the magnitude found in the ''positive'' studies. Boffetta et al. (1988, p. 404) noted that, in addition, studies failing to show a statistically significant association—

> * * * often had low power to detect any association, had insufficient latency periods, or compared incidence or mortality rates among workers to national rates only, resulting in possible biases caused by the ''healthy worker effect.''

Some commenters noted that limitations such as insufficient duration of exposure, inadequate latency allowance, small worker populations, exposure misclassification, and comparison to external populations with no adjustment for a healthy worker effect may explain why not all of the studies showed a statistically significant association between dpm exposure and an increased prevalence of lung cancer. According to these commenters, if an epidemiologic study shows a statistically significant result, this often occurs in spite of methodological weaknesses rather than because of them. MSHA agrees that limitations such as those listed make it more difficult to obtain a statistically significant result when a real relationship exists.

(b) Best Available Epidemiologic Evidence

As explained above, it is statistically significant that 41 of the 47 available epidemiologic studies reported an elevated risk of lung cancer for workers exposed to dpm. MSHA finds it even more informative, however, to examine the collective results of the eight studies identified in Section III.2.c.i(2)(a) as providing the best currently available epidemiologic evidence. These studies, selected using the criteria described earlier, are: Boffetta et al. (1988), Boffetta et al. (1990), Brüske-Hohlfeld et al. (1999), Garshick et al. (1987), Garshick et al. (1988,1991), Johnston et al. (1997), Steenland et al. (1990,1992,1998), and Säverin et al. (1999). All eight of these studies reported an increased risk of lung cancer for workers with the longest diesel exposures and for those most likely to have been exposed, compared to unexposed workers. Tables showing the results from each of these studies are provided in Section III.2.c.1(2)(a).

The sign test of statistical significance can also be applied to the collective results of these eight studies. If there were no underlying association between exposure to diesel exhaust and an increased risk of lung cancer, or anything else systematically favoring a positive result, then there should be equal probabilities (equal to one-half) that any one of these eight studies would turn out positive or negative. Therefore, under the null hypothesis that positive and negative results are equally likely, the probability that all eight studies would show either a positive or a negative association is $(0.5)^8 = 0.0039$, or 0.39 percent. This shows that the collective results of the eight studies comprising the best available epidemiologic evidence are statistically significant at a confidence level exceeding 99 percent (i.e., $100 - 2 \times 0.39$).

When the risk of disease or death increases in response to higher cumulative exposures, this is described by a ''positive'' exposure-response relationship. Like consistency of results, the existence of a positive exposure-response relationship is important in establishing that the exposures in question actually cause an increase in risk. Among the eight studies MSHA has identified as comprising the best available epidemiologic evidence, there are five that provide evidence of increasing lung cancer risk with increasing cumulative exposure: Boffetta, et al. (1990), Brüske-Hohlfeld et al. (1999), Johnston et al. (1997), Säverin et al. (1999), and Steenland et al. (1990, 1992, 1998). The results supporting such a relationship are provided in the table accompanying discussion of each of these studies in Section III.2.c.i(2)(a).

Although some have interpreted the results from the two studies by Garshick et al. as also providing evidence of a positive exposure-response relationship (*e.g.,* Cal-EPA, 1998), this interpretation is highly sensitive to the statistical models and techniques used to analyze the data (HEI, 1999; Crump 1999). Therefore, for purposes of this risk assessment, MSHA is not relying on Garshick et al. (1987) or Garshick et. al (1988, 1991) to demonstrate the existence of a positive exposure-response relationship. MSHA used the study for purposes of hazard identification only. The Garshick studies contributed to the weight of evidence favoring a causal interpretation, since they show statistically significant excesses in lung cancer risk for the exposed workers.

The relative importance of the five studies identified in demonstrating the existence of a positive exposure-response relationship varies with the quality of exposure assessment. Boffetta et al. (1990) and Brüske-Hohlfeld et al. (1999) were able to show such a relationship based on the estimated duration of occupational exposure for exposed workers, but quantitative measures of exposure intensity (i.e., dpm concentration) were unavailable. Although duration of exposure is frequently used as a surrogate of cumulative exposure, it is clearly preferable, as many commenters pointed out, to base estimates of cumulative exposure and exposure-response analyses on quantitative measurements of exposure levels combined with detailed work histories. Positive exposure-response relationships based on such data were reported in all three studies: Johnston et al. (1997), Steenland et al. (1998), and Säverin et al. (1999).

(c) Studies With Quantitative or Semiquantitative Exposure Assessments

Several commenters stressed the fact that most of the available epidemiologic studies contained little or no quantitative information on diesel exposures and that those studies containing such information (such as Steenland et al., 1998) generated it using questionable assumptions. Some commenters also faulted MSHA for insufficiently addressing this issue. For example, one commenter stated:

> * * * the Agency fails to highlight the lack of acceptable (or any) exposure measurements concurrent with the 43 epidemiology studies cited in the Proposed Rule.* * * the lack of concurrent exposure data is a significant deficiency of the epidemiology studies at issue and is a major factor that prevents application of those epidemiology results to risk assessment. [EMA]

MSHA agrees that the nature and quality of exposure information should be an important consideration in evaluating the strength of epidemiologic evidence. That is why MSHA included exposure assessment as one of the criteria used to evaluate and rank studies in Section 2.c.1(2)(a) of this risk assessment. Two of the most recent studies, both conducted specifically on miners, utilize concurrent, quantitative exposure data and are included among the eight in MSHA's selection of best available epidemiologic evidence (Johnston et al., 1997 and Säverin et al., 1999). As a practical matter, however, epidemiologic studies rarely have concurrent exposure measurements; and, therefore, the commenter's line of

reasoning would exclude nearly all of the available studies from this risk assessment—including all six of the negative studies. Since Section 101(a)(6) of the Mine Act requires MSHA to consider the ''best available evidence'' (emphasis added), MSHA has not excluded studies with less-than-ideal exposure assessments, but, instead, has taken the quality of exposure assessment into account when evaluating them. This approach is also consistent with the recognition by the HEI Expert Panel on Diesel Emissions and Lung Cancer that ''regulatory decisions need to be made in spite of the limitations and uncertainties of the few studies with quantitative data currently available'' (HEI, 1999; p. 39).

The degree of quantification, however, is not the only relevant consideration in evaluating studies with respect to exposure assessment. MSHA also considered the likely effects of potential exposure misclassification. As expressed by another commenter:

> * * * [S]tudies that * * * have poor measures of exposure to diesel exhaust have problems in classification and will have weaker results. In the absence of information that misclassification is systematic or differential, in which case study results would be biased towards either positive or no-effect level, it is reasonable to assume that misclassification is random or nondifferentiated. If so,* * * study results are biased towards a risk ratio of 1.0, a ratio showing no association between diesel exhaust exposure and the occurrence of lung cancer. [Dr. James Weeks, representing UMWA]

In her review of Bhatia et al. (1998), Silverman (1998) proposed that ''[o]ne approach to assess the impact of misclassification would be to exclude studies without quantitative or semiquantitative exposure data.'' According to Dr. Silverman, this would leave only four studies among those considered by Dr. Bhatia: Garshick et al. (1988), Gustavsson et al. (1990), Steenland et al. (1992), and Emmelin et al. (1993).[68] All four of these studies showed higher rates of lung cancer for the workers estimated to have received the greatest cumulative exposure, as compared to workers who had accumulated little or no diesel exposure. Statistically significant results were reported in three of these four studies. Furthermore, the two more recent studies utilizing fully quantitative exposure assessments (Johnston et al., 1997; Säverin et al., 1999) were not evaluated or otherwise considered in the articles by Drs. Bhatia and Silverman. Like the other four studies, these too reported elevated rates of lung cancer for workers with the highest cumulative exposures. Specific results from all six of these studies are presented in Tables III–4 and III–5.

Once again, the sign test of statistical significance can be applied to the collective results of the four studies identified by Dr. Silverman plus the two more recent studies with quantitative exposure assessments. As before, under the null hypothesis of no underlying effect, the probability would equal one-half that any one of these six studies would turn out positive or negative. The probability that all six studies would show either a positive or a negative association would, under the null hypothesis, be $(0.5)^6 = 0.0156$, or 1.56 percent. This shows that the collective results of these six studies, showing an elevated risk of lung cancer for workers estimated to have the greatest cumulative exposure, are statistically significant at a confidence level exceeding 96 percent (i.e., $100 - 2 \times 1.56$).

As explained in the previous subsection, three studies showing evidence of increased risk with increasing exposure based on quantitative or semi-quantitative exposure assessments are included in MSHA's selection of best available epidemiologic evidence: Johnston et al. (1997), Steenland et al. (1998), and Säverin et al. (1999). Not only do these studies provide consistent evidence of elevated lung cancer risk for exposed workers, they also each provide evidence of a positive exposure-response relationship—thereby significantly strengthening the case for causality.

(d) Studies Involving Miners

Eleven studies involving miners are summarized and discussed in Section 2.c.i(2)(a) of this risk assessment. Commenters' observations and criticisms pertaining to the individual studies in this group are also addressed in that section. Three of these studies are among the eight in MSHA's selection of best available epidemiologic evidence: (Boffetta et al., 1988; Johnston et al., 1997; Säverin et al., 1999). All three of these studies provide evidence of an increased risk of lung cancer for exposed miners. Although MSHA places less weight on the remaining eight studies, seven of them show some evidence of an excess lung cancer risk among the miners involved. The remaining study (Christie et al., 1995) reported a greater all-cause SMR for the coal miners involved than for a comparable population of petroleum workers but did not compare the miners to a comparable group of workers with respect to lung cancer.

The NMA submitted a review of six of these studies by Dr. Peter Valberg, who concluded that ''[t]hese articles do not implicate diesel exhaust, per se, as strongly associated with lung cancer in miners * * * The reviewed studies do not form a consistent and cohesive picture implicating diesel exhaust as a major risk factor for miners.'' Similarly, Dr. Jonathan Borak reviewed six of the studies on behalf of MARG and concluded:

> [T]he strongest conclusion that can be drawn from these six studies is that the miners in those studies had an increased risk of lung cancer. These studies cannot relate such increased [risk] to any particular industrial exposure, lifestyle or combination of such factors.

Apparently, neither Dr. Valberg nor Dr. Borak disputed MSHA's observation that the miners involved in the studies they reviewed exhibited, overall, an excess risk of lung cancer. It is possible that any excess risk found in epidemiologic studies may be due to extraneous unknown or uncontrolled risk factors (i.e., confounding variables). However, neither Drs. Valberg or Borak, nor the NMA or MARG, offered evidence, beyond a catalog of speculative possibilities, that the excess lung cancer risk for these miners was due to anything other than dpm exposure.

Nevertheless, MSHA agrees that the studies reviewed by Drs. Valberg and Borak do not, by themselves, conclusively implicate dpm exposure as the causal agent. Miners are frequently exposed to other occupational hazards associated with lung cancer, such as radon progeny, and it is not always possible to distinguish effects due to dpm exposure from effects due to these other occupational hazards. This is part of the reason why MSHA did not restrict its consideration of evidence to epidemiologic studies involving miners. What implicates exposure to diesel exhaust is the fact that diesel-exposed workers in a variety of different occupations, under a variety of different working conditions (including different types of mines), and in a variety of different geographical areas consistently exhibit an increased risk of lung cancer.

Drs. Valberg and Borak did not review the two studies that utilize quantitative dpm exposure assessments: Johnston et al. (1997) and Saverin et al. (1999). In recently received comments Dr. Valberg, writing for the NMA brought up four issues on the Saverin et al. 1999. These issues were potential exposure misclassification, potential flaws in the sampling method, potential smoker

[68] Emmelin et al. (1993) was considered but excluded from the meta-analysis by Bhatia et al. (1998) for reasons explained by the authors.

misclassification, and insufficient latency. Two of these issues have already been extensively discussed in section 2.c.i.2.a.ii and therefore will not be repeated here. Dr. Valberg suggested that the potential flaw in the sampling method would tend to over-estimate exposure and that there was insufficient latency. If, in fact, both of these issues are relevant, they would act to UNDERESTIMATE the lung cancer risk in this cohort instead of OVERESTIMATE it. MSHA regards these, along with Boffetta et al. (1988), Burns and Swanson (1991),[69] and Lerchen et al. (1987) to be the most informative of the available studies involving miners. Results on miners from these five studies are briefly summarized in the following table, with additional details provided in Section 2.c.1(2)(a) and Tables III–4 and III–5 of this risk assessment. The cumulative exposures at which relative risks from the Johnston and Säverin studies are presented are equivalent, assuming that TC constitutes 80 percent of total dpm. The cumulative dpm exposure of 6.1 mg-yr/m^3 is the multiplicative product of exposure duration and dpm concentration for the most highly exposed workers in each of these two studies.

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Results from best available studies involving miners.

Study	Mine Type	Exposure Assessment	Smoking Adjustm't	Result
Boffetta et al. (1988)	various	Occupational history	yes	RR = 2.67 for miners, compared to workers never employed in diesel -exposed occupations.†
Burns and Swanson (1991)	unknown	Occupational history	yes	OR = 5.03 for mining machinery operators.†
Johnston et al. (1997)	UG coal	Occupational history & indirect dpm measurements	yes	For cumulative dpm exposure = 6.12 mg-yr/m^3 : RR = 5.5 using mine-adjusted statistical model; RR= 11.0 using mine-unadjusted statistical model.
Lerchen et al. (1987)	various	Occupational history	yes	OR = 2.1 for underground non-uranium mining.
Säverin et al. (1999)	UG potash	Occupational history & TC measurements	smoking uncorrelated with TC within cohort	RR = 2.17 for most highly exposed group, compared to least exposed group. For cumulative TC exposure = 4.9 mg-yr/m^3 : RR = 1.16 to 2.70 depending on statistical model.

†Statistically significant at a 95-percent confidence level.

Although MSHA places less weight on the studies by Burns and Swanson and by Lerchen than on the other three, it is significant that the five best available studies involving miners all support an increased risk of lung cancer attributable to dpm exposure.

(2) Meta-Analyses

MSHA recognizes that simply tabulating epidemiologic studies as positive or negative can sometimes be misleading. There are generally a variety of outcomes that could render a study positive or negative, some studies contain different analyses of related data sets, some studies involve multiple

[69] Listed in Table III–5 under Swanson et al., 1993.

comparisons of various subgroups, and the studies differ widely in the reliability of their results. Therefore, MSHA is not limiting its assessment of the epidemiologic evidence to such a tabulation or relying only on the sign test described above. MSHA has also considered the results of two statistical meta-analyses covering most of the available studies (Lipsett and Campleman, 1999; Bhatia et al., 1998). These meta-analyses weighted and pooled independent results from those studies meeting certain inclusion requirements to form overall estimates of relative risk for exposed workers based on the combined body of data. In addition to forming pooled estimates of the effect of diesel exposure, both meta-analyses analyzed sources of heterogeneity in the individual results and investigated but rejected publication bias as an explanation for the generally positive results reported. Both meta-analyses derived a statistically significant increase of 30 to 40 percent in the risk of lung cancer, attributable to occupational dpm exposure.

Lipsett and Campleman (1999) systematically analyzed and combined results from most of the studies summarized in Tables III–4 and III–5. Forty-seven studies published between 1957 and 1995 were identified for initial consideration. Some studies were excluded from the pooled analysis because they did not allow for a period of at least 10 years for the development of clinically detectable lung cancer. Others were excluded because of bias resulting from incomplete ascertainment of lung cancer cases in cohort studies or because they examined the same cohort population as another study. One study was excluded because standard errors could not be calculated from the data presented. The remaining 30 studies, contributing a total of 39 separate estimates of exposure effect (for distinct occupational groups within studies), were analyzed using a random-effects analysis of variance (ANOVA) model.

Potential effects of publication bias (i.e., the likelihood that papers with positive results may be more likely to be published than those with negative results) were investigated by plotting the logarithm of relative risk estimated from each study against its estimated precision, as expressed by the inverse of its standard error. According to the authors, the resulting ''funnel plot'' was generally consistent with the absence of significant publication bias, although there were relatively few small-scale, statistically insignificant studies. The investigators performed a further check of potential publication bias by comparing results of the included studies with the only relevant unpublished report that became available to them during the course of their analysis. Smoking-adjusted relative risks for several diesel-exposed occupations in the unpublished study were, according to the investigators, consistent with those found in the studies included in the meta-analysis.

Each of the 39 separate estimates of exposure effect was weighted by a factor proportional to its estimated precision. Sources of heterogeneity in results were investigated by subset analysis—using categorical variables to characterize each study's design, target population (general or industry-specific), occupational group, source of control or reference population, latency, duration of exposure, method of ascertaining occupation, location (North America or Europe), covariate adjustments (age, smoking, and/or asbestos exposure), and absence or presence of a clear healthy worker effect (as manifested by lower than expected all-cause mortality in the occupational population under study).

Sensitivity analyses were conducted to evaluate the sensitivity of results to inclusion criteria and to various assumptions used in the analysis. This included (1) substitution of excluded ''redundant'' studies of the same cohort population for the included studies and (2) exclusion of studies involving questionable exposure to dpm. An influence analysis was also conducted to examine the effect of dropping one study at a time, to determine if any individual study had a disproportionate effect on results of the ANOVA.

The pooled relative risk from all 39 exposure effects (estimated from 30 studies) was RR = 1.33, with a 95-percent confidence interval (CI) extending from 1.21 to 1.46. For the subgroup of 13 smoking-adjusted exposure effects (nine studies) from populations ''most likely to have had substantial exposure'' to dpm, the pooled effect was RR = 1.47, with a CI from 1.29 to 1.67. Based on the all of the various analyses they conducted, the authors concluded:

> Although substantial heterogeneity existed in the initial pooled analysis, stratification on several factors substantially reduced heterogeneity, producing subsets of studies with increased relative risk estimates that persisted through various influence and sensitivity analyses. * * *
>
> In studies that adjusted for confounding by cigarette smoking, not only did the positive association between diesel exhaust exposure and lung cancer persist but the pooled risk estimate showed a modest increase, with little evidence of heterogeneity.
>
> * * * [T]his meta-analysis provides quantitative evidence consistent with several prior reviews, which have concluded that the epidemiologic evidence supports a causal relationship between occupational exposure to diesel exhaust and lung cancer. [Lipsett and Campleman, 1999]

The other meta-analysis was conducted by Bhatia et al. (1998) on epidemiologic studies published in peer-reviewed journals between 1957 and 1993. In this analysis, studies were excluded if actual work with diesel equipment ''could not be confirmed or reliably inferred'' or if an inadequate latency period was allowed for cancer to develop, as indicated by less than 10 years from time of first exposure to end of follow-up. Studies of miners were also excluded, because of potential exposure to radon and silica. Likewise, studies were excluded if they exhibited selection bias or examined the same cohort population as a study published later. A total of 29 independent results on exposure effects from 23 published studies were identified as meeting the inclusion criteria.

To address potential publication bias, the investigators identified several unpublished studies on truck drivers and noted that elevated risks for exposed workers observed in these studies were similar to those in the published studies utilized. Based on this and a ''funnel plot'' for the included studies, the authors concluded that there was no indication of publication bias.

After assigning each of the 29 separate estimates of exposure effect a weight proportional to its estimated precision, Bhatia et al. (1998) used a fixed-effects ANOVA model to calculate pooled relative risks based on the following groupings: all 29 results; all case-control studies; all cohort studies; cohort studies using internal reference populations; cohort studies making external comparisons; studies adjusted for smoking; studies not adjusted for smoking; and studies grouped by occupation (railroad workers, equipment operators, truck drivers, and bus workers). Elevated risks of lung cancer were shown for exposed workers overall and within every individual group of studies analyzed. A positive duration-response relationship was observed in those studies presenting results according to employment duration. The weighted, pooled estimates of relative risk were identical for case-control and cohort studies and nearly identical for studies with or without smoking adjustments.

The pooled relative risk from all 29 exposure effects (estimated from 23 studies) was RR = 1.33, with a 95-percent confidence interval (CI), adjusted for heterogeneity, extending

from 1.24 to 1.44. For just the smoking-adjusted studies, it was 1.35 (CI: 1.20 to 1.52); and for cohort studies making internal comparisons, it was 1.43 (CI: 1.29 to 1.58). Based on their evaluation of the all the analyses on various subgroups, Bhatia et al. (1998) concluded that the elevated risk of lung cancer observed among exposed workers was unlikely to be due to chance, that confounding from smoking was unlikely to explain all of the excess risk, and that ''this meta-analysis supports a causal association between increased risks for lung cancer and exposure to diesel exhaust.''

The pooled relative risks estimated in both meta-analyses equal 1.33 and exceed 1.4 for studies making internal comparisons, or comparisons to similar groups of workers. Both meta-analyses found these results to be statistically significant, meaning that they cannot be explained merely by random or unexplained variability in the risk of lung cancer that occurs among both exposed and unexposed workers. Although both meta-analyses relied, by necessity, on an overlapping selection of studies, the inclusion criteria were different and some studies included in one meta-analysis were excluded from the other. They used different statistical models for deriving a pooled estimate of relative risk, as well as different means of analyzing heterogeneity of effects. Nevertheless, they derived the same estimate of the overall exposure effect and found similar sources of heterogeneity in the results from individual studies.[70] One commenter observed that—

> Lung cancer relative risks for occupational ''control groups'' vary over a range from 0.4 to 2.7 * * *. Therefore, the level of relative risks being reported in the Dpm epidemiology fall within this level of natural variation. [IMC Global]

This argument is refuted by the statistical significance of the elevation in risk detected in both meta-analyses in combination with the analyses accounting for heterogeneity of exposure effects.

The EMA objected that MSHA's focus on these two meta-analyses ''presents an incomplete picture because the counter-arguments of Silverman (1998) were not discussed in the same detail.'' IMC global also faulted MSHA for dismissing Dr. Silverman's views without adequate explanation.

In her review,[71] Dr. Silverman characterized Bhatia et al. (1998) as a ''careful meta-analysis'' and acknowledged that it ''add[s] to the credibility that diesel exhaust is carcinogenic * * *.'' She also explicitly endorsed several of its most important conclusions. For example, Dr. Silverman stated that ''[t]he authors convincingly show that potential confounding by cigarette smoking is likely to have little impact on the estimated RRs for diesel exhaust and lung cancer.'' She suggested, however, that Bhatia et al. (1998) ''ultimately do not resolve the question of causality.'' (Silverman, 1998)

Dr. Silverman imposed an extremely high standard for what is needed to ultimately resolve the question of causality. The precise question she posed, along with her answer, was as follows:

> Has science proven causality beyond any reasonable doubt? Probably not. [Silverman, 1998, emphasis added.]

Neither the Mine Act nor applicable case law requires MSHA to prove causality ''beyond any reasonable doubt.'' The burden of proof that Dr. Silverman would require to close the case and terminate research is not the same burden of proof that the Mine Act requires to warrant protection of miners subjected to far higher levels of a probable carcinogen than any other occupational group. In this risk assessment, MSHA is evaluating the collective weight of the best available evidence—not seeking proof ''beyond any reasonable doubt.''[72]

The EMA objected to MSHA's reliance on the two meta-analyses because of ''* * * serious deficiencies in each'' but did not, in MSHA's opinion, identify any such deficiencies. The EMA pointed out that ''most of the original studies in each were the same, and the few that were not common to each were not of significance to the outcome of either meta-analysis.'' MSHA does not regard this as a deficiency. Since the object of both meta-analyses was to analyze the available epidemiologic evidence linking dpm exposure with lung cancer, using defensible inclusion criteria, it is quite understandable that they would rely on overlapping information. The principal differences were in the types and methods of statistical analysis used, rather than in the data subjected to analysis; and MSHA considers it informative that different approaches yielded very similar results and conclusions. It is noteworthy, moreover, that both of the meta-analyses explicitly addressed the EMA's concern by performing analyses on various different sub-groupings of the available studies. The sensitivity of results to the inclusion criteria was also explicitly investigated and considered. MSHA believes that the conclusions of these meta-analyses did not depend on unreasonable inclusion or exclusion criteria.

The EMA also argued that—

> [a] meta-analysis cannot compensate for basic deficiencies in the studies used to create the meta-analysis, and this fact is not clearly stated by MSHA. Instead, MSHA follows the tack of the meta-analysis authors, who claim that the meta-analysis somehow overcomes deficiencies of the individual studies selected and presents a stronger case. This is simply not true. [EMA]

MSHA agrees that a meta-analysis cannot correct for all deficiencies that may be present in individual studies. It can, however, correct for certain types of deficiencies. For example, individual studies may lack statistical power because of small study populations. By pooling results from several such studies, a meta-analysis may achieve a level of statistical significance not attainable by the individual studies. Furthermore, both of the meta-analyses used well-defined inclusion criteria to screen out those studies with the most severe deficiencies. In addition, they both found that it was the more rigorous and technically more valid studies that reported the strongest associations between excess lung cancer and dpm exposure. They also performed separate analyses that ruled out inflationary effects of such ''deficiencies'' as lack of a smoking adjustment. For example,

[70] Several commenters suggested that because the two meta-analyses both received direct or indirect funding from the same governmental agency, they were not independently conducted. These commenters speculated that Dr. Allan Smith, a co-author of Cal-EPA (1998) and Bhatia et al. (1998), contributed to both meta-analyses. Although an earlier version of Lipsett and Campleman (1999) appeared as an appendix to Cal-EPA (1998), commenters provided no evidence that Dr. Smith contributed anything to that appendix. Dr. Smith is not listed as a co-author of Lipsett and Campleman (1999).

[71] Silverman (1998) reviewed Bhatia et al. (1998) but not Lipsett and Campleman (1999) or the earlier version of that meta-analysis (Lipsett and Alexeeff, 1998) cited in MSHA's proposed preamble.

[72] It is noteworthy that, in describing research underway that might resolve the issue of causality, Dr. Silverman stressed the need for studies with quantitative exposure measurements and stated that ''underground miners may, in fact, be the most attractive group for study because their exposure to diesel exhaust is at least five times greater than that of previously studied occupational groups.'' (Silverman, 1998) She then mentioned a study on underground miners in Germany that had recently been initiated. The study of German underground potash miners (Säverin et al., 1999), published after Dr. Silverman's article, utilizes quantitative exposure measurements and is included in MSHA's selection of best available epidemiologic evidence (see Section 3.a.iii(1)(a) of this risk assessment). MSHA also includes in that selection another underground miner study utilizing quantitative exposure measurements (Johnston et al., 1997). The 1997 study was available prior to Dr. Silverman's article but is not listed among her references.

Lipsett and Campleman (1999) reported a pooled RR = 1.43 for 20 smoking-adjusted results, as compared to a pooled RR = 1.25 for 19 results with no smoking adjustment.

IMC Global and MARG submitted five specific criticisms of the meta-analyses, to which MSHA will respond in turn.

(1) publication bias

* * * both studies * * * rely only on published studies. * * * the authors rely on statistical analysis in an attempt to uncover possible publication bias.* * * the only safeguard to protect against possible publication bias is to seek out unpublished results * * *. [IMC Global]

Both meta-analyses compared the results of published and unpublished studies and found them to be similar. Bhatia et al. (1998) found several unpublished studies of lung cancer among truck drivers that ''* * * were not included in our analysis; however the risk ratios of these studies are similar to the [sic] those in published studies among truck drivers.'' (Bhatia et al., p. 90) Lipsett and Campleman (1999) checked ''[s]moking-adjusted relative risks for several diesel-exposed occupations'' in an unpublished report on U.S. veterans and found them ''* * * consistent with those reported here.'' They remarked that ''although publication bias cannot be completely ruled out, it is an unlikely explanation for our findings.'' (Lipsett and Campleman, p. 1015) In addition to comparing results directly against unpublished studies, both meta-analyses used the statistical method of ''funnel plots'' as an indirect means of checking for the existence of significant publication bias. It should also be noted that MSHA did not exclude unpublished studies from this risk assessment.

(2) Selection Bias

* * * [the] meta-analyses have to provide a much more convincing rationale as to why all miners were excluded even when the confounders that are mentioned are not likely or important, for example in studies conducted in potash and salt mines. * * * IMC Global sees no reason why the older studies of potash workers [Waxweiler *et al.*, 1973] and more recent studies on New South Wales coal miners [Christie *et al.*, 1995] should not be included * * *. [IMC Global]

Studies were selectively included or excluded, without good or sufficient explanation. [MARG]

Contrary to the commenters' characterization, both meta-analyses listed each study excluded from the analysis of pooled relative risk and gave a good reason for its exclusion. For example, both meta-analyses excluded studies that failed to allow for a minimum 10-year latency period for lung cancer to develop after first exposure. With respect to the exclusion of all studies on miners, Bhatia et al. (1998) pointed out that ''[s]ince studies of miners often indicate higher relative risks for lung cancer than those considered in this meta-analysis, this was a conservative exclusion.'' Even if studies on miners had been considered, Waxweiler et al. (1973) and Christie et al. (1995) would have been excluded from both meta-analyses because of their failure to meet the 10-year minimum latency requirement.

(3) Lack of Actual Exposure Data

* * * [N]ondifferential exposure or disease misclassification can sometimes produce bias away from the null * * * Thus, tests for heterogeneity performed in both these meta-analyzes won't detect or correct this problem. [IMC Global]

Lipsett and Campleman acknowledged that ''[e]xposure misclassification is a problem common to all studies of cancer and diesel emissions. In no case were there direct measurements of historical diesel exhaust exposures of the subjects.'' However, as Dr. Silverman pointed out in her review, ''* * * this bias is most likely to be nondifferential, and the effect would probably have been to bias point estimates toward the null value. Thus the summary RR of 1.33 may be an underestimate of the true lung cancer effect associated with diesel exposure.'' (Silverman, 1998)

(4) Smoking as a Confounder

* * * The use of data manipulation and modeling adjustments in both these meta-analyses cannot rectify the flaws in the initial studies. [IMC Global]

* * * misclassification of this exposure [cigarette smoking] could result in residual confounding of individual studies and, consequently, metaanalyses, of those studies. [MARG]

Contrary to the commenter's suggestion, neither of the meta-analyses made any attempt to manipulate or adjust the data in order to rectify what the commenter regards as ''flaws'' in the way smoking or other potential confounders were treated in the initial studies. Both meta-analyses, however, compared the pooled RR for studies with a smoking adjustment to the pooled RR for studies without any such adjustment. Both meta-analysis calculated a pooled RR for the smoking-adjusted studies greater than or equal to that for the unadjusted studies. In addition, Bhatia et al. (1998) analyzed the impact of the smoking adjustment for the subgroup of studies reporting results both with and without such an adjustment and found that the ''small reduction in the pooled RR estimates would not be consistent with a major effect from residual confounding.'' Dr. Silverman concluded that ''[t]he authors convincingly show that potential confounding by cigarette smoking is likely to have little impact on the estimated RRs for diesel exhaust and lung cancer.'' (Silverman, 1998)

(5) Inadequate Control in the Underlying Studies for Diet

As noted by Lipsett and Campleman, ''Diet may also confound the diesel-lung cancer association.'' The researchers also caution that this risk factor was not controlled for in the nearly 50 diesel studies they examined. [MARG]

Since inhalation is the primary route of dpm exposure, and the lung is the primary target organ, MSHA considers potential dietary confounding to be of minor importance in the diesel-lung cancer association. Lipsett and Campleman acknowledged that diet might be a relevant consideration for long-haul truck drivers, but stated that ''diet would probably not be an important confounder in studies of other occupations, particularly those using internal or other occupationally active reference populations.'' Studies making internal comparisons, or comparisons to similar groups of workers, are unlikely to be seriously confounded by dietary differences, because the groups of workers being compared are likely to have very similar dietary habits, on average. The pooled relative risk for cohort studies making comparisons internally or to other active workers was 1.48 (95% CI = 1.28 to 1.70). (Lipsett and Campleman, 1999, Table 3) This was considerably higher than the pooled RRs for studies making comparisons against regional or national populations, where dietary differences (and also differences with respect to other potential confounders) would be more important.

(3) Potential Systematic Biases

Citing failure to account for dietary differences as an example, some commenters argued that the meta-analyses may simply propagate weaknesses shared by the individual studies. These commenters contended that many of the studies MSHA considered in this risk assessment share methodological similarities and that, therefore, a ''deficiency'' causing bias in one study would probably also bias many other studies in the same direction. According to these commenters, no matter how great a majority of studies report a 30- to 40-percent increase in the risk of lung cancer for exposed workers, the

possibility of systematic bias prevents the collective evidence from being strong or sufficient.

Although this point has some theoretical foundation, it has no basis in fact for the particular body of epidemiologic evidence relating lung cancer to diesel exposure. The studies considered were carried out by many different researchers, in different countries, using different methods, and involving a variety of different occupations. Elevated risk was found in cohort as well as case-control studies, and in studies explicitly adjusting for potential confounders as well as studies relying on internal comparisons within homogeneous populations. The possibility that systematic bias explains these results is also rendered less plausible by results from studies of a radically different type: the elevated risk of lung cancer associated with chronic environmental exposures to $PM_{2.5}$ (Dockery et al. 1993; Pope et al., 1995).

Furthermore, the commenters advancing this argument presented no evidence that the studies shared any deficiencies of a type that would systematically shift results in the direction of showing a spurious association. As explained in Subsection 2.c.i(2)(a), exposure misclassification, healthy worker effect, and low power due to insufficient latency generally have the opposite effect—systematically diluting and masking results. Although many studies may share a similar susceptibility to bias by dietary differences or residual smoking effects,[73] there is no reason to expect that such effects will consistently bias results in the same direction, across all occupations and geographic regions.

Associations between dpm exposure and excess lung cancer are evident in a wide variety of occupational and geographical contexts, and it is unlikely that all (or most) would be biased in the same direction by lifestyle effects. There is no reason to suppose that, in nearly all of these studies, exposed subjects were more likely than unexposed subjects to have lifestyles (apart from their occupations) that increased their risk of lung cancer. On the other hand, exposures to other occupational carcinogens, such as asbestos dust, radon progeny, and silica, could systematically cause studies in which they are not taken into account to exhibit spurious associations between lung cancer and occupational diesel exhaust exposures. Silica dust and radon progeny are frequently present in mining environments (though not usually in potash mines), and this was the reason that studies on miners were excluded from the two meta-analyses.

IMC Global argued that because of the possibility of being misled by systematic biases, epidemiologic evidence can be used to identify only those hazards that, at a minimum, double the risk of disease (i.e., RR ≥ 2.0). IMC Global explained this viewpoint by quoting an epidemiologist as follows:

> * * * [E]pidemiologic methods can only yield valid documentation of large relative risks. Relative risks of low magnitude (say, less than 2) are virtually beyond the resolving power of the epidemiologic microscope. We can seldom demonstrably eliminate all sources of bias, and we can never exclude the possibility of unidentified and uncontrolled confounding. If many studies—preferably based on different methods—are nevertheless congruent in producing markedly elevated relative risks, we can set our misgivings aside. If however, many studies produce only modest increases, those increases may well be due to the same biases in all the studies. [Dr. Samuel Shapiro, quoted by IMC Global]

It is important to note that, unlike IMC Global, Dr. Shapiro did not suggest that results of RR < 2.0 be counted as ''negative.'' He contended only that low RRs do not completely rule out the possibility of a spurious association due to unidentified or uncontrolled confounding. More importantly, however, this restriction would allow workers to be exposed to significant risks and is, therefore, unacceptable for regulatory purposes. For purposes of protecting miners from lung cancer, certainty is not required; and an increase in the relative risk of less than 100 percent can increase the absolute risk of lung cancer by a clearly unacceptable amount. For example, if the baseline risk of lung cancer is six per thousand, then increasing it by 33 percent amounts to an increase of two per thousand for exposed workers.

IMC Global went on to argue that—

> * * * only a few of these studies have relative risks that exceed 2.0, and some of the studies that do exceed 2.0 exhibit biases that make them unsuitable for rulemaking purposes in our opinion. * * * Thus, in IMC Global's opinion, the epidemiologic evidence demonstrates an artificial association that can be explained through common biases probably due to smoking habits and lifestyle factors. [IMC Global]

This line of reasoning leaps from the possibility that systematic biases might account for observed results to a conclusion that they actually do so. Furthermore, after proposing to allow for possible biases by requiring that only relative risks in excess of 2.0 be counted as positive evidence, IMC Global has ignored its own criterion and discounted results greater than 2.0 for the same reason. Contrary to IMC Global's claim that ''only a few of the studies have relative risks that exceed 2.0,'' Tables III–4 and III–5 show 23 separate results greater than 2.0, applying to independent categories of workers in 18 different studies.

According to Stöber and Abel (1996), the potential confounding effects of smoking are so strong that ''residual smoking effects'' could explain even statistically significant results observed in studies where smoking was explicitly taken into account. MSHA agrees that variable exposures to non-diesel lung carcinogens, including relatively small errors in smoking classification, could bias individual studies. However, the potential confounding effect of tobacco smoke and other carcinogens can cut in either direction. Spurious positive associations of dpm exposure with lung cancer would arise only if the group exposed to dpm had a greater exposure to these confounders than the unexposed control group used for comparison. If, on the contrary, the control group happened to be more exposed to confounders, then this would tend to make the association between dpm exposure and lung cancer appear negative. Therefore, although smoking effects could potentially distort the results of any single study, this effect could reasonably be expected to make only about half the studies that were explicitly adjusted for smoking come out positive. Smoking is unlikely to have been responsible for finding an excess prevalence of lung cancer in 17 out of 18 studies in which a smoking adjustment was applied. Based on a 2-tailed sign test, this possibility can be rejected at a confidence level greater than 99.9 percent.

Even in the 29 studies for which no smoking adjustment was made, tobacco smoke and other carcinogens were important confounders only to the extent that the populations exposed and unexposed to diesel exhaust differed systematically with respect to these other exposures. Twenty-four of these studies, however, reported some degree of excess lung cancer risk for the diesel-exposed workers. This result could be attributed to other occupational carcinogens only in the unlikely event that, in nearly all of these studies, diesel-exposed workers happened to be more highly exposed to these other carcinogens than the control groups of workers unexposed to diesel.

Like IMC Global, Stöber and Abel (1996) do not, in MSHA's opinion, adequately distinguish between a possible bias and an actual one.

[73] The term ''residual smoking effects'' refers to the potentially confounding effects of smoking that may remain after a smoking adjustment has been made.

Potential biases due to extraneous risk factors are unlikely to account for a significant part of the excess risk in all studies showing an association. Excess rates of lung cancer were associated with dpm exposure in all epidemiologic studies of sufficient size and scope to detect such an excess. Although it is possible, in any individual study, that the potentially confounding effects of differential exposure to tobacco smoke or other carcinogens could account for the observed elevation in risk otherwise attributable to diesel exposure, it is unlikely that such effects would give rise to positive associations in 41 out of 47 studies. As stated by Cohen and Higgins (1995):

> * * * elevations [of lung cancer] do not appear to be fully explicable by confounding due to cigarette smoking or other sources of bias. Therefore, at present, exposure to diesel exhaust provides the most reasonable explanation for these elevations. The association is most apparent in studies of occupational cohorts, in which assessment of exposure is better and more detailed analyses have been performed. The largest relative risks are often seen in the categories of most probable, most intense, or longest duration of exposure. In general population studies, in which exposure prevalence is low and misclassification of exposure poses a particularly serious potential bias in the direction of observing no effect of exposure, most studies indicate increased risk, albeit with considerable imprecision. [Cohen and Higgins (1995), p. 269].

Several commenters identified publication bias as another possible explanation for the heavy preponderance of studies showing an elevated risk of lung cancer for exposed workers. As described earlier, both of the available meta-analyses investigated and rejected the hypothesis of significant publication bias affecting the overall results. This was based on both a statistical technique using ''funnel plots'' and a direct comparison between results of published and unpublished studies. Commenters presented no evidence that publication bias actually exists in this case. After the 1988 NIOSH and 1989 IARC determinations that diesel exhaust was a ''potential'' or ''probable'' human carcinogen, negative results would have been of considerable interest, and, in the absence of any evidence specifically applying to dpm studies, there is no reason to assume they would not have been published.

(4) Causality

MSHA must draw its conclusions based on the weight of evidence. In the absence of any statistical evidence for differential confounding or significant publication bias, the weight of epidemiologic evidence strongly favors a causal connection. On the one side, it is evident that virtually all of the studies that adjusted for smoking and other known confounders, or controlled for them by comparing against similar groups of workers, showed positive associations (i.e., relative risk or odds ratio > 1.0). Also on this side of the balance are all eight of the studies MSHA identified as comprising the best available human evidence. These include three studies reporting positive exposure-response relationships based on quantitative dpm exposure assessments: two recent studies specifically on underground miners (one coal and one potash) and one on trucking industry workers.[74] On the other side of the balance is the possibility that publication bias or other systematic biases may have been responsible for some unknown portion of the overall 30- to 40-percent elevation in lung cancer risk observed—a possibility that, while conceivable, is based on speculation. After considering other viewpoints (addressed here and in the next subsection), MSHA has accepted what in its view is the far more likely alternative: that the vast majority of epidemiologic studies showed an elevated risk in association with occupational exposures to diesel exhaust because such exposures cause the risk of lung cancer to increase. The toxicity experiments discussed in Subsection 2.d.iv of this risk assessment support the causal interpretation that MSHA has placed on the associations observed in epidemiologic studies.

In this risk assessment, MSHA is basing its conclusions primarily on epidemiologic studies. However, the results obtained from animal studies confirm that diesel exhaust can increase the risk of lung cancer in some species and help show that dpm (rather than the gaseous fraction of diesel exhaust) is the causal agent. The fact that dpm has been proven to cause lung cancer in laboratory rats only under conditions of lung overload does not make the rat studies irrelevant to miners. The very high dpm concentrations currently observed in some mines could impair or even overwhelm lung clearance for miners already burdened by respirable mineral dusts, thereby inducing lung cancer by a mechanism similar to what occurs in rats (Nauss et al., 1995). It must also be noted, however, that most of the human studies show an increased risk of lung cancer at dpm levels lower than what might be expected to cause overload. Therefore, the human studies suggest that overload is not a necessary condition for dpm to induce or promote lung cancer among humans. Salvi et al. (1999) reported marked inflammatory responses in the airways of healthy human volunteers after just one hour of exposure to dpm at a concentration of 300 $\mu g/m^3$. Animal studies provide evidence that inhalation of dpm has related effects, such as induction of free oxygen radicals, that could promote the development of human lung cancers by mechanisms not requiring lung overload. (See Sec. III.2.d.iv(2).)

Similarly, the weight of genotoxicity evidence helps support a causal interpretation of the associations observed in the epidemiologic studies. This evidence shows that dpm dispersed by alveolar surfactant can have mutagenic effects, thereby providing a genotoxic route to carcinogenesis that is independent of overloading the lung with particles. After a comprehensive review of the evidence, IPCS (1996) concluded that both the particle core and the associated organic materials have biological activity. The biological availability of carcinogens present in the organic portion of dpm may, however, differ significantly in different species. Chemical byproducts of phagocytosis, which occurs even when the lung is not overloaded, may provide another genotoxic route. Inhalation of diesel emissions has been shown to cause DNA adduct formation in peripheral lung cells of rats and monkeys, and increased levels of human DNA adducts have been found in association with occupational exposures. (See Sec. III.2.d.iv(1)) None of this evidence suggests that a lung cancer threshold exists for humans exposed to dpm, despite its importance in the rat model. Nor does this evidence suggest that lung overload is necessary for dpm to induce lung cancer in humans. Indeed, lung overload may be only one of many mechanisms through which lung cancer is produced in humans.

Results from the epidemiologic studies, the animal studies, and the genotoxicity studies are coherent and mutually supportive. After considering all these results, MSHA has concluded that the epidemiologic studies, supported by the experimental data establishing the plausibility of a causal connection, provide strong evidence that chronic occupational dpm exposure increases the risk of lung cancer in humans.

In a review, submitted by MARG, of MSHA's proposed risk assessment, Dr. Jonathan Borak asserted that MSHA's determination that results from the

[74] These studies (respectively: Johnston et al., 1997; Säverin et al., 1999; Steenland et al., 1998) are discussed in detail in Subsection 2.c.i(2)(a) of this risk assessment.

epidemiologic and toxicity studies were ''coherent and mutually reinforcing'' involved circular reasoning. He supported this assertion by incorrectly attributing to MSHA the view that ''most of the individual [epidemiologic] studies are not very good'' and that their suggestion of an association between dpm and lung cancer is ''made credible in light of the animal data.'' To complete his argument that MSHA relied on circular reasoning, Dr. Borak then suggested that the epidemiologic data provided MSHA's sole basis for considering the animal data relevant to humans. In a similar vein, Kennecott Minerals claimed there was an ''absence of toxicological support for epidemiologic findings that are themselves inconclusive.''

Contrary to Dr. Borak's assertion, MSHA has not characterized most of the epidemiologic studies as ''not very good.'' Nor has MSHA suggested that the epidemiologic evidence would not be credible or plausible in the absence of supporting animal data. As Dr. Borak correctly noted, MSHA acknowledged that ''none of the existing human studies is perfect'' and that ''no single one of the existing epidemiological studies, viewed in isolation, provides conclusive evidence of a causal connection * * *.'' That a study is not ''perfect,'' however, does not imply that it is ''not very good.'' MSHA's position has consistently been that, as demonstrated by the two available meta-analyses, the collective epidemiologic evidence is not merely credible but statistically significant and indicative of a causal association. Although MSHA views the toxicity data as supporting and reinforcing the epidemiologic evidence, MSHA believes that the collective epidemiologic evidence is highly credible in its own right.

Furthermore, MSHA does not consider the animal data relevant to humans simply because of the positive epidemiologic evidence. The animal evidence is also credible in its own right. As MSHA has repeatedly pointed out, dust concentrations in some mines have been measured at levels of the same order of magnitude as those found to have caused lung cancer in rats. Such high exposures, especially when combined with occupational exposures to respirable mineral dusts and exposures to particles in tobacco smoke, could overload the human lung and promote lung cancer by a mechanism similar to that hypothesized for rats. (Hattis and Silver, 1992, Figures 9, 10, 11). Also, many of the animal experiments have elucidated genotoxic effects that, while apparently not responsible for the excess lung cancers observed for rats, may be responsible for some or all of the excess risk reported for humans.

MSHA has not relied on circular reasoning. If either the animal data or the toxicity data had failed to show any link between dpm and effects implicated in the induction or promotion of lung cancer, then MSHA's conclusion would have been weakened. The existence of experimental evidence confirming that there is such a link is not imaginary and is logically independent of the epidemiologic evidence. Therefore, contrary to Dr. Borak's characterization, the ''coherency and reinforcement'' arising from the epidemiologic, animal, and genotoxicity data are not the product of circular reasoning. A more apt description is that the three sources of evidence, like three legs of a tripod, support the same conclusion.

Many commenters argued that a causal connection between dpm exposure and an increased human risk of lung cancer should not be inferred unless there is epidemiologic evidence showing a positive exposure-response relationship based on quantitative measures of cumulative dpm exposure. MSHA does not agree that a quantitative exposure-response relationship is essential in establishing causality. Such a relationship is only one of several factors, such as consistency and biological plausibility, that epidemiologists examine to provide evidence of causality. As mentioned earlier, however, there are three studies providing quantitative exposure-response relationships. One of these studies (Steenland et al., 1998) controlled for age, race, smoking, diet, and asbestos exposure, but relied on ''broad assumptions'' to estimate historical exposure levels from later measurements. Two of the studies, however, (Johnston et al., 1997, and Säverin et al., 1999) utilized measurements that were either contemporaneous with the exposures (Johnston) or that were made under conditions very similar to those under which the exposures took place (Säverin). Both of these studies were conducted on underground miners. The Säverin study used exposure measurements of total carbon (TC). All three of the studies combined exposure measurements for each job with detailed occupational histories to form estimates of cumulative dpm exposure; and all three reported evidence of increasing lung cancer risk with increasing cumulative exposure.

Several commenters, expressing and endorsing the views of Dr. Peter Valberg, incorrectly asserted that the epidemiologic results obtained across different occupational categories were inconsistent with a biologically plausible exposure-response relationship. For example, MARG argued that—

> It is biologically implausible that, if Dpm were (causally) increasing lung cancer risk by 50% for a low exposure (say, truck drivers), then the lung cancer risk produced by Dpm exposure in more heavily exposed worker populations (railroad shop workers) would fall in this same range of added risk. The added lung-cancer risk for bus garage workers is half that of either railroad workers or truck drivers, but Dpm concentrations are considerably higher. [MARG]

Earlier, MARG had argued to the contrary that, due to their lack of concurrent exposure measurements, these studies could not reliably be used for hazard identification. MARG then attempted to use them to perform the rather more difficult task of making quantitative comparisons of relative risk. If cumulative exposures are unknown, as MARG argued elsewhere, then there is little basis for comparing responses at different cumulative exposures.

In an analysis submitted by the West Virginia Coal Association, Dr. Valberg extended this argument to miners as follows:

> * * * If dpm concentrations for truck drivers is in the range of 5–50 μg/m^3, then we can assign the 0.49 excess risk (Bhatia's meta-analysis result) to the 5–50 μg/m^3 exposure. Hence, dpm concentrations for miners in the range of 100–2,000 μg/m^3 should have yielded excess risks forty times larger, meaning that the RR for exposed miners would be expected to be about 21 (i.e., 1 + 19.6), whereas reported risk estimates are less than 3 (range from 0.74 2.67). Such an utter lack of concordance argues against a causal role for dpm in the reported epidemiologic associations.

Based on a similar line of reasoning, IMC Global asserted that ''* * * the assumptions that MSHA used to develop [Figure III–4] * * * do not make sense in the context of a dose-response relationship between lung cancer and Dpm exposure.'' This was one of the reasons IMC Global gave for objecting to MSHA's comparison (in Section III.1.d) of exposure levels measured for miners to those reported for different occupations. IMC Global proposed that, as a consequence of this argument, MSHA should delete this comparison from its risk assessment.

MSHA sees three major flaws in Dr. Valberg's argument and rejects it for the following reasons:

(1) The argument glosses over the important distinction between exposure concentrations (intensity) and cumulative exposure (dose). Total

cumulative exposure is the product of intensity and duration of exposure. Depending on duration, high intensity exposure may result in similar (or even lower) cumulative exposure than low intensity exposure. Furthermore, different industries, in different nations, introduced diesel equipment at different times. The studies being considered were carried out in a variety of different countries and covered a variety of different historical periods. Therefore, the same number of years in different studies can correspond to very different durations of occupational exposure.

Many of the miners in the studies Dr. Valberg considered may have been occupationally exposed to dpm for relatively short periods of time or even not at all. Various forms of exposure misclassification would tend to obscure any exposure-response relationship across industries. Such obscuring would result from both exposure misclassification within individual studies and also variability in the degree of exposure misclassification in different industries.

Furthermore, the exposure levels or intensities assigned to the various occupations would not necessarily be proportional to cumulative exposures, even if the average number of years of exposure were the same. Different job conditions, such as longer-than-average work hours, could have major, variable impacts on cumulative exposures. For example, lower dpm concentrations have been measured for truck drivers than for other occupationally-exposed workers. However, the truck drivers studied, due to their work conditions may have been in their trucks for longer than the standard 40-hour work week and therefore have larger cumulative dpm exposures. Truck drivers commonly congregate in parking areas and sleep in their trucks with the engines idling, thereby disproportionately increasing their cumulative dpm exposures compared to miners and other types of workers.

(2) The commenters advancing this argument assumed that an exposure-response relationship spanning occupations at different levels of exposure intensity would take the form of a straight line. This assumption is unwarranted, since carcinogens do not necessarily follow such a simple pattern across a broad range of exposure levels. There is little basis for assuming that the relationship between cumulative dpm exposures and the relative risk of lung cancer would appear as a straight line when plotted against exposure levels that may differ by a factor of 100. Steenland et al. (1998) reported a better statistical ''fit'' to the data using a model based on the logarithm of cumulative exposure as compared to simple cumulative exposure. Even across the relatively limited range of exposures within the trucking industry, the logarithmic exposure model exhibits pronounced curvature towards the horizontal at the higher cumulative exposures (Steenland et al., 1998, Fig. 5). If this model is extrapolated out to the much higher exposures currently found in underground mining, then (as shown in Subsection 3.b.ii(3)(b) of this risk assessment) it diverges even more from a straight-line model. Toxicological evidence of curvature in the dose-response relationship has also been reported (Ichinose et al., 1997b, p.190).

Furthermore, the exposure-response pattern may depend on other aspects of exposure, besides how much is accumulated. For example, the National Research Council (NRC) has adopted a risk model for radon-induced lung cancer in which the relative risk (RR) at any age depends on both accumulated exposure and the rate (reflecting the intensity of exposure) at which total exposure was accumulated. In this model, which was derived empirically from the epidemiologic data, exposures accumulated over long time periods at relatively low rates result in a greater risk of lung cancer than the same total exposures accumulated over shorter time periods at relatively higher rates (NRC, 1999). A similar effect for dpm could cause apparent anomalies in the pattern of relative risks observed for occupations ranked simply with respect to the intensity of their average exposures.

(3) Mean exposures and relative risks reported for miners involved in the available studies were mischaracterized. Although dpm levels as high as 2000 μg/m^3 have been measured in some mines, the levels at most mines surveyed by MSHA were substantially lower (see Figures III–1 and III–2). The average levels MSHA measured at underground mines were 808 μg/m^3 and 644 μg/m^3 for M/NM and coal mines using diesel equipment for face haulage, respectively (Table III–1). However, these were not necessarily the levels experienced by miners involved in the available studies. The mean TC exposure concentration reported by Säverin et al. (1999), for work locations having the highest mean concentration, was 390 μg/m^3—corresponding to a mean dpm concentration of about 490 μg/m^3. In the only other study involving miners for which exposure measurements were available, Johnston et al. (1997) reported dpm concentrations for the most highly exposed category of workers (locomotive drivers), ranging from 44 μg/m^3 to 370 μg/m^3. Therefore, the mean dpm concentration experienced by the most highly exposed miners involved in these two studies was not ''forty times larger'' than the level imputed to truck drivers, but closer to seven times larger.[75] Applying Dr. Valberg's procedure, this yields an ''expected'' relative risk of about 4.4 for the underground miners who happened to work at mines included in these particular studies ($1 + 7 \times (0.49)$). Miners exposed at higher levels would, of course, face a greater risk.

Dr. Valberg asserted that the highest relative risk reported for miners was 2.67 (from Boffetta et al., 1988). Dr. Valberg failed to note, however, that the upper 95-percent confidence limit for miners' relative risk in this study was 4.37, so that this result hardly qualifies as an ''utter lack of concordance'' with the 4.4 ''expected'' value for miners. Furthermore, even higher relative risks for miners have been reported in other studies. Burns and Swanson (1991) reported 5.0 for operators of mining machinery, with an upper 95-percent confidence limit of 16.9. The relative risk estimated for the most highly exposed miners in the study by Johnston et al. (1997) was either 5.5 or 11.0, depending on the statistical model used. These results appear to be quite consistent with the data for truck drivers.

(5) Other Interpretations of the Evidence. After reviewing the same body of scientific evidence as MSHA, Dr. Peter Valberg came to a very different conclusion with respect to the likelihood of causality:

> Flawed methodology (lack of adequate control for smoking); values for relative risks (''RR'') that are low and often not statistically elevated above 1.0; inadequate treatment of sources of variability; reliance on multiple comparisons; and inadequate control over how authors choose to define dpm exposure surrogates (that is, job category within a profession, cumulative years of work, age at time of exposure, etc.), all undermine the assignment of causality to dpm exposure.

On the other hand, many scientific organizations and governmental agencies have reviewed the available epidemiologic and toxicological evidence for carcinogenicity and, in accordance with MSHA's conclusion, identified dpm as a probable human carcinogen—at levels far lower than those measured in some mines—or

[75] The estimate of seven times larger dpm exposure in miners is the result of averaging data from Säverin et al. (1999) with data from Johnston et al. (1997) and comparing the combined average miner exposure to the average truck driver dpm exposure.

placed it in a comparable category. These include:

Year

2000 National Toxicology Program (NTP);
1999 (tentative) U.S. Environmental Protection Agency (EPA);
1998 (tentative) (American Conference of Governmental Industrial Hygienists (ACGIH); Currently on Y2K NIC list. Probable vote in 10/2000;
1998 California Environmental Protection Agency (Cal–EPA);
1998 Federal Republic of Germany;
1996 International Programme on Chemical Safety (IPCS), a joint venture of the World Health Organization, the International Labour Organization, and the United Nations Environment Programme;
1989 International Agency for Research on Cancer (IARC);
1988 National Institute for Occupational Safety and Health (NIOSH)

Nevertheless, several commenters strongly objected to MSHA's conclusion, claiming that the evidence was obviously inadequate and citing scientific authorities who, they claimed, rejected MSHA's inference of a causal connection. In some cases, views were inaccurately attributed to these authorities, and misleading quotations were presented out of context. For example, the Nevada Mining Association stated that its own review of the scientific literature led to—

> * * * the only reasonable conclusion possible: there is no scientific consensus that there is a causal link between dpm exposure and lung cancer. The HEI [1999 Expert Panel] report concludes that the causal link between diesel exhaust and lung cancer remains unproven, and that further study and analysis are clearly required. [Nevada Mining Assoc.]

Although HEI (1999) recommended further study and analysis for purposes of quantitative risk assessment, the report contains no findings or conclusions about the ''causal link.'' To the contrary, the report explicitly states that the panel ''. . . was not charged to evaluate either the broad toxicologic or epidemiologic literature concerning exposure to diesel exhaust and lung cancer for hazard identification purposes, which has been done by others.'' (HEI, 1999, p. 1) Furthermore, the HEI panel ''. . . recognize[d] that regulatory decisions need to be made in spite of the limitations and uncertainties of the few studies with quantitative data currently available.'' (HEI, 1999, p. 20)

MARG, along with the Nevada Mining Association and several other commenters, mischaracterized the Expert Panel's findings as extending beyond the subject matter of the report. This report was limited to evaluating the suitability of the data compiled by Garshick et al. (1987, 1988) and Steenland et al. (1990, 1992, 1998) for quantitative risk assessment. Contrary to the characterization by these commenters, HEI's Expert Panel explicitly stated:

> [The Panel] was not charged to evaluate the broad toxicologic or epidemiologic literature for hazard identification purposes, which has been done by others. State, national, and international agencies have all reviewed the broader animal and human evidence for carcinogenicity and, in either their draft or final reports, have all identified diesel exhaust as [a] probable human carcinogen or placed it in a comparable category.'' [HEI, 1999, p. 1]

The Panel then identified most of the organizations and governmental institutions listed above (HEI, 1999, p. 8).

One commenter (MARG) also grossly misrepresented HEI (1999) as having stated that ''the available epidemiologic work has 'study design flaws, including uncontrolled, confounding and lack of exposure measures, leading to a lack of convincing evidence.' '' (MARG post-hearing comments) The opinion falsely attributed to HEI was taken from a sentence in which HEI's Diesel Epidemiology Expert Panel was describing opinions expressed in ''[s]ome reviews critical of these data.'' (HEI, 1999, p. 10) The Panel did not suggest that these opinions were shared by HEI or by any members of the Panel. In fact, the cited passage came at the end of a paragraph in which the Panel cited a larger number of other review articles that had ''discusse[d] this literature in depth'' and had expressed no such opinions. In the same paragraph, the Panel confirmed that ''[t]he epidemiologic studies generally show higher risks of lung cancer among persons occupationally exposed to diesel exhaust than among persons who have not been exposed, or who have been exposed to lower levels or for shorter periods of time.'' (HEI, 1999, p. 10)

Several commenters noted that the U.S. EPA's Clean Air Scientific Advisory Committee (CASAC) issued a report (CASAC, 1998) critical of the EPA's 1998 draft Health Assessment Document for Diesel Emissions (EPA, 1998) and rejecting some of its conclusions. After the HEI (1999) Expert Panel report was published, the EPA distributed a revised draft of its Health Assessment Document (EPA, 1999). In the 1999 draft, the EPA characterized human exposures to diesel exhaust as ''highly likely'' to be carcinogenic to humans at ambient (i.e., environmental) exposure levels. After reviewing this draft, CASAC endorsed a conclusion that, at ambient levels, diesel exhaust is likely to be carcinogenic to humans. Although CASAC voted to recommend that the designation in the EPA document be changed from ''highly likely'' to ''likely,'' this change was recommended specifically for ambient rather than occupational exposures. The CASAC report states that ''[a]lthough there was mixed opinion regarding the characterization of diesel emissions as 'highly likely' to be a human carcinogen, the majority of the Panel did not agree that there was sufficient confidence (i.e., evidence) to use the descriptor 'highly' in regard to environmental exposures.'' (CASAC, 2000, emphasis added)

MSHA recognizes that not everyone who has reviewed the literature on lung cancer and diesel exposure agrees about the collective weight of the evidence it presents or about its implications for regulatory decisions. IMC Global, for example, stated:

> After independently reviewing most [of the] * * * epidemiologic studies, the literature reviews and the two meta-analyzes, IMC Global believes * * * MSHA has misrepresented the epidemiologic evidence in the Proposed Rule. The best conclusion that we can reach based on our review of this information is that different reputable studies reach conflicting conclusions * * *. [IMC Global]

IMC Global continued by expressing concern that MSHA had ''dismissed'' opposing arguments critical of the positive studies, especially ''regarding lack of statistical significance; small magnitudes of relative risk * * *; and the impact of confounding factors, especially smoking * * * . [IMC Global]''

MSHA has addressed these three issues, as they relate to the evaluation of individual studies, in Section 2.c.i(2)(a) of this preamble. The argument that confounding factors such as smoking may have been systematically responsible for the positive results was discussed above, under the heading of ''Potential Systematic Biases.'' Statistical significance of the collective evidence is not the same thing as statistical significance of individual studies. Application of the sign test, as described Subsection 3.a.iii(1) above, is one way that MSHA has addressed statistical significance of the collective evidence. Another approach was also described above, under the heading of ''Meta-Analyses.''

IMC Global quoted Morgan et al. (1997) as concluding that ''[a]lthough

there have been a number of papers suggesting that diesel fumes may act as a carcinogen, the weight of the evidence is against this hypothesis.'' This conclusion was based largely on the authors' contention, shared by IMC Global, that the epidemiologic results were inconsistent and of insufficient strength (i.e., RR < 2.0) to rule out spurious associations due to potential confounders. MSHA, on the other hand, interprets the epidemiologic studies as remarkably consistent, given their various limitations, and has argued that the strength of evidence from individual studies is less important than the strength of evidence from all studies combined. Dr. Debra Silverman has referred to the ''striking consistency'' of this evidence. (Silverman, 1998)

Ironically, Morgan et al. point out many of the very limitations in individual studies that may actually explain why the studies do not yield entirely equivalent results. The 1997 Morgan article was written before the meta-analyses became available and resolved many, if not all, of the apparent inconsistencies in the epidemiologic results. Since none of the existing human studies is perfect and many contain important limitations, it is not surprising that reported results differ in magnitude and statistical significance. The meta-analyses described earlier showed that the more powerful and carefully designed studies tended to show greater degrees of association. MSHA has addressed the joint issues of consistency and strength of association above, under the heading of ''Consistency of Epidemiologic Evidence.''

The Engine Manufacturers Association (EMA) quoted Cox (1997) as concluding: ''* * * there is no demonstrated biological basis for expecting increased risk at low to moderate levels of [diesel] exposure.'' (Cox, 1997, as quoted by EMA] The EMA, however, prematurely terminated this quotation. The quoted sentence continues: ''* * * low to moderate levels of exposure (those that do not lead to lasting soot deposits, chronic irritation, and perhaps GSH enzyme depletion in the lung).'' MSHA does not regard concentrations of dpm exceeding 200 μg/m³ as ''low to moderate,'' and the EMA presented no evidence that the effects Dr. Cox listed do not occur at the high exposure levels observed at some mines. Salvi et al. (1999) reported marked inflammatory responses in the airways of healthy human volunteers after just one hour of exposure to dpm at a concentration of 300 μg/m³. The deleted caveat ending the quotation is especially important in a mining context, since mine atmospheres generally contain respirable mineral dusts that may diminish clearance rates and contribute to meeting thresholds for chronic irritation and inflammation leading to oxidative damage. Based on miners' testimony at the public hearings and workshops, there is, in fact, reason to believe that exposed miners experience lasting soot deposits and chronic irritation as a result of their exposures.

With respect to the epidemiologic evidence, the EMA quoted Dr. Cox as concluding: ''* * * among studies that demonstrate an increased relative risk, it appears plausible that uncontrolled biases in study design and data analysis methods can explain the statistical increases in relative risk without there being a true causal increase.'' (Cox, 1997, quoted by EMA) Dr. Cox refers to non-causal explanations for positive epidemiologic results as ''threats to causal inference.'' In considering Dr. Cox's discussion of the evidence, it is important to bear in mind that his purpose was ''* * * not to establish that any (or all) of these threats do explain away the apparent positive associations between [dpm] and lung cancer risk * * * but only to point out that they plausibly could * * *.'' (Cox, 1997, p. 813) Dr. Cox's stated intent was to identify non-causal characteristics of positive studies that could potentially ''explain away'' the positive results. This is a relatively simple exercise that could misleadingly be applied to even the strongest of epidemiologic studies. As stated earlier, no epidemiologic study is perfect, and it is always possible that unknown or uncontrolled risk factors may have given rise to a spurious association. Neither the EMA nor Dr. Cox pointed out however, that there are characteristics common to the negative studies that plausibly explain why they came out negative: insufficient latency allowance, nondifferential exposure misclassification, inappropriate comparison groups (including healthy worker effect, negative confounding by smoking or other variables. A similar approach could also be used to explain why many of the positive studies did not exhibit stronger associations. As observed by Dr. Silverman, ''an unidentified negative confounder may have produced bias across studies, systematically diluting RRs.''

b. Significance of the Risk of Material Impairment to Miners

The fact that there is substantial and persuasive evidence that dpm exposure can materially impair miner health in several ways does not imply that miners will necessarily suffer such impairments at a significant rate. This section will consider the significance of the risk faced by miners exposed to dpm.

i. Meaning of Significant Risk

(1) Legal Requirements

The benzene case, cited earlier in this risk assessment, provides the starting point for MSHA's analysis of this issue. Soon after its enactment in 1970, OSHA adopted a ''consensus'' standard for exposure to benzene, as authorized by the OSH Act. The standard set an average exposure limit of 10 parts per million over an 8-hour workday. The consensus standard had been established over time to deal with concerns about poisoning from this substance (448 U.S. 607, 617). Several years later, NIOSH recommended that OSHA alter the standard to take into account evidence suggesting that benzene was also a carcinogen. (*Id.* at 619 *et seq.*). Although the ''evidence in the administrative record of adverse effects of benzene exposure at 10 ppm is sketchy at best,'' OSHA was operating under a policy that there was no safe exposure level to a carcinogen. (*Id.,* at 631). Once the evidence was adequate to reach a conclusion that a substance was a carcinogen, the policy required the agency to set the limit at the lowest level feasible for the industry. (*Id.* at 613). Accordingly, the Agency proposed lowering the permissible exposure limit to 1 ppm.

The Supreme Court rejected this approach. Noting that the OSH Act requires ''safe or healthful employment,'' the court stated that—

> * * * 'safe' is not the equivalent of 'risk-free' * * * a workplace can hardly be considered 'unsafe' unless it threatens the workers with a significant risk of harm. Therefore, before he can promulgate any permanent health or safety standard, the Secretary is required to make a threshold finding that a place of employment is unsafe—in the sense that significant risks are present and can be eliminated or lessened by a change in practices. [Id., at 642, italics in original].

The court went on to explain that it is the Agency that determines how to make such a threshold finding:

> First, the requirement that a 'significant' risk be identified is not a mathematical straitjacket. It is the Agency's responsibility to determine, in the first instance, what it considered to be a 'significant' risk. Some risks are plainly acceptable and others are plainly unacceptable. If, for example, the odds are one in a billion that a person will die from cancer by taking a drink of chlorinated water, the risk clearly could not be considered significant. On the other hand, if the odds are one in a thousand that regular inhalation of gasoline vapors that are 2%

benzene will be fatal, a reasonable person might well consider the risk significant and take appropriate steps to decrease or eliminate it. Although the Agency has no duty to calculate the exact probability of harm, it does have an obligation to find that a significant risk is present before it can characterize a place of employment as 'unsafe.' [*Id.,* at 655].

The court noted that the Agency's ''* * * determination that a particular level of risk is 'significant' will be based largely on policy considerations.'' (Id., note 62).

Some commenters contended that the concept of significant risk, as enunciated by the Supreme Court in the Benzene case, requires support by a quantitative dose-response relationship. For example, one commenter argued as follows:

* * * OSHA had contended in * * * [the benzene] case that ''because of the lack of data concerning the linkage between low-level exposures and blood abnormalities, it was impossible to construct a dose-response curve at this time''. 448 U.S. at 632–633. The court rejected the Agency's attempt to support a standard based upon speculation that ''the benefits to be derived from lowering'' the permissible exposure level from 10 to 1 ppm were 'likely' to be 'appreciable'.'' 448 U.S. at 654.

One year after the Benzene case, the Court in American Textile Mfr's Inst. v. Donovan, 452 U.S. 490 (1981), upheld OSHA's ''cotton dust'' standard for which a dose-response curve had been established by the Agency. The Court relied upon the existence of such data to find that OSHA had complied with the Benzene mandate, stating: ''In making its assessment of significant risk, OSHA relied on dose-response curve data * * * It is difficult to imagine what else the agency could do to comply with this Court's decision in the Benzene case.'' Id. at 505, n. 25. See also Public Citizen Research Group v. Tyson, 796 F. 2d 1479, 1496, 1499 (D.C. Cir. 1986) (where a dose response curve was constructed for the ethylene oxide standard and the agency [had] gone to great lengths to calculate, within the bounds of available scientific data, the significance of the risk); United Steelworkers of America v. Marshall, 647 F. 2d 1189, 1248 (D.C. Cir. 1980), cert. denied , 453 U.S. 913 (1981) (where in promulgating a new lead standard ''OSHA amassed voluminous evidence of the specific harmful effects of lead at particular blood levels and correlated these blood lead levels with air lead levels''). [NMA]

A dose-response relationship has been established between exposure to $PM_{2.5}$ (of which dpm is a major constituent) and the risk of death from cardiovascular, cardiopulmonary, or respiratory causes (Schwartz et al.,1996; EPA, 1996). Furthermore, three different epidemiologic studies, including two carried out specifically on mine workers, have reported evidence of a quantitative relationship between dpm exposure and the risk of lung cancer (Johnston et al., 1997, Steenland et al., 1998, Säverin et al., 1999). However, the Secretary has carefully reviewed the legal references provided by the commenters and finds there is no requirement in the law that the determination of significant risk be based on such a relationship. The cited court rulings appear to describe sufficient means of establishing a significant risk, rather than necessary ones. Indeed, as stated earlier in this section, the Benzene court explained that:

* * * the requirement that a 'significant' risk be identified is not a mathematical straitjacket. It is the Agency's responsibility to determine, in the first instance, what it considered to be a 'significant' risk. * * * the Agency has no duty to calculate the exact probability of harm * * *.

The Agency has set forth the evidence and rationale behind its decision to propose a rule restricting miner exposure to dpm, obtained an independent peer review of its assessment of that evidence, published the evidence and tentative conclusions for public comment, held hearings, kept the record open for further comments for months after the hearings, and re-opened the record so that stakeholders could comment on the most recent evidence available. Throughout these proceedings, the Agency has carefully considered all public comments concerning the evidence of adverse health effects resulting from occupational dpm exposures. Based on that extensive record, and the considerations noted in this section, the Agency is authorized under the statute and relevant precedents to act on this matter—despite the fact that a more conclusive or definitively established exposure-response relationship might help address remaining doubts among some members of the mining community.

As the Supreme Court pointed out in the benzene case, the appropriate definition of significance also depends on policy considerations of the Agency involved. In the case of MSHA, those policy considerations include special attention to the history of extraordinary occupational risks leading to the Mine Act. That history is intertwined with the toll to the mining community of silicosis and coal workers' pneumoconiosis (CWP or ''black lung''), along with billions of dollars in Federal expenditures.

(2) Standards and Guidelines for Risk Assessment

Several commenters suggested that this risk assessment, as originally proposed, deviated from established risk assessment guidelines, because it did not provide a sufficiently quantitative basis for evaluating the significance of miners's risks due to their dpm exposures. One of these commenters (Dr. Jonathan Borak) maintained that a determination of significant risk based on a ''qualitative'' assessment ''has no statistical meaning.''

MSHA recognizes that a risk assessment should strive to provide as high a degree of quantification and certainty as is possible, given the best available scientific evidence. However, in order to best protect miners' health, it is not prudent to insist on a ''perfect'' risk assessment. Nor is it prudent to delay assessing potentially grave risks simply because the available data may be insufficient for an ideal risk assessment. The need for regulatory agencies to act in the face of uncertainty was recognized by the HEI's Diesel Epidemiology Expert Panel as follows: ''The Panel recognizes that regulatory decisions need to be made in spite of the limitations and uncertainties of the few studies with quantitative data currently available.'' (HEI, 1999) When there is good, qualitative evidence—such as the sight and smell of heavy smoke—that one's house is on fire, an inference of significant risk may be statistically meaningful even without quantitative measurements of the smoke's density and composition.

Moreover, as will be demonstrated below, the question of whether a quantitative assessment is or is not essential is, in this case, moot: this risk assessment does, in fact, provide a quantitative evaluation of how significant the risk is for miners occupationally exposed to dpm.

ii. Significance of Risk for Underground Miners Exposed to Dpm

An important measure of the significance of a risk is the likelihood that an adverse effect actually will occur. A key factor in the significance of risks that dpm presents to miners is the very high dpm concentrations to which a number of those miners are currently exposed—compared to ambient atmospheric levels in even the most polluted urban environments, and to workers in diesel-related occupations for which positive epidemiologic results have been reported. Figure III–4 compared the range of median dpm exposure levels measured for mine workers at various mines to the range of medians estimated for other occupations, as well as to ambient environmental levels. Figure III–11 presents a similar comparison, based on the highest mean dpm level observed at

any individual mine, the highest mean level reported for any occupational group other than mining, and the highest monthly mean concentration of dpm estimated for ambient air at any site in the Los Angeles basin.[76] As shown in Figure III–11, underground miners are currently exposed at mean levels up to 10 times higher than the highest mean exposure reported for other occupations, and up to 100 times higher than the highest mean environmental level even after adjusting the environmental level upwards to reflect an equivalent occupational exposure.

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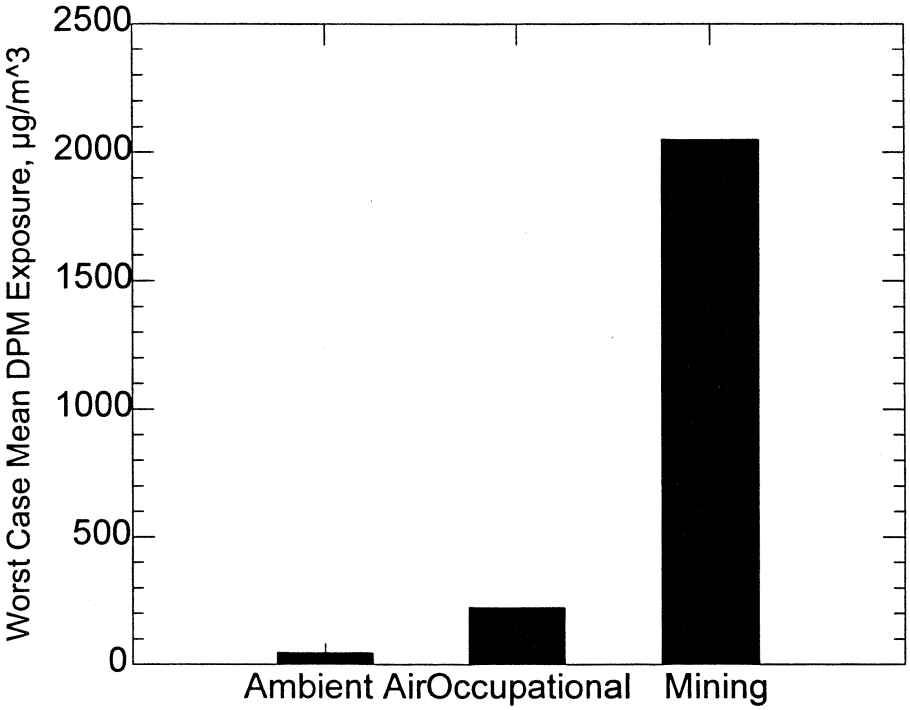

Figure III-11. — Worst case observed or reported mean diesel particulate exposure concentrations for urban ambient air, occupations other than mining, and mining. Worst case for mining is mean dpm measured within an underground mine. Worst case for occupations other than mining is mean respirable particulate matter, other than cigarette smoke, reported for railroad workers classified as hostlers (Woskie et al., 1988). Worst case for ambient air is mean estimated for peak months at most heavily polluted site in Los Angeles area (Cass and Gray, 1995), multiplied by 4.7 to adjust for comparability with occupational lifetime exposure levels. For additional information on means and ranges see Section III.1.d.

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Given the significant increases in mortality and other acute health effects associated with increments of 25 µg/m^3 in fine particulate concentration (see Table III–3), the relative risk of acute effects for some miners (especially those already suffering respiratory problems) appears to be extremely high. Acute responses to dpm exposures have been detected in studies of stevedores, whose exposures were likely to have been less than one tenth the exposure of some miners on the job. Likewise, the risk of lung cancer due to dpm exposure would appear to be far greater for those underground miners who are exposed at such high levels than for other workers or general urban populations.

Several commenters asserted that current dpm exposures in underground mines are lower than they were when MSHA conducted its field surveys and that MSHA had not taken this into account when assessing the significance of dpm risk to miners. A related comment was that MSHA had not designed its sampling studies to provide a statistically representative cross section of the entire industry but had nevertheless used the results in concluding that the risk to underground miners was significant.

In accordance with § 101.(a)(6) of the Mine Act, MSHA is basing this risk assessment on the best available evidence. None of the commenters provided evidence that dpm levels in underground coal mines had declined significantly since MSHA's field studies, or provided quantitative estimates of any purported decline in average dpm concentrations, or submitted data that would better represent the range of dpm concentrations to which underground miners are typically exposed at the present time. Although MSHA's field studies were not designed to be statistically representative in a way that

[76] For comparability with occupational lifetime exposure levels, the environmental ambient air concentration has been multiplied by a factor of approximately 4.7. This factor reflects a 45-year occupational lifetime with 240 working days per year, as opposed to a 70-year environmental lifetime with 365-days per year, and assumes that air inhaled during a work shift comprises half the total air inhaled during a 24-hour day.

can be readily quantified, they were performed at locations selected, according to MSHA's best engineering judgement, to be typical of the type of diesel equipment used. Furthermore, as will be shown below, MSHA's evaluation of the significance of risks presented to underground miners by their dpm exposures does not rely on the highest levels, or even the average levels, that MSHA has measured. As documented in Section 1.d of this risk assessment, some of the highest of MSHA's measurements were made as recently as 1996–1997. In 1996 MSHA published the diesel equipment safety rule that focused primarily on the safe storage, handling, and transport of diesel fuel underground, training of mine personnel, minimum ventilating air quantities for diesel powered equipment, monitoring of gaseous diesel exhaust emissions, maintenance requirements, incorporation of fire suppression systems, and design features for nonpermissible machines. In developing this diesel equipment safety rule for underground coal mines, however, MSHA did not explicitly consider the health risks to miners of a working lifetime of dpm exposure at very high levels, nor the actions that could be taken to specifically reduce dpm exposure levels. It was understood that the agency would be evaluating the health risks of dpm exposure at a later date. (61 FR 55420). With the implementation of the diesel safety rule in underground coal mines, MSHA believes that dpm concentrations may have declined, in the past two to three years. It is important to note, as is shown below, the cancer risks of dpm exposure are clearly significant even at a concentration of 300 μg/m³—less than half of the average level that MSHA observed in its field studies. However, MSHA also believes that a reduction in exposure of more than 50 percent is highly implausible, even with the safety standard implemented. It is also important to note that the diesel equipment rule applied only to underground coal mines and not underground metal/nonmetal mines.

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A number of other governmental and nongovernmental bodies have concluded that, even at the far lower levels evident in other occupational environments or in ambient air, the health risks of dpm exposure are of sufficient significance that exposure should be limited:

(1) In 1988, after a thorough review of the scientific literature, the National Institute for Occupational Safety and Health (NIOSH) recommended that diesel exhaust be controlled to the *lowest feasible exposure level*. The document did not contain a recommended exposure limit.

(2) In 1996, the Federal Republic of Germany classified dpm as "probably carcinogenic for humans" and established legally binding technical limits on dpm concentrations in occupational environments. The classification requires that the "best available technology" be used for emission reduction. The technical concentration limits, applying to all workplaces except coal mines, are the lowest limits thought to be feasible in Germany with current technology. Expressed as limits on elemental carbon (EC), they are: 300 μg/m³ for tunneling and non-coal mining; 100 μg/m³ for all other workplaces (except coal mines).

(3) An ad hoc committee of the Canada Centre for Mineral and Energy Technology (CANMET) has recommended that a limit of 500 μg/m³ RCD be adopted as a goal for underground mining environments.

(4) The International Programme on Chemical Safety (IPCS), which is a joint venture of the World Health Organization, the International Labour Organisation, and the United Nations Environment Programme, performed a comprehensive evaluation of the scientific evidence linking diesel exhaust with adverse health effects (IPCS, 1996). IPCS concluded that inhalation of diesel exhaust is of concern with respect to both neoplastic and non-neoplastic diseases and that the particulate phase appears to have the greatest effect on health. As a result of this evaluation, the IPCS recommended that "in the occupational environment, good work practices should be encouraged, and adequate ventilation must be provided to prevent excessive exposure."

(5) In light of the significant health risks associated with environmental exposures to fine particulates ($PM_{2.5}$), in 1997 the U.S. Environmental Protection Agency revised national air quality standards regulating PM to include $PM_{2.5}$ in the ambient air. Diesel particulate matter was a major constituent of $PM_{2.5}$ in many of the areas forming the basis of the EPA's health risk assessment. (EPA, 1996)

(6) In 1998, the California Environmental Protection Agency identified dpm as a toxic air contaminant, as defined in their Health and Safety Code, Section 39655. According to that section, a toxic air contaminant is an air pollutant which may cause or contribute to an increase in mortality or in serious illness, or which may pose a present or potential hazard to human health. This conclusion, unanimously adopted by the California Air Resources Board and its Scientific Review Panel on Toxic Air Contaminants, initiates a process of evaluating strategies for reducing dpm concentrations in California's ambient air.

(7) In 1999, the American Conference of Governmental Industrial Hygienists (ACGIH) proposed a Threshold Limit Value of 50 μg/m³ for the dpm component of diesel exhaust and placed dpm on its Notice of Intended Changes. This ACGIH proposal was based on a determination that occupational exposure levels exceeding 50 μg/m³ would present a significant "incremental" or excess risk of lung cancer.

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Earlier in this risk assessment, MSHA identified three types of material impairment that can result from occupational exposures to dpm. The next three subsections present the Agency's evaluation of how much of a risk there is that miners occupationally exposed to dpm will actually incur such consequences. Each part addresses the risk of incurring one of the three types of material impairment identified earlier.

(1) Sensory Irritations and Respiratory Symptoms (including allergenic responses)

It is evident from the direct testimony of numerous miners working near diesel equipment that their exposures pose a significant risk of severe sensory irritations and respiratory symptoms.

This was underscored during the workshops and public hearings by several miners who noted that such effects occurred immediately and consistently after episodes of intense exposure (Section 2.b.i). There is also persuasive experimental evidence that exposure at levels found in underground mines frequently cause eye and nose irritation (Rudell et al., 1996) and pulmonary inflammation (Salvi et al., 1999). Section 2.a.ii and 3.a.i of this risk assessment explain why these effects constitute ''material impairments'' under the Mine Act and why they threaten miners' safety as well as health. Therefore, it is clear that even short-term exposures to excessive concentrations of dpm pose significant risks.

MSHA's quantitative evaluation of how significant the risks of sensory irritations and respiratory symptoms are for miners is limited, by the quantitative evidence available, to acute respiratory symptoms linked to fine particulate exposures ($PM_{2.5}$) in ambient air pollution studies.MSHA recognizes that, for miners exposed to dpm, this type of risk cannot be quantified with great confidence or precision based on the available evidence. This is because $PM_{2.5}$ is not solely comprised of dpm and also because miners, as a group, have different demographic and health characteristics from the general populations involved in the relevant studies. However, MSHA believes that the quantitative evidence suffices to establish a lower bound on the significance of this type of risk to miners exposed to dpm. Even at this lower bound, which is likely to substantially underestimate the degree of risk, the probability that a miner's occupational exposure to dpm will cause adverse respiratory effects is clearly significant.

As shown in Table III–3, the risk of acute lower respiratory tract symptoms has been reported to increase, at a 95-percent confidence level, by 15 to 82 percent (RR = 1.15 to 1.82) for each incremental increase of 20 $\mu g/m^3$ in the concentration of $PM_{2.5}$ in the ambient air. This means that the relative risk estimated for a given $PM_{2.5}$ concentration ranges between $(1.15)^k$ and $(1.82)^k$, where k = the concentration of $PM_{2.5}$ divided by 20 $\mu g/m^3$. For example, for a $PM_{2.5}$ concentration of 40 $\mu g/m^3$, the RR is estimated to be between $(1.15)^2$ and $(1.82)^2$, or 1.32 to 3.31. MSHA believes that part of the reason why the range is so wide is that the composition of $PM_{2.5}$ varied in the data from which the estimates were derived.

MSHA acknowledges that there are substantial uncertainties involved in converting 24-hour environmental exposures to 8-hour occupational exposures. However, since mining often involves vigorous physical activity (thereby increasing breathing depth and frequency) and sleep is characterized by reduced respiration, it is highly likely that miners would inhale at least one-third of their total 24-hour intake of air during a standard 8-hour work shift. If it is assumed that the acute respiratory effects of inhaling dpm at a concentration of 60 $\mu g/m^3$ over an 8-hour workshift are at least as great as those at a concentration of 20 $\mu g/m^3$ over a 24-hour period, then it is possible to estimate a lower bound on the relative risk of such effects.

Based solely on the fact that dpm consists almost entirely of particles much smaller than 2.5 micrometers in diameter, the dpm would be expected to penetrate the lower respiratory tract at least as effectively as $PM_{2.5}$. Also, given the complex chemical composition of dpm, and its generation within a confined space, there is no reason to suspect that dpm in an underground mining environment is less potent than ambient $PM_{2.5}$ in inducing respiratory symptoms. Under these assumptions, a short-term environmental exposure to $PM_{2.5}$ at a concentration of 20 $\mu g/m^3$ would correspond to a short-term occupational exposure to dpm at a concentration of 60 $\mu g/m^3$. Consequently, the RR at an occupational exposure level of Y $\mu g/m^3$ would equal the RR calculated for an ambient exposure level of $20 \times (Y/60)$ $\mu g/m^3$. For example, the relative risk (RR) of acute lower respiratory symptoms at an occupational exposure level of 300 $\mu g/m^3$ dpm would, at a minimum, correspond to the RR at an ambient exposure level equal to 5×20 $\mu g/m^3$ $PM_{2.5}$. (See Table III–3) A dpm concentration of 300 $\mu g/m^3$ happens to be the level at which Salvi et al. (1999) found a marked pulmonary inflammatory response in healthy human volunteers after just one hour of exposure.

Under these assumptions, the risk of lower respiratory tract symptoms for a miner exposed to dpm for a full shift at a concentration of 300 $\mu g/m^3$ or more, would be at least twice the risk of ambient exposure (i.e., RR = $(1.15)^5$ = 2.01). This would imply that for miners exposed to dpm at or above this level, the risk of acute lower respiratory symptoms would double, at a minimum. The Secretary considers such an increase in risk to be clearly significant.

(2) Premature Death From Cardiovascular, Cardiopulmonary, or Respiratory Causes

As in the case of respiratory symptoms, the nature of the best available evidence limits MSHA's quantitative evaluation of how large an excess risk of premature death, due to causes other than lung cancer, there is for miners exposed to dpm. As before, this evidence consists of acute effects linked to fine particulate exposures ($PM_{2.5}$) in ambient air pollution studies. Therefore, the analysis is subject to similar uncertainties. However, also as before, MSHA believes that the quantitative evidence suffices to place a lower bound on the increase in risk of premature mortality for miners occupationally exposed to dpm. As will be shown below, even this lower bound, which is likely to substantially underestimate the degree of increase, indicates that a miner's occupational exposure to dpm has a clearly significant impact on the likelihood of premature death.

Schwartz et al. (1996) found an average increase of 1.5 percent in daily mortality associated with each increment of 10 $\mu g/m^3$ in the daily concentration of fine particulates. Higher increases were estimated specifically for ischemic heart disease (IHD: 2.1 percent), chronic obstructive pulmonary disease (COPD: 3.3 percent), and pneumonia (4.0 percent). The corresponding 95-percent confidence intervals for the three specific estimates were, respectively, 1.4% to 2.8%, 1.0% to 5.7%, and 1.8% to 6.2%, per increment of 10 $\mu g/m^3$ in daily $PM_{2.5}$ exposure. Within the range of dust concentrations studied, the response appeared to be linear, with no threshold. The investigators checked for but did not find any consistent or statistically stable relationship between increased mortality and the atmospheric concentration of ''coarse'' respirable particles—i.e., those with aerodynamic diameter greater than 2.5 micrometers but less than 10 micrometers.

As explained earlier, it is highly likely that miners would inhale at least one-third of their total 24-hour intake of air during a standard 8-hour work shift. Therefore, under the same assumptions made in the previous subsection, the 24-hour average concentrations of $PM_{2.5}$ measured by Schwartz et al. are no more potent, in their impact on mortality risk, than eight-hour average concentrations that are three times as high. As discussed in Section 2.a.iii of this risk assessment, underground miners may be less, equally, or more susceptible than the general population to the acute

mortality effects of fine particulates such as dpm. However, miners who smoke tobacco and/or suffer various respiratory ailments fall into groups identified as likely to be especially sensitive (EPA, 1996). Consequently, for such miners occupationally exposed to dpm, the relative risk of each type of premature mortality would be at least equal to the corresponding lower 95-percent confidence limit specified above.

Therefore, MSHA estimates that, on average, each increment of 30 μg/m^3 in the dpm concentration to which miners are exposed increases the risk of premature death due to IHD, COPD, and pneumonia by a factor of at least 1.4 percent, 1.0 percent, and 1.8 percent, respectively. A lower bound on the increased risk expected at an occupational dpm concentration greater than 30 μg/m^3, is obtained by raising the relative risks equivalent to these factors (i.e., 1.014, 1.01, and 1.018) to a power, k, equal to the ratio of the concentration to 30 μg/m^3. For a concentration of 300 μg/m^3, k = 10; so MSHA estimates the lower bounds on relative risk to be: $(1.014)^{10} = 1.149$ for IHD; $(1.01)^{10} = 1.105$ for COPD; and $(1.018)^{10} = 1.195$ for pneumonia. This means that for miners exposed to dpm at or above this level, MSHA expects the risks to increase by at least 14.9 percent for IHD, 10.5 percent for COPD, and 19.5 percent for pneumonia. The Secretary considers increases of this magnitude to be clearly significant, since the causes of death to which they apply are not rare among miners.

(3) Lung Cancer

In contrast to the two types of risk discussed above, the available epidemiologic data can be used to relate the risk of lung cancer directly to dpm exposures. Therefore, the significance of the lung cancer risk can be evaluated without having to make assumptions about the relative potency of dpm compared to the remaining constituents of $PM_{2.5}$. This removes an important source of uncertainty present in the other two evaluations.

There are two different ways in which the significance of the lung cancer risk may be evaluated. The first way is based on the relative risk of lung cancer observed in the best available epidemiologic studies involving miners (identified as such in Subsections 3.a.iii(1)(b) and (d) of this risk assessment). As will be explained below, this approach leads to an estimated tripling of lung cancer risk for miners exposed to dpm, compared to a baseline risk for unexposed miners. The second way is to calculate the lung cancer risk expected at exposure levels MSHA has observed in underground mines, assuming a specified occupational lifetime and using the exposure-response relationships estimated for underground miners by Johnston et al. (1997) and Säverin et al. (1999). As will be explained further below, this second approach yields a wide range of estimates, depending on which exposure-response relationship and statistical model is used. All of the estimates, however, show at least a doubling of baseline lung cancer risk, assuming dpm exposure for a 45-year occupational lifetime at the average concentration MSHA has observed. Most of the estimates are much higher than this. If the exposure-response relationship estimated for workers in the trucking industry by Steenland et al. (1998) is extrapolated to the much higher exposure levels for miners, the resulting estimates fall within the range established by the two mine-specific studies, thereby providing a degree of corroboration. Since lung cancer is not a rare disease, the Secretary considers even the very lowest estimate—a doubling of baseline risk—to represent a clearly significant risk.

Both of these methods provide quantitative estimates of the degree by which miners' risk of lung cancer is increased by their occupational dpm exposures. The estimate based on exposure-response relationships is more refined, in that it ties the increased risk of lung cancer to specific levels of cumulative dpm exposure. However, this added refinement comes at the price of an additional source of uncertainty: the accuracy of the exposure-response relationship used to calculate the estimate. This additional uncertainty is reflected, in MSHA's evaluation, by a broad range of relative risk estimates, corresponding to the range of exposure-response relationships derived using different statistical models and epidemiologic data. The next two subsections present the details of MSHA's two approaches to analyzing lung cancer risk for miners exposed to dpm, along with MSHA's responses to the relevant public comments.

(a) Risk Assessment Based on Studies Involving Miners

As one commenter pointed out, the epidemiologic evidence showing an elevated risk of lung cancer for exposed workers is mostly based on occupations estimated to experience far lower exposure levels, on average, than those observed in many underground mines:

> * * * [U]nderground coal, metal and non-metal miners face a significant risk of lung cancer from occupational exposure to diesel particulate. Numerous epidemiologic studies of workers exposed to levels far below those experienced by coal, metal and non-metal miners have found the risk for exposed workers to be 30–50% greater than for unexposed workers. [Washington State Dept. of Labor and Industries]

Indeed, although MSHA recognizes that results from animal studies should be extrapolated to humans with caution, it is noteworthy that dpm exposure levels recorded in some underground mines (see Figures III–1 and III–2) have been well within the exposure range that produced tumors in rats (Nauss et al., 1995).

Both existing meta-analyses of the human studies relating dpm exposure and lung cancer excluded studies on miners but presented evidence showing that, averaged across all other occupations, dpm exposure is responsible for an increase of about 40 percent in lung cancer risk (See Section 3.a.iii(2) of this risk assessment). Even a 40-percent increase in the risk of lung cancer would clearly be significant, since this would amount to more than two cases of lung cancer per year per thousand miners at risk, and to an even greater risk for smoking miners. The best available evidence, however, indicates (1) that exposure levels in underground mines generally exceed exposures for occupations included in the meta-analyses and (2) that lung cancer risks for exposed miners are elevated to a greater extent than for other occupations.

As Dr. Valberg and other commenters pointed out, the epidemiologic studies used in the meta-analyses involved much lower exposure levels than those depicted for mines in Figures III–1 and III–2. The studies supporting a 40-percent excess risk of lung cancer were conducted on populations whose average exposure is estimated to be less than 200 μg/m^3—less than one tenth the average concentration MSHA observed in some underground mines. More specifically, average exposure levels in the two most extensively studied industries—trucking (including loading dock workers) and railroads—have been reported to be far below the levels observed in underground mining environments. For workers at docks employing diesel forklifts—the occupational group estimated to be most highly exposed within the trucking industry—the highest average dpm concentration reported was about 55 μg/m^3 EC at an individual dock (NIOSH, 1990). As explained in Subsection 1.d of this risk assessment, this corresponds to

less than 150 μg/m³ of dpm, on average. Published dpm measurements for railworkers have generally also been less than 150 μg/m³ (measured as respirable particulate matter other than cigarette smoke). The reported mean of 224 μg/m³ for hostlers displayed in Figure III–11 represents only the worst-case occupational subgroup (Woskie et al., 1988). In contrast, in the study on underground potash miners by Säverin et al. (1999), the mean TC concentration measured for production areas was 390 μg/m³—corresponding to a mean dpm concentration of about 490 μg/m³. As shown in Table III–1, the mean dpm exposure level MSHA observed in underground production areas and haulageways was 644 μg/m³ for coal mines and 808 μg/m³ for M/NM.

In accordance with the higher exposure levels for underground miners, the five studies identified in Section III.3.a.iii(1)(d) as comprising the best available epidemiologic evidence on miners all show that the risk of lung cancer increased for occupationally exposed miners by substantially more than 40 percent. The following table presents the relative risk (RR) of lung cancer for miners in these studies, along with the geometric mean based on all five studies:

Study	Relative risk of lung cancer
Boffetta et al., 1988	2.67
Burns & Swanson, 1991	5.03
Johnston et al., 1997 (mine-adjusted model applied at highest cumulative exposure)	5.50
Lerchen et al., 1987	2.1
Säverin et al., 1999 (highest vs least exposed)	2.17
Geometric mean	3.2

As shown in this table, the estimated RR based on these five studies is 3.2 for miners exposed to dpm. In other words, the risk of lung cancer for the highly exposed miners is estimated to be 3.2 times that of a comparable group of occupationally unexposed workers. The geometric mean RR remains 3.2 if the two studies on which MSHA places less weight (by Burns & Swanson and by Lerchen) are excluded from the calculation. This represents a 220-percent increase in the risk of lung cancer for exposed miners, in contrast to the 40-percent increase estimated, on average, for other occupationally exposed workers. The Secretary believes that a 40-percent increase in the risk of lung cancer already exceeds, by a wide margin, the threshold for a clearly significant risk. However, a 220-percent increase to more than three times the baseline rate is obviously of even greater concern.

Some commenters questioned whether increased lung cancer risks of this magnitude were plausible, since they were not aware of any unusually high lung cancer rates among workers at mines with which they were familiar and which used diesel equipment. There are several reasons why an elevated risk of lung cancer might not currently be conspicuous among U.S. miners exposed to dpm. Lung cancer not only may require a latency period of 30 or more years to develop, but it may also not develop until beyond the normal retirement age of 65 years. Cases of lung cancer developing after retirement may not all be known to members of the mining community. Also, in a population that includes many tobacco smokers, it may be difficult to discern cases of lung cancer specifically attributable to dpm exposure when they first begin to become prevalent. Two commenters expressed some of the relevant considerations as follows. Although they were referring to coal miners, the same points apply to M/NM miners.

> Because the latency period for lung cancer is so long, and diesel-powered equipment has only been used extensively in U.S. coal mines for about 25 years, the epidemic may well be progressing unnoticed. [UMWA]

> If Dpm exposure will cause cancer, there is a huge population of miners here in the West that have already been exposed. Considering the latency periods indicated by MSHA, these miners should be beginning to develop cancers. [Canyon Fuels]

(b) Risk Assessment Based on Miners' Cumulative Exposure

Although it is evident that underground miners currently face a significant risk of lung cancer due to their occupational exposure to dpm, there are certain advantages in utilizing an exposure-response relationship to quantify the degree of risk at specific levels of cumulative exposure. As some commenters pointed out, for example, dpm exposure levels may change over time due to changes in diesel fuel and engine design. The extent and patterns of diesel equipment usage within mines also has changed significantly during the past 25 years, and this has affected dpm exposure levels as well. Furthermore, exposure levels at the mines involved in epidemiologic studies were not necessarily typical or representative of exposure levels at mines in general. A quantitative exposure-response relationship provides an estimate of the risk at any specified level of cumulative exposure. Therefore, using such a relationship to assess risk under current or anticipated conditions factors in whatever differences in exposure levels may be relevant, including those due to historical changes.

(i) Exposure-Response Relationships from Studies Outside Mining

Stayner et al. (1998) summarized quantitative risk assessments based on exposure-response relationships for dpm published through 1998. These assessments were broadly divided into those based on human studies and those based on animal studies. Depending on the particular studies, assumptions, statistical models, and methods of assessment used, estimates of the exact degree of risk varied widely even within each broad category. However, as presented in Tables III and IV of Stayner et al. (1998), all of the very different approaches and methods published through 1998 produced results indicating that levels of dpm exposure measured at some underground mines present an unacceptably high risk of lung cancer for miners—a risk significantly greater than the risk they would experience without the dpm exposure.[77]

Quantitative risk estimates based on the human studies were generally higher than those based on analyses of the rat inhalation studies. As indicated by Tables 3 and 4 of Stayner et al. (1998), a working lifetime of exposure to dpm at 500 μg/m³ yielded estimates of excess lung cancer risk ranging from about 1 to 200 excess cases of lung cancer per thousand workers based on the rat inhalation studies and from about 50 to 800 per thousand based on the epidemiologic assessments. Stayner et al. (1998) concluded their report by stating:

> The risk estimates derived from these different models vary by approximately three orders of magnitude, and there are substantial uncertainties surrounding each of

[77] In comments submitted by MARG, Dr. Jonathan Borak asserted that MSHA had ''misrepresented the findings of a critical study'' by stating that all methods showed an ''unacceptably high risk'' at exposure levels found at some mines. Dr. Borak claimed that Stayner et al. (1998) had described an analysis by Crump et al. ''that reached an opposite conclusion.'' Dr. Borak failed to distinguish between a finding of high risk and a finding of changes in that risk corresponding to changes in estimated exposures. The findings to which Dr. Borak referred pertained only to the exposure-response relationship within the group of exposed workers. Garshick (1981), Crump (1999), and HEI (1999) all noted that the risk of lung cancer was nevertheless elevated among the exposed workers, compared to unexposed workers in the same cohort, and they all identified reasons why the data used in this study might fail to detect a positive exposure-response relationship among the exposed workers.

these approaches. Nonetheless, the results from applying these methods are consistent in predicting relatively large risks of lung cancer for miners who have long-term exposures to high concentrations of DEP [i.e., dpm]. This is not surprising given the fact that miners may be exposed to DEP [dpm] concentrations that are similar to those that induced lung cancer in rats and mice, and substantially higher than the exposure concentrations in the positive epidemiologic studies of other worker populations.

Restricting attention to the exposure-response relationships derived from human data, Table IV of Stayner et al. (1998) presented estimates of excess lung cancer risk based on exposure-response relationships derived from four different studies: Waller (1981) as analyzed by Harris (1983); Garshick et al. (1987) as analyzed by Smith and Stayner (1991); Garshick et al. (1988) as analyzed by California EPA (1998); and Steenland et al. (1998). Harris (1983) represented upper bounds on risk; and all of the other estimates represented the most likely value for risk, given the particular data and statistical modeling assumptions on which the estimate was based. Three different ranges of estimates were presented from the California EPA analysis, corresponding to various statistical models and assumptions about historical changes in dpm exposure among the railroad workers involved. As mentioned above and in the proposed version of this risk assessment, the low end of the range of estimates was 50 lung cancers per 1000 workers occupationally exposed at 500 $\mu g/m^3$ for a 45-year working lifetime. This estimate was one of those based on railroad worker data from Garshick et al. (1988).

Several commenters objected to MSHA's reliance on any of the exposure-response relationships derived from the data compiled by Garshick et al. (1987) or Garshick et al. (1988). These objections were based on re-analyses of these data by Crump (1999) and HEI (1999), using different statistical methods and assumptions from those used by Cal-EPA (1998). For example, the NMA quoted HEI (1999) as concluding:

At present, the railroad worker cohort study * * * has very limited utility for QRA [quantitative risk assessment] of lifetime lung cancer risk from exposure to ambient levels of diesel exhaust * * * [NMA, quoting HEI (1999)]

From this, the NMA argued as follows:

What then is the relevance of this data to the proceedings at issue? Simply put, there is no relevance. The leading epidemiologist [sic], including Dr. Garshick himself, now agree that the data are inappropriate for conducting risk assessment. [NMA]

MSHA notes that the HEI (1999) conclusion cited by the NMA referred to quantitative risk assessments at ambient, not occupational, exposure levels. Also, HEI (1999) did not apply its approach (i.e., investigating the correlation between exposure and relative risk within separate job categories) to the Armitage-Doll model employed by Cal-EPA in some of its analyses. (Results using this model were among those summarized in Table IV of Stayner et al., 1998). Therefore, the statistical findings on which HEI (1999) based its conclusion do not apply to exposure-response relationships estimated using the Armitage-Doll model. Furthermore, although HEI concluded that the railroad worker data have ''very limited utility for QRA * * * at ambient levels'' [emphasis added], this does not mean, even if true, that these data have ''no relevance'' to this risk assessment, as the NMA asserted. Even if they do not reliably establish an exposure-response relationship suitable for use in a quantitative risk assessment, these data still show that the risk of lung cancer was significantly elevated among exposed workers. This is the only way in which MSHA is now using these data in this risk assessment.

In the proposed risk assessment, MSHA did not rely directly on the railroad worker data but did refer to the lowest published quantitative estimate of risk, which happened, as of 1998, to be based on those data. MSHA's reasoning was that, even based on the lowest published estimate, the excess risk of lung cancer attributable to dpm exposure was clearly sufficient to warrant regulation. If risk assessments derived from the railroad worker data are eliminated from consideration, the lowest estimate remaining in Table IV of Stayner et al. (1998) is obviously even higher than the one that MSHA used to make this determination in the proposed risk assessment. This estimate (based on one of the analyses performed by Steenland et al., 1998) is 89 excess cases of lung cancer per year per thousand workers exposed at 500 $\mu g/m^3$ for a 45-year working lifetime.

HEI (1999) also evaluated the use of the Steenland data for quantitative risk assessment, but did not perform any independent statistical analysis of the data compiled in that study. Some commenters pointed out HEI's reiteration of the cautionary remark by Steenland et al. (1998) that their exposure assessment depended on ''broad assumptions.'' The HEI report did not rule out the use of these data for quantitative risk assessment but suggested that additional statistical analyses and evaluations were desirable, along with further development of exposure estimates using alternative assumptions. MSHA has addressed comments on various aspects of the analysis by Steenland et al., including the exposure assumptions, in Section 2.c.i(2)(a) of this risk assessment.

One commenter noted that Steenland et al. (1998) had recognized the limitations of their analysis and had, therefore, advised that the results ''should be viewed as exploratory.'' The commenter then asserted that MSHA had nevertheless used these results as ''the basis for a major regulatory standard'' and that ''[t]his alone is sufficient to demonstrate that MSHA's proposal lacks the necessary scientific support.'' [Kennecott Minerals]

The Secretary does not accept the premise that MSHA should exclude ''exploratory'' results from its risk assessment, even if it is granted that those results depend on broad assumptions possibly requiring further research and validation before they are widely accepted by the scientific community. Steenland et al. (1998) estimated risks associated with specific cumulative exposures, based on estimates of historical exposure patterns combined with data originally described by Steenland et al., 1990 and 1992. Regardless of whether the cumulative exposure estimates used by Steenland et al. (1998) are sufficiently reliable to permit pinpointing the risk of lung cancer at any given exposure level, the quantitative analysis indicates that as cumulative exposure increases, so does the risk. Therefore, the 1998 analysis adds significantly to the weight of evidence supporting a causal relationship. However, MSHA did not use or propose to use exposure-response estimates derived by Steenland et al. (1998) as the sole basis for any regulatory standard.

The exposure-response relationships presented by Steenland et al. were derived from exposures estimated to be far below those found in underground mines. As Stayner et al. (1998) point out, questions are introduced by extrapolating an exposure-response relationship beyond the exposures used to determine the relationship. The uncertainties implicit in such extrapolation are demonstrated by comparing results from two statistical models based on five-year lagged exposures—one using simple cumulative exposure and the other using the natural logarithm of cumulative exposure (Steenland et al., 1998, Table II).

Assuming that, on average, EC comprises 40 percent of total dpm,[78] the formula for calculating a relative risk (RR) using Steenland's simple cumulative exposure model is

$$RR = \exp(0.4 \times 0.389 \times CumExp),$$

where CumExp is occupationally accumulated dpm exposure (expressed in mg-yr/m^3), ignoring the most recent five years. Again assuming EC=0.4×dpm, the corresponding formula using Steenland's Log(CumExp) model is

$$RR = \exp(0.1803 \times (\mathrm{Log}(0.4 \times 1000 \times CumExp + BG) - \mathrm{Log}(BG))),$$

still ignoring occupational dpm exposure in the most recent five years.[79]

The risk estimates from these two models are similar at the cumulative exposure levels estimated for workers involved in the study, but the projected risks diverge markedly at the higher exposures projected for underground miners exposed to dpm for a 45-year occupational lifetime. For example, a cumulative dpm exposure of 2.5 mg-yr/m^3 (i.e., 45 years of occupational exposure at an average dpm concentration of about 55.6 μg/m^3) is within the range of cumulative exposures from which these exposure-response relationships were estimated. At this level of cumulative exposure, the models (both lagged five years) yield relative risk estimates of 1.48 (based on simple cumulative exposure) and 1.64 (based on the logarithm of cumulative exposure, with BG=70 μg-yr/m^3). On the other hand, 45 years of occupational exposure at an average dpm concentration of 808 μg/m^3 amounts to a cumulative dpm exposure of 36,360 μg-yr/m^3, or about 36.4 mg-yr/m^3. At this level, which lies well beyond the range of data used by Steenland et al. (1998), the simple and logarithmic exposure models produce relative risk estimates of about 300 and 2.6, respectively.

Despite the divergence of these two models at high levels of cumulative exposure, they can provide a useful check of excess lung cancer risks estimated using exposure-response relationships developed from other studies. For highly exposed miners, the Steenland models both produce estimates of lung cancer risk within the range established by the two miner studies discussed below. This corroborates the upper and lower limits on such risk as estimated by the various statistical models used in those two studies.

(ii) Exposure-Response Relationships From Studies on Miners

As described in Section 2.c.i(2)(a) of this risk assessment, two epidemiologic studies, both conducted on underground miners, provide exposure-response relationships based on fully quantitative dpm exposure assessments. Johnston et al. (1997) conducted their study on a cohort of 18,166 underground coal miners, and Säverin et al. (1999) conducted theirs on a cohort of 5,536 underground potash miners. Each of these studies developed a number of possible exposure-response relationships, depending on the statistical model used for analysis and, in the case of Säverin et al. (1999), inclusion criteria for the cohort analyzed. For purposes of this risk assessment, MSHA has converted the units of cumulative exposure in all of these exposure-response relationships to mg-yr/m^3.

Two exposure-response relationships derived by Johnston et al. (1997) are used in this risk assessment, based on a ''mine-adjusted'' and a ''mine-unadjusted'' statistical model. In both of these models, cumulative dpm exposure is lagged by 15 years.[80] This reflects the long latency period required for development of lung cancer and means that the most recent 15 years of exposure are ignored when the relative risk of lung cancer is estimated. The exposure-response relationships, as reported by the investigators, were expressed in terms of g-hr/m^3 of cumulative dpm exposure. MSHA has converted the exposure units to mg-yr/m^3 by assuming 1920 work hours per year.

Two different methods of statistical analysis were applied by Säverin et al. (1999) to both the full cohort and to a subcohort of 3,258 miners who had worked underground, in relatively stable jobs, for at least ten years. Thus, the investigators developed a total of four possible exposure-response relationships from this study. Since they were based on measurements of total carbon (TC), these exposure-response relationships were expressed in terms mg-yr/m^3 of cumulative TC exposure. MSHA has converted the exposure units to mg-yr/m^3 of cumulative dpm exposure by assuming that, on average, TC comprises 80 percent of total dpm.

The following table summarizes the exposure-response relationships obtained from these two studies. Each of the quantitative relationships is specified by the unit relative risk (RR) per mg-yr/m^3 of cumulative dpm exposure. To calculate the relative risk estimated for a given cumulative dpm exposure (CE), it is necessary to raise the unit RR to a power equal to CE. For example, if the unit RR is 1.11 and CE = 20, then the estimated relative risk is $(1.11)^{20} = 8.1$. Therefore, the estimated relative risk of lung cancer increases as CE increases. For the two Johnston models, CE does not include exposure accumulated during the 15 years immediately prior to the time in a miner's life at which the relative risk is calculated.

EXPOSURE-RESPONSE RELATIONSHIPS OBTAINED FROM TWO STUDIES ON UNDERGROUND MINERS

Study and statistical model	Unit RR per mg-yr/m^3 dpm
Säverin et al. (1999):†	
Poisson, full cohort	1.024
Cox, full cohort	1.089
Poisson, subcohort	1.110
Cox, subcohort	1.176
Johnston et al. (1997):‡	
15-year lag, mine-adjusted	1.321
15-year lag, mine-unadjusted	1.479

† Unit RR calculated from Tables III and IV, assuming TC = 0.8×dpm.

‡ Unit RR calculated from Table 11.2, assuming 1920 work hours per year.

For example, suppose a miner is occupationally exposed to dpm at an average level of 500 μg/m^3. Then each year of occupational exposure would contribute 0.5 mg-yr/m^3 to the miner's cumulative dpm exposure. Suppose also that this miner's occupational exposure

[78] The assumption is that, on average, EC = TC/2 and TC = 0.8×dpm.

[79] BG, expressed in μg-yr/m^3, accounts for an assumed background (i.e., non-occupational) EC exposure level of 1.0 μg/m^3. At age 70, after a 45-year worklife and an additional 5-year lag after retirement, BG is assumed to equal 70 μg-yr/m^3. ''Log'' refers to the natural logarithm, and ''exp'' refers to the antilogarithm of the subsequent quantity.

[80] The 15-year lagged mine-unadjusted and mine-adjusted models are respectively denoted by M/03 and M/06 in Table 11.2 of Johnston et al. (1997). As explained earlier, the individual mines considered in this study differed significantly with respect to both dpm exposures and lung cancer experience. The investigators could not determine exactly how much, if any, of the increased lung cancer risk associated with dpm exposure depends on other, unknown factors differentiating the individual mines. The mine-adjusted model allocates a significant number of the lung cancers otherwise attributable to dpm exposure to the ''norm'' for specific mines. Therefore, if the differences in lung cancer prevalence between mines is actually due to corresponding differences in mean dpm exposure, then this model will mask a significant portion of the risk due to dpm exposure. After adjusting for miners' age and smoking habits, the mine-unadjusted model attributes differences in the prevalence of lung cancer between mines to corresponding differences in mean dpm exposure. However, the mine-adjusted model has the advantage of taking into account differences between mines with respect to potentially confounding factors, such as radon progeny and silica levels.

begins at age 45 and continues for 20 years until retirement at age 65. Consequently, at or above age 65, this hypothetical miner would have accumulated a total of 10 mg-yr/m^3 of occupational dpm exposure. According to the Säverin-Cox-subcohort model, the relative risk estimated for this miner after retirement is RR = $(1.176)^{10}$ = 5.1. This means that, at or above age 65, the retired miner's risk of lung cancer is estimated (by this model) to be about five times that of another retired miner having the same age and smoking history but no occupational dpm exposure.

Since the two Johnston models exclude exposure within the last 15 years, it is instructive to calculate the relative risk using these models for the same hypothetical retiree at age 75. Since this miner retired at age 65, immediately after 20 years of occupational exposure, the cumulative exposure used in applying the Johnston models must be reduced by the 2.5 mg-yr/m^3 accumulated from age 60 to age 65. Therefore, according to the Johnston mine-adjusted model, the relative risk estimated for this retired miner at age 75 is RR = $(1.321)^{7.5}$ = 8.1. At age 80 or above, however, this model predicts that the relative risk would increase to RR = $(1.321)^{10}$ = 16.2.

The six exposure-response relationships obtained from these two studies establish a range of quantitative risk estimates corresponding to a given level of cumulative dpm exposure. This range provides lower and upper limits on the risk of lung cancer for workers exposed at the given level, relative to similar workers who were not occupationally exposed. The lower limit of this range is established by Säverin's full cohort Poisson model. Therefore, the lowest estimate of relative risk after 45 years of occupational dpm exposure is RR = $(1.024)^{45 \times 0.644}$ = 2.0 at a mean concentration of 644 μg/m^3 or RR = $(1.024)^{45 \times 0.808}$ = 2.4 at mean concentration of 808 μg/m^3. These exposure levels correspond to the averages presented in Table III–1 for underground coal and underground M/NM mines, respectively.

A relative risk of 2.0 amounts to a doubling of the baseline lung cancer risk, and all of the models project relative risks of at least 2.0 after 45 years of exposure at these levels. Therefore, MSHA expects that underground miners exposed to dpm at these levels for a full 45-year occupational lifetime would, at a minimum, experience lung cancer at a rate twice that of unexposed but otherwise similar miners. Five of the six statistical models, however, predict a relative risk much greater than 2.0 after 45 years at a mean dpm concentration of 644 μg/m^3. The second-lowest estimate of relative risk, for example, is RR = $(1.089)^{45 \times 0.644}$ = 11.8, predicted by Säverin's full cohort Cox model.[81]

In the next subsection of this risk assessment, relative risks will be combined with baseline lung cancer and mortality data to estimate the lifetime probability of dying from lung cancer due to occupational dpm exposure.

(iii) Excess Risk at Specific Dpm Exposure Levels

The ''excess risk'' discussed in this subsection refers to the lifetime probability of dying from lung cancer resulting from occupational exposure to dpm for 45 years. This probability is expressed as the expected excess number of lung cancer deaths per thousand miners occupationally exposed to dpm at a specified level. The excess is calculated relative to baseline, age-specific lung cancer mortality rates taken from standard mortality tables. In order to properly estimate this excess, it is necessary to calculate, at each year of life after occupational exposure begins, the expected number of persons surviving to that age with and without dpm exposure at the specified level. At each age, standard actuarial adjustments must be made in the number of survivors to account for the risk of dying from causes other than lung cancer.

Table III–7 shows the excess risk of death from lung cancer estimated across the range of exposure-response relationships obtained from Säverin et al. (1999) and Johnston et al. (1997). Estimates based on the 5-year lagged models from Steenland et al. (1998) fall within this range and are included for comparison. Based on each of the eight statistical models, the excess risk was estimated at four levels of dpm exposure: 200 μg/m^3, 500 μg/m^3, 644 μg/m^3 (the mean dpm concentration observed by MSHA at underground coal mines, as shown in Table III–1), and 808 μg/m^3 (the mean dpm concentration observed by MSHA at underground M/NM mines, as shown in Table III–1).

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[81] Some commenters contended that MSHA cannot establish a reliable exposure-response relationship because of potential interferences in MSHA's dpm concentration measurements. More specifically, some of these commenters claimed that MSHA's dpm measurements in underground coal mines were significantly inflated by submicrometer coal dust.

As explained in Subsection 1.a of this risk assessment, the sampling device MSHA used to measure dpm in underground coal mines was designed specifically to allow for the submicrometer fraction of coal dust. Both the size-selective and RCD methods are reasonably accurate when dpm concentrations exceed 300 μg/m^3. Moreover, neither of these methods was used to establish the exposure-response relationships presented by Säverin et al. (1999) or Johnston et al. (1997).

Table III-7. — Lifetime excess risk of lung cancer mortality at specific Dpm exposure levels.

Study and Statistical Model	Excess Lung Cancer Deaths per 1000 Occupationally Exposed Workers†			
	200 μg/m³	500 μg/m³	644 μg/m³	808 μg/m³
Säverin et al. (1999)				
Poisson, full cohort	15	44	61	83
Cox, full cohort	70	280	422	577
Poisson, subcohort	93	391	563	693
Cox, subcohort	182	677	761	802
Steenland et al. (1998)				
5-year lag, log of cumulative exposure	67	89	95	101
5-year lag, simple cumulative exposure	159	620	721	771
Johnston et al. (1997)				
15-year lag, mine-adjusted	313	724	770	800
15-year lag, mine-unadjusted	513	783	811	830

† Assumes 45-year occupational exposure at 1920 hours per year from age 20 to retirement at age 65. Lifetime risk of lung cancer adjusted for competing risk of death from other causes and calculated through age 85. Baseline lung cancer and overall mortality rates from NCHS (1996).

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All of the estimates in Table III–7 assume that occupational exposure begins at age 20 and continues until retirement at age 65. Excess risks were calculated through age 85 as in Table IV of Stayner et al. (1998). Table III–7 differs from Table IV of Stayner et al. in that results from Johnston et al. and Säverin et al. are substituted for results based on the two studies by Garshick et al. Nevertheless, at 500 μg/m³, the range of excess risks shown in Table III–7 is nearly identical to the range (50 to 810 μg/m³) presented in Table IV of Stayner et al. (1998).

MSHA considers the exposure levels shown in Table III–1 to be typical of current conditions in underground coal mines using diesel face equipment. At the mean dpm concentration observed by MSHA at underground M/NM mines (808 μg/m³), the eight estimates range from 83 to 830 excess lung cancer deaths per 1000 affected miners. At the mean dpm concentration observed by MSHA at underground coal mines (644 μg/m³), the estimates range from 61 to 811 excess lung cancer deaths per 1000 affected miners. MSHA recognizes that these risk estimates involved extrapolation beyond the exposure experience of the miner cohorts in Säverin et al. (1999) and Johnston et al. (1997). However, the degree of extrapolation was less for those two studies than the extrapolation that was necessary for the diesel-exposed truck drivers in Steenland et al. The lowest excess lung cancer risk in dpm exposed miners found in Table III–7 is 61/1000 per 45-year working lifetime. Based on the quantitative rule of thumb established in the benzene case, this estimate indicates a clearly significant risk of lung cancer attributable to dpm exposure at current levels. [*Industrial Union* vs. *American Petroleum*; 448 U.S. 607, 100 S.Ct. 2844 (1980)].

c. The Rule's Expected Impact on Risk

MSHA strongly disagrees with the views of some commenters who asserted that the proposed rules would provide no known or quantifiable health benefit to mine workers. On the contrary, MSHA's assessment of the best available evidence indicates that reducing the very high exposures currently existing in underground mines will significantly reduce the risk of three different kinds of material impairment to miners: (1) Acute sensory irritations and respiratory symptoms (including allergenic responses); (2) premature death from cardiovascular, cardiopulmonary, or respiratory causes; and (3) lung cancer. Furthermore, as will be shown below, the reduction in lung cancer risk expected as a result of the rule can readily be quantified based on the estimates of excess risk at exposure levels given in Table III–7.

Even though the coal rule is an equipment based standard limiting emissions to 5.0 gm/hr and 2.5 gm/hr dpm output, MSHA estimates that these emissions limits will result in ambient dpm concentration in an underground coal mines of approximately 200 μg/m³. MSHA believes this is a reasonable estimate to use in light of several sample calculations which indicate that using available controls in underground mining sections with dirty equipment can reduce emissions to that level or further. For example, in part IV of this preamble, MSHA discusses the comparison of the machine-based standard in this final rule with the State of Pennsylvania's diesel law. MSHA provides data showing that a permissible engine equipped with a 95% filter and using the approval plate air quantity will result in a calculated ambient concentration of dpm of 142 μg/m³. In part V of this preamble, MSHA uses the "Estimator"—a computerized spreadsheet designed to calculate dpm ambient levels from given engine emissions and mine ventilation rates and the impact of various controls on those ambient levels. Table V–3 of part V presents Estimator results using another permissible engine to show that the ambient levels would be approximately 200 μg/m³ when applying various filters and using various intake dpm concentrations.

An alternative approach to estimating exposures once the rule is implemented is to look at the factors affecting dpm production. Dpm exposure is related to the emissions from engines, ventilation,

and engine duty cycle. If emissions drop from 25 and 50 gm/hr (dpm concentration range emitted from current permissible engines) to 2.5 and 5.0 gm/hr (as required under the rule), there would be a ten-fold reduction in exposure. With current ventilation required for the diesel equipment, the ambient concentrations would also be reduced accordingly. Thus, assuming that emissions will be reduced down to 200 μg/m³ is a conservative approach in estimating benefits.

Using exposure-response relationships and assumptions described in Subsections 3.b.ii(1) and 3.b.ii(2) of this risk assessment, MSHA estimated lower bounds on the significance of risks faced by miners occupationally exposed to dpm with respect to (1) acute sensory irritations and respiratory symptoms or (2) premature death from cardiovascular, cardiopulmonary, or respiratory causes. MSHA expects the rules to significantly and substantially reduce all three kinds of risk. However, MSHA is unable, based on currently available data, to quantify with confidence the reductions expected for the first two kinds. A 24-hour exposure at 20 μg/m³ may not have the same short-term effects as an 8-hour exposure at 60 μg/m³. Furthermore, this concentration is only 30 percent of the maximum dpm concentration that MSHA expects once the rules are fully implemented and represents an even smaller fraction of average dpm concentrations many underground miners currently experience. It is unclear whether the same incremental effects on acute respiratory symptoms and premature mortality would apply at the much higher exposure levels found in underground mines. Additionally, as MSHA suggested in the proposed preamble and several commenters repeated, the toxicity of dpm and $PM_{2.5}$ may differ because of differences in composition. Finally, underground miners as a group may differ significantly from the populations for which the $PM_{2.5}$ exposure-response relationships were derived.

Therefore, MSHA's quantitative assessment of the rule's impact on risk is restricted to its expected impact on the third kind of risk—the risk of lung cancer. As explained in Part IV of the preamble, the rule is expected to limit dpm concentrations to which miners in underground coal mines are exposed to approximately 200 μg/m³. Assuming that, in the absence of this rule, underground coal miners would be occupationally exposed to dpm for 45 years at a mean level of 644 μg/m³, the following table contains the estimated reductions in lifetime risk expected to result from full implementation of the rule, based on the various exposure-response relationships obtained from Säverin et al. (1999) and Johnston et al. (1997). These estimates were obtained by calculating the difference between the corresponding estimates of excess lung cancer mortality, at 644 μg/m³ and 200 μg/m³, shown in Table III–7. The Regulatory Impact Analysis (RIA), presented later in this preamble, contains further quantitative discussion of the benefits anticipated from this rule.

REDUCTION IN LIFETIME RISK OF LUNG CANCER MORTALITY EXPECTED AS RESULT OF REDUCING EXPOSURE LEVEL FROM 644 μG/M³ TO 200μG/M³

Study and statistical model	Expected reduction in lung cancer deaths per 1000 affected miners†
Säverin et al. (1999):	
Poisson, full cohort	46
Cox, full cohort	352
Poisson, subcohort	470
Cox, subcohort	579
Johnston et al. (1997):	
15-year lag, mine-adjusted	457
15-year lag, mine-unadjusted	298

†Calculated from Table III–7.

Although the Agency expects that health risks will be substantially reduced by this rule, the best available evidence indicates that a significant risk of adverse health effects due to dpm exposures will remain even after the rule is fully implemented. As explained in Part V of this preamble, however, MSHA has concluded that, due to monetary costs and technological limitations, the underground coal mining sector as a whole cannot feasibly reduce dpm concentrations further at this time.

4. Conclusions

MSHA has carefully considered all of the evidence and public comment submitted during these proceedings to determine whether dpm exposures, at levels observed in some mines, present miners with significant health risks. This information was evaluated in light of the legal requirements governing regulatory action under the Mine Act. Particular attention was paid to issues and questions raised by the mining community in response to the Agency's ANPRM and NPRM and during workshops on dpm held in 1995. Based on its review of the record as a whole, the agency has determined that the best available evidence warrants the following conclusions:

1. Exposure to dpm can materially impair miner health or functional capacity. These material impairments include acute sensory irritations and respiratory symptoms (including allergenic responses); premature death from cardiovascular, cardiopulmonary, or respiratory causes; and lung cancer.

2. At dpm levels currently observed in underground mines, many miners are presently at significant risk of incurring these material impairments due to their occupational exposures to dpm over a working lifetime.

3. By reducing dpm concentrations in underground mines, the rule will substantially reduce the risks of material impairment faced by underground miners exposed to dpm at current levels.

In its response to MSHA's proposals, the NMA endorsed these conclusions to a certain extent, as follows:

> The members of NMA have come to recognize that it would be prudent to limit miners' exposure to the constituents of diesel exhaust in the underground environment. [NMA]

A number of commenters, however, urged MSHA to defer rulemaking for either the coal or M/NM sector, or both, until results were available from the NCI/NIOSH study currently underway. For example, referring to the M/NM proposal, one commenter stated:

> Vulcan agrees with MSHA that underground miner Dpm exposure needs to be addressed by mine operators. Vulcan agrees with MSHA that a permissible exposure level (PEL) should be established, but disagrees that adequate information is currently available to set a PEL. [Vulcan Materials]

MSHA believes that expeditious rulemaking, in both underground mining sectors, is necessary for the following reasons:

(1) The NCI/NIOSH study currently in progress will eventually provide additional information on lung cancer mortality. Non-cancer health effects, such as sensory irritations, respiratory symptoms, or premature death from cardiovascular, cardiopulmonary, or respiratory causes will not be addressed. MSHA believes that these non-cancer effects constitute material impairments.

(2) NIOSH itself has recommended that, "* * * given the length of time to complete this study and the current state of knowledge regarding dpm exposures and health effects in miners," MSHA should "proceed with rulemaking based on the evidence currently available as presented in this

FR notice.'' [NIOSH testimony by Paul Schulte, dated 5/27/99]

(3) Given the very high exposure levels measured at some underground mines, miners should not be required to serve as human guinea pigs in order to remove all doubts about the excess risks of dpm exposures in underground mines. While additional studies are in progress, miners should be protected by reducing dpm concentrations to a level more nearly commensurate with exposures in other industries.

Referring to some commenters' position that further scientific study was necessary before regulatory action could be justified, a miner at one of the dpm workshops held in 1995 said:

> * * * if I understand the Mine Act, it requires MSHA to set the rules based on the best set of available evidence, not possible evidence * * * Is it going to take us 10 more years before we kill out, or are we going to do something now * * *? (dpm Workshop; Beckley, WV, 1995).

Similar concern with the risk of waiting for additional scientific evidence was expressed by another miner, who testified:

> * * * I got the indication that the diesel studies in rats could no way be compared to humans because their lungs are not the same * * * But * * * if we don't set the limits, if you remember probably last year when these reports come out how the government used human guinea pigs for radiation, shots, and all this, and aren't we doing the same thing by using coal miners as guinea pigs to set the value? (dpm Workshop; Beckley, WV, 1995).

MSHA shares these sentiments. That is why MSHA considers it imperative to protect miners based on the weight of existing evidence, rather than to wait for the results of additional studies.

IV. Discussion of Final Rule

This part of the preamble describes each of the provisions of the final rule. As appropriate, this part references discussions in other parts of this preamble: In particular, the background discussions and controls in part II, and the feasibility discussions in part V.

Table IV–1 will be referenced throughout this discussion. The table provides information about each engine approved by MSHA for use in underground coal mines. This table reflects the emission results based on the MSHA approval data.

The top rows of the table provide information about permissible configurations, designated by the MSHA approval numbers which contain an ''A''; the remainder of the table provides information about nonpermissible configurations, designated by the MSHA approval numbers which contain a ''B''. Within each engine grouping, the permissible engines are listed in order of MSHA approval number, and the nonpermissible engines are listed in increasing ''Rated Horsepower''.

The table has ten columns. The first column gives the MSHA approval number. The second and third column lists the engine manufacturer and the engine model designation. The fourth column lists the rated horsepower of the engine as approved by MSHA. The fifth column gives the Particulate Index (PI) expressed in cubic feet per minute (cfm), the sixth column lists the DPM emissions expressed in gm/hr—weighted average over the 8 mode test cycle specified in 30 CFR 7.89, the seventh column weighted average horsepower, the eighth is the dpm expressed in grams per bhp-hr (calculated by dividing column six by column seven), the ninth column gives the filter efficiency needed to meet a 5.0 gm/hr standard, and the tenth column gives the filter efficiency needed to meet a 2.5 gm/hr standard.

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Table IV-1

MSHA Approved Diesel Engines under Part 7, subpart E

Approval No.	Manufacturer	Engine Model	Rated	PI	DPM gm/hr	Weighted Avg.	DPM	Filter Efficiency	Filter Efficiency
		* Meets EPA	Horse power	CFM	Weighted Avg.	Horsepower	gr/bhp-hr	To Obtain 5.0gm/hr	To Obtain 2,5gm/hr
A001	DEUTZ	MWM 916	94	15000	25.49	51.1	0.50		90.2
A002	CATERPILLAR	3306 PCNA	150	27000	45.88	87.2	0.53		94.6
A003	CATERPILLAR	3304 PCNA	100	17500	29.74	58.1	0.51		91.6
A004	ISUZU	QD 100-306	70	50000	84.96	40.7	2.09		97.1
A004	ISUZU	QD 100-306	66	10000	16.99	34	0.50		85.3
A005	Caterpillar	3306PCTA	190	31000	52.68	95	0.55		95.3
B070	Farymann	43F	14	4000	6.80	7.00	0.97	26.4	63.2
B042	Lister Petter	LPU2 MKI	17.5	5000	8.50	9.1	0.93	41.2	70.6
B053	Kubota	V1200*	25.8	1500	2.55	13	0.20	0.0	1.9
B041	Lister Petter	LPU3 MKI	26.3	7000	11.89	13.7	0.87	58.0	79.0
B062	Deutz	F2L1011*	28.2	1000	1.70	14	0.12	0.0	0.0
B044	Lister Petter	LPU3 MKII	29	4500	7.65	15.1	0.51	34.6	67.3
B015	DEUTZ	F2L 1011F*	30	3500	5.95	15.6	0.38	15.9	58.0
B040	Lister Petter	LPU4 MKI	35	9500	16.14	18.2	0.89	69.0	84.5
B043	Lister Petter	LPU4 MKII	38.6	6000	10.20	20.1	0.51	51.0	75.5
B026	DEUTZ	F3L 912W*	40	2500	4.25	21.7	0.20	0.0	41.2
B061	Deutz	F3L1011*	41.6	1500	2.55	21	0.12	0.0	1.9
B033	PERKINS	104-19	42.5	7000	11.89	22.4	0.53	58.0	79.0
B014	DEUTZ	F3L 1011F*	44	5000	8.50	23.3	0.36	41.2	70.6
B054	Deutz	F3M1011F*	46	3500	5.95	24.2	0.25	15.9	58.0
B031	DEUTZ	F3L 912W *	47	2500	4.25	24.7	0.17	0.0	41.2
B025	DEUTZ	F4L 912W*	54	3500	5.95	28.9	0.21	15.9	58.0
B060	Deutz	F4L1011*	56.3	2000	3.40	28	0.12	0.0	26.4
B038	ISUZU	QD60 (C240)	57	5500	9.35	27.6	0.34	46.5	73.3
B027	PERKINS	704-26	58	8000	13.59	28.8	0.47	63.2	81.6
B013	DEUTZ	F4L 1011F	59	6500	11.05	31.1	0.36	54.7	77.4
B055	Deutz	F4M1011F*	61	4500	7.65	32.30	0.24	34.6	67.3
B029	DEUTZ	F4L 912W*	62	3500	5.95	32.9	0.18	15.9	58.0
B024	DEUTZ	F5L 912W*	67	4500	7.65	36.2	0.21	34.6	67.3
B019	DEUTZ	BF4L 1011F*	74	4500	7.65	40	0.19	34.6	67.3
B030	DEUTZ	F5L 912W *	76	4000	6.80	41.1	0.17	26.4	63.2
B006	ISUZU	QD 100-301	79	8500	14.44	43.5	0.33	65.4	82.7
B023	DEUTZ	F6L 912W*	80	5000	8.50	43.4	0.20	41.2	70.6
B056	Deutz	BF4M1011F*	82	5500	9.35	44.75	0.21	46.5	73.3
B028	DEUTZ	F6L 912W *	93	5000	8.50	49.3	0.17	41.2	70.6
B001	DEUTZ	MWM 916	94	11500	19.54	46.2	0.42	74.4	87.2

B004	CATERPILLAR	3304 PCNA	100	15000	25.49	52.8	0.48	80.4	90.2
B022	PERKINS	1004-40T	108	9000	15.29	55.4	0.28	67.3	83.7
B064	Caterpillar	3054DIT	108	9000	15.29	54.00	0.28	67.3	83.7
B045	ISUZU	4BG1T-MA	111	13000	22.09	57.7	0.38	77.4	88.7
B011	DEUTZ	BF4M 1012EC*	113	4000	6.80	59.1	0.12	26.4	63.2
B020	PERKINS	1004-40TW*	122	7500	12.74	62.6	0.20	60.8	80.4
B065	Caterpillar	3054DITA*	122	7500	12.74	61.00	0.21	60.8	80.4
B059	Deutz	BF4M1013*	127	4500	7.65	64	0.12	34.6	67.3
B046	ISUZU	6BG1-MA	129	16000	27.19	67.1	0.41	81.6	90.8
B039	ISUZU	QD145	135	12000	20.39	70.5	0.29	75.5	87.7
B034	DEUTZ	F6L 413FW*	137	7000	11.89	75.4	0.16	58.0	79.0
B003	CATERPILLAR	3306 PCNA	150	23000	39.08	79.2	0.49	87.2	93.6
B021	PERKINS	1006-60T	152	12000	20.39	82.8	0.25	75.5	87.7
B066	Caterpillar	3056DIT	152	12000	20.39	76.00	0.27	75.5	87.7
B008	DEUTZ	BF4M 1013EC*	158	7500	12.74	82.5	0.15	60.8	80.4
B005	GENERAL MOTORS	L57, 6.5L* - 1994	160	9500	16.14	83.5	0.19	69.0	84.5
B052	Cummins	5.9-175 w/cat* - 1994	175	3500	5.95	93.70	0.06	15.9	58.0
B052	Cummins	5.9-175 w/ocat* - 1994	175	5000	8.50	93.70	0.09	41.2	70.6
B035	DEUTZ	F8L 413FW	182	9500	16.14	100.6	0.16	69.0	84.5
B067	Navistar	A185	185	15000	25.49	93.00	0.27	80.4	90.2
B058	Deutz	BF6M1013*	194	5500	9.35	97	0.10	46.5	73.3
B016	GENERAL MOTORS	L65, 6.5L - 1998	195	24000	40.78	101.8	0.40	87.7	93.9
B068	Navistar	A225* - 1994	215	11000	18.69	108.00	0.17	73.3	86.6
B063	Caterpillar	3306PCTA	215	31000	52.68	108.00	0.49	90.5	95.3
B036	DEUTZ	F10L 413FW	228	12000	20.39	125.7	0.16	75.5	87.7
B050	Detroit Diesel	Series 40 DDEC*	230	4500	7.65	118.6	0.06	34.6	67.3
B057	Deutz	BF6M1013C*	233	8500	14.44	117.00	0.12	65.4	82.7
B051	Cummins	ISB235* - 1998	235	6000	10.20	113.6	0.09	51.0	75.5
B069	Navistar	B250* - 1994	250	6000	10.20	125.00	0.08	51.0	75.5
B007	DEUTZ	BF6M 1013ECP	261	19000	32.29	136.2	0.24	84.5	92.3
B010	CATERPILLAR	3306 DITA*	270	6000	10.20	154.5	0.07	51.0	75.5
B037	DEUTZ	F12L 413FW	274	14000	23.79	150.8	0.16	79.0	89.5
B017	CATERPILLAR	3306 ATAAC*	300	12000	20.39	172.5	0.12	75.5	87.7
B047	Detroit Diesel	Series 50 DDEC*	315	5000	8.50	166.7	0.05	41.2	70.6
B048	Detroit Diesel	Series 60 11.1 DDEC*	325	5500	9.35	179.7	0.05	46.5	73.3
B012	CATERPILLAR	3176 ATAAC	335	8000	13.59	191	0.07	63.2	81.6
B002	DEUTZ	BF6M 1015C*	402	17500	29.74	219.1	0.14	83.2	91.6
B049	Detroit Diesel	Series 60 12.7 DDEC*	475	8500	14.44	249	0.06	65.4	82.7
B018	CATERPILLAR	3406E*	500	12500	21.24	274.8	0.08	76.5	88.2
B009	DEUTZ	BF8M 1015C*	536	18000	30.59	289.7	0.11	83.7	91.8
B032	Detroit Diesel	8V-2000TA DDEC*	650	10000	16.99	364.7	0.05	70.6	85.3

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The final rule would add six new sections to 30 CFR part 72 on March 20, 2001.

Section 72.500 Emission Limits for Permissible Diesel Powered Equipment.

Organization. As with the proposed rule, this section establishes the controls applicable to permissible equipment. As proposed, 30 CFR 72.500 also had included other requirements—controls for nonpermissible heavy-duty vehicles in 30 CFR 72.500(b) and requirements for the maintenance of such controls in 72.500(c). In this final rule, MSHA has retained the requirements for dpm reduction for permissible equipment in this section but has moved the requirements for nonpermissible heavy-duty vehicles to a new 30 CFR 72.501. MSHA has also moved the maintenance requirements for emission controls to a new 30 CFR 72.503. These organizational changes were made to make it easier for the mining community to locate specific requirements in the final rule.

Summary of final rule. The final rule requires all permissible equipment to meet an emissions limit of 2.5 grams of dpm per hour. The existing fleet has 18 months to meet this limit. In addition, any permissible engine introduced into the fleet of an underground coal mine after the effective date of this rule will have to meet that standard upon being introduced into the mine. MSHA means by ''introduced'' any equipment added to the mine's diesel equipment inventory. This includes newly purchased equipment, used equipment, or a piece of equipment receiving a replacement engine with a different serial number than the engine it is replacing. It also includes engines or equipment coming from one mine into another. It does not include a piece of equipment whose engine was previously part of the mine's inventory and rebuilt.

Infeasibility of a concentration limit for underground coal mines. The preamble accompanying the proposed rule explained why the Agency was not proposing an ambient concentration limit for underground coal mines as it was proposing for underground metal and nonmetal mines. The Agency was not confident at the time the rule was proposed that there was a measurement method for dpm that provided accurate, consistent and verifiable results at lower concentration levels in underground coal mines. The available measurement methods for determining dpm concentrations in underground coal mines were carefully evaluated by the Agency, including field testing, before the Agency reached this conclusion. The Agency continued to collect data and has consulted with NIOSH in an attempt to resolve questions about the measurement of dpm in underground coal mines. There were no comments received that objected to the fact that the Agency was not proposing an ambient concentration limit for underground coal mines as it was proposing for underground metal and nonmetal mines.

Why dpm emissions from permissible equipment need to be controlled. The preamble accompanying the proposed rule also explained why the agency was proposing to limit the emissions from permissible equipment in particular. Dpm concentration samples taken in the field indicate that permissible equipment used for face haulage makes the largest contribution to high dpm levels. Dpm samples taken in the intake air to working sections where diesel face haulage was used showed relatively low dpm levels. When diesel particulate filters were not used, dpm samples taken on the working section and in returns from those sections generally showed dpm levels in excess of 500 $\mu g/m^3$.

Other permissible equipment can also generate significant dpm emissions because this equipment utilizes the same engines as used in face haulage equipment. Since the time of the proposal, the diesel inventory for permissible machines has not changed significantly. The same four permissible engines that were available at the time the proposal was written continue to be the power source for the current permissible fleet. Table IV–1 shows that these four engines produce higher dpm emissions on a gm/hr basis than nonpermissible engines with the same horsepower. Commenters did not present evidence that dpm concentrations in areas where permissible equipment is used have decreased since the proposed rule was published.

Why the final rule uses a machine based emission limit instead of a requirement for the addition of a filter with a specified filtration efficiency. The final rule for permissible equipment is different from that proposed. As proposed by MSHA (63 FR 17491 et.seq.), 30 CFR 72.500(a) would have required mine operators to install on permissible vehicles a system capable of removing on average, at least 95% of dpm by mass. Operators were required to complete these filter installations within 18 months from the date of publication of the final rule; no action to control emissions from permissible equipment was required before that date.

The use of an emissions limit for permissible machines in the final rule stems directly from an alternative which MSHA placed before the mining community in the preamble to the filter-efficiency based rule that was proposed. In that preamble, the agency also described a number of alternative approaches considered, and asked the mining community to comment on whether there were other approaches for the control of dpm from permissible equipment that might accomplish the same task with more flexibility. 63 FR 17498, 17499, 17556, 17563. The agency also described the approach being taken by the State of Pennsylvania that combined a filter efficiency standard with a tailpipe limit.

The Agency emphasized that it was particularly interested in comment on an alternative approach it described that would establish a machine based limit on emissions in lieu of a filter efficiency requirement (see, *e.g.,* 63 FR 17556, 17563). In fact, a separate ''Question and Answer'' was included in the preamble to highlight this alternative, immediately after the description of the proposed rule. 63 FR 17501, 17653.

Based on the record, MSHA has concluded that the original proposal had deficiencies which are avoided by this alternative approach.

MSHA received many comments objecting to exclusive reliance on filters. Commenters stated that MSHA was denying operators the benefit of the full range of available dpm controls outlined in MSHA's Toolbox (the history and content of which are described in Part II of this preamble). These commenters stated that mine operators should be allowed to chose the combination of controls that best suit their operations.

On the other hand, other commenters favored requiring a filter on all underground mining equipment (including permissible equipment). Some of these commenters noted that controls are only effective if properly maintained, and some asserted that filters are easier to monitor in this regard than engines. Similarly, commenters argued that in the absence of a requirement for a filter on each piece of equipment, operators would rely primarily on increased ventilation to control dpm concentrations, and asserted that the industry had a very poor record of maintaining ventilation controls. Also, one commenter asserted that filters were the only known control that would limit the number of nanoparticles emitted as well as reducing the mass of dpm discharged, whereas newer diesel engines designed to produce less dpm mass may actually

increase the number of nanoparticles emitted.

A number of commenters pointed out that even if filters were required, relying on a filter-efficiency standard would be inappropriate. These commenters noted that even if a particular efficiency (*e.g.,* 95%) is achievable with a ''dirty'' engine like those currently composing the underground coal permissible fleet, such efficiency may not be feasible on the modern, clean burning engines that will eventually take their place. That is, if the emissions from a ''cleaner'' engine are lower to begin with, the filter mounted on a machine with such an engine would have to be much more efficient than the one mounted on a machine with a dirtier engine to remove the same percentage of dpm. Commenters stated that since it might not be possible to meet the proposed requirement for a 95% efficient filter with a newer engine, MSHA's proposed rule might well inhibit the introduction of cleaner engines into underground coal mines, and thus force operators to rely on older and dirtier engines which would require more maintenance.

There was also considerable discussion at the hearings and in the written comments about the experience of Pennsylvania, which has a 95% filter efficiency standard for permissible and other diesel equipment, as well as a requirement that each piece of equipment meet an emissions standard. Commenters clarified the development of that approach, its requirements and procedures, and implementation issues to date; many noted problems in meeting the standard as currently set forth. Other commenters noted that what might be feasible for Pennsylvania, a state which heretofore has not permitted diesel equipment underground, might not be feasible for operators in other states with existing fleets.

As proposed, the rule would have ensured that the emissions from the most polluting, commonly used engine (Caterpillar 3306PCNA, 150 horsepower, 45.88 gm/hr) would be reduced by 95%, resulting in tailpipe emissions of 2.29 gm/hr (5% of 44.88 gm/hr). After carefully considering all of the discussion at the hearings and the written comments, MSHA has concluded that the alternative approach on which it initially invited comment, a dpm emissions limit for each machine, has a number of advantages over the approach initially proposed. While MSHA has evidence that there are filters readily available for the existing permissible fleet which are 95% efficient it lacks evidence of the technological feasibility of filter performance at a 95% level for the cleaner engines which will eventually replace the current fleet. Moreover, the same problem exists at any filter efficiency rating. Changing the proposed rule to require that filters on permissible equipment must only be 70% efficient, as suggested by a commenter, does not guarantee they can provide this efficiency for future engines. At the same time it sets a limit for the current fleet that is far below what can be achieved. Thus, while a requirement for a high filter efficiency could have the perverse effect of inhibiting the introduction of cleaner engine technologies or other technologies that could be forthcoming that could make substantial reductions in dpm levels, a low filter efficiency requirement fails to provide protection for miners from dpm emissions from engines in today's fleet. Accordingly, MSHA has concluded that requiring a specific filter efficiency is not a good idea, either by itself or (as is the case in Pennsylvania) as a supplement to a machine emissions limit.

The machine emission limit specified in this final rule achieves the desired goal of significantly reducing the mass of dpm emitted from the permissible machines without specifying a filter efficiency. Using the 2.5 gm/hr emission limit provides a consistent target and resolves the issue relative to lower filter efficiency or cleaner engines.

With this final rule, MSHA is allowing the mine operator a wide choice of approaches from the toolbox to control dpm such as low emission diesel engines, aftertreatment controls (catalytic converters and/or dpm filters), fuel with a very low level sulfur content, alternative fuels, and fuel additives in order to meet the machine emission limit. Other aspects of the MSHA toolbox are already a requirement in underground coal mines such as the use of approved diesel engines, fuel with a sulfur content less than 500 ppm, optional EPA approved fuel additives, regular maintenance by qualified mechanics, prohibition of unnecessary idling, and training of mechanics and equipment operators. In practice, however, MSHA expects all permissible equipment to need filtration to achieve the required limit.

The final rule does not, however, permit operators to satisfy the requirements for permissible equipment by increasing ventilation or by using enclosed cabs, although the Toolbox describes both as methods for reducing miner exposure to dpm. While MSHA encourages operators to take such steps, the Agency concluded that it would not be appropriate to make an adjustment to or an exemption from the machine emissions limit when such controls are used.

In the case of ventilation, while increasing mine ventilation does reduce dpm concentrations in the ambient air, such a change does not impact a requirement based strictly on the emissions emitted from an individual machine. One variation of the alternative proposed by MSHA would have allowed a credit for added ventilation in determining whether a machine met the required emissions limit. However, after careful consideration the agency has concluded that this approach is inappropriate. It should be noted that while the agency acknowledges the evidence offered by many commenters that reliance upon ventilation as a primary dpm control is inappropriate in light of the record of violations of ventilation standards—even though not all of the data supplied supported the general conclusion being expressed and does not reflect the implementation of the new diesel equipment rule—this is not the basis on which the agency has determined not to allow operators a credit for increasing ventilation. Rather, MSHA concluded that such an approach would not be necessary in light of its conclusion about the capabilities of paper filters alone to enable the permissible fleet to meet the requirement. Controlling engine emissions to the required levels would have called for a ventilation rate of five times the engine particulate index air quantity. This quantity would have been specified in the Approved Ventilation Plan. Such a ventilation rate is achievable in only a few mines. At the same time, once the proper filter is installed, the emissions are controlled to the required levels; allowing a credit for ventilation makes no difference in practice given the range of available filters. While providing a ventilation credit would allow operators to use a less efficient filter, this would reduce dpm emissions less in such mines; and since the use of more efficient filters is feasible, the Act requires MSHA to pick the more protective approach. Moreover, due to the mobility of the equipment, a ventilation credit for outby equipment would be difficult to monitor and enforce. The Agency has indirectly allowed for ventilation by allowing a higher outby emission rate. The higher outby emission rate for light-duty equipment was based on the duty cycle and the normally higher ventilation rates in outby areas. Additionally, allowing for a ventilation credit based on the specific air volume would have become too complicated to administer

in certain cases (for example, permissible equipment in multi-entry systems, or permissible equipment used in outby areas). Ventilation regulations for single and multiple units of permissible diesel equipment are based primarily on the approval plate quantity. Depending on a ventilation quantity other than that on the approval plate would have complicated an already complex issue.

While enclosed cabs or booths can be used to lower exposures for a machine operator, cabs do not currently exist for permissible underground coal mining equipment. Even if developed for permissible equipment, these enclosures would not provide protection for other miners working in that same area. Moreover, there will be no sampling to assure that the miners are protected. Consequently, the final rule requires that even if a cab were developed for permissible equipment, dpm emission limits would have to be maintained the same as other permissible equipment.

Having made the determination that an emissions limit is preferable to a filter efficiency requirement, and not to provide credit for ventilation or an exemption for the use of cabs, MSHA turned to the question of whether filters should always be required. Some commenters noted that controls are only effective if properly maintained, and asserted that filters are easier to monitor in this regard than engines. Also, one commenter asserted that filters were the only known control that would limit the number of nanoparticles emitted as well as dpm mass, whereas newer diesel engines designed to produce less dpm mass may actually increase the number of nanoparticles emitted.

With respect to maintenance, MSHA notes that while the provisions of the recently promulgated diesel equipment regulations dealing with maintenance and the training of qualified maintenance personnel were in effect at the time of the hearing, the full effect of implementation of these provisions may not have been apparent to the commenters. These regulations when fully implemented, should address many of the concerns expressed by the commenters in this regard.

With respect to nanoparticles, section 5 of Part II of this preamble notes that there is very little information at this time about the possible risk of such particles. Moreover, the evidence on whether filters can protect against such particles is unclear. In any event, it will be some time before the newest generation of diesel engines becomes commonplace in underground mines.

Accordingly, MSHA has concluded that at this time, it is not necessary to require filters that specifically limit nanoparticles. MSHA will, however, continue to monitor the situation. If it becomes apparent that the evidence warrants further action, the agency will not hesitate to act upon that information. In practice, as noted above, current permissible equipment will have to be filtered to meet the emissions standard.

In this regard, one commenter stated that if MSHA does not require filters on all equipment underground, it would be more difficult for the individual states to require filters on all diesel equipment. MSHA does not agree with the commenter. States can impose a more stringent standard than MSHA's requirements. While MSHA recognizes that Pennsylvania and West Virginia and other States are going to take a close look at the Federal government's standard, each State faces different circumstances—*e.g.,* the number and nature of diesel powered equipment already underground, the economic situation of the state's coal industry, etc. MSHA's discussion of the risks of dpm exposure in Part III suggest that further controls would be warranted where it is technologically and economically feasible for the underground coal mining industry as a whole to implement such controls; and while MSHA has concluded this is not feasible for the US industry as a whole, an individual State might well conclude it is feasible for the situation that exists in that State.

Some commenters requested that some or all of the State of Pennsylvania approach be adopted by MSHA. The Pennsylvania law requires an MSHA approved engine, a catalytic converter, and a 95% filter. Additionally, Pennsylvania establishes a ventilating air requirement calculated to dilute the dpm emitted from the filter to 120μ/m^3. With respect to permissible equipment, MSHA's requirement for a machine dpm emission limit of 2.5 grams per hour is essentially equivalent to the emissions standard required under Pennsylvania law.

MSHA did not adopt a calculated ambient dpm concentration based on the approval plate air quantity. Instead, MSHA set the emission standard to represent the dpm emitted from the individual machine. However, since MSHA already requires an approval plate quantity based on the gaseous emissions, an ambient dpm concentration can be calculated from the engine's dpm emission data, the filter efficiency, and the approval plate air quantity. For example, as noted on Table IV–1, the Caterpillar 3306 PCNA engine produces 45.88 gm/hr of dpm from the Category A, permissible configuration. This engine has an approval plate quantity of 9500 cfm or 269m^3/minute of air. When equipped with a 95% dpm filter, the resultant calculated laboratory ambient quantity for a single machine using the Caterpillar 3306 PCNA engine would be 142μ/m^3. This is based on the following formula: (dpm,gm/hr) / 60 * ((100–95%)* 1000 / (approval plate quantity, m^3/minute)* 1000. To reduce the emissions of this engine to the level specified in the Pennsylvania law would require additional air or a higher efficiency filter.

One commenter presented data from a laboratory test conducted on different filter media. The data indicated that the highest efficiency achieved was 81% using the ISO 8178, C1 test cycle. This commenter suggested that MSHA adopt an approach similar to the Pennsylvania approach but establish a 0.5 milligram per cubic meter (mg/m^3) calculated ambient concentration instead of the 120μ/m^3 (0.120 mg/m^3). This commenter's approach included the use of a minimum 70% efficient filter and a recalculation of the approval plate air quantity to achieve the 500μ/m^3 (0.5 mg/m3) concentration.

As with the Pennsylvania approach, MSHA basically agrees with the commenter's general approach. The dpm emission limits specified in this final rule limits the machine's dpm output, requiring the mine operator to choose an engine and aftertreatment device, if necessary, to meet the standard. This approach as previously stated significantly reduces dpm emissions and is based on laboratory testing of the engine and filter. However, since MSHA currently has a requirement for the use of approval plate air quantities in underground coal, MSHA did not impose an additional calculated approval plate air quantity as suggested by the commenters. MSHA is not imposing a minimum filter efficiency as suggested by the commenters because MSHA believes that the mine operator should be able to use all the available tools to meet the standards. MSHA believes that all of the current permissible engines will require filtration to meet the standard; however with this approach taken in the final rule, MSHA is not limiting future technologies.

A commenter asked why the Agency had not chosen to utilize the particulate index established during the MSHA approval process for each engine as the basis of any dpm regulation.

As discussed in Part II of this preamble, the requirement for determining the particulate index was

contained in the Agency's diesel equipment regulations. It implemented a recommendation of the Diesel Advisory Committee which called for a particulate index to be set for approved diesel engines. The particulate index specifies the quantity of air needed to dilute the particulate generated by the engine to 1 milligram of diesel particulate matter per cubic meter of air and is based on data collected under the engine approval test described in 30 CFR 7.89.

MSHA established the particulate index to be used as a guide to the mining community in making certain decisions about the control of dpm while the Agency finalized regulations that specifically addressed dpm. This information is available to the mining industry from the manufacturer and MSHA. The particulate index enables the mining community to compare the particulate levels generated by different engines in terms of a ventilating air quantity. For example, if the particulate indices for diesel engines of the same horsepower were established as 7,500 cubic feet of air per minute (cfm) and 12,000 cfm respectively, an equipment manufacturer, mine operator, and MSHA personnel can use this information, along with consideration of the type of machine the engines would power and the area of the mine in which it would be used, to make certain decisions. A mine operator can use this information when choosing an engine to roughly estimate an engine's contribution of diesel particulate to the mine's total respirable dust. MSHA would use this information when evaluating mine dust control plans. Equipment manufacturers can use the particulate index to design and install exhaust after-treatments. MSHA posts this information on its website at http://www.msha.gov/S&HINFO/DESLREG/1907b5.HTM for permissible engines and at *http://www.msha.gov/S&HINFO/DESLREG/1909a.HTM* for nonpermissible engines.

Had the Agency decided to take an approach in this regulation similar to the approach taken by the state of Pennsylvania in its diesel law, or to establish an ambient dpm concentration limit, the particulate index could have been used directly to compute an estimated level of dpm that could be achieved with various quantities of ventilation air. Instead, as was discussed above, the Agency chose to limit the quantity of dpm emitted from the machine, and is therefore expressing the standard in that fashion.

Nevertheless, there is a relationship between the PI and the machine limits established under this rule. The determination of the quantity of dpm emitted from the machine is based on the same information from the engine approval tests in 30 CFR 7.89 as was used to establish the particulate index. Both means of expressing the dpm characteristics of the machine start with determining the permissible fleet. With the exception of the Isuzu QD100 engine which is only used in two machines in the permissible fleet, the Caterpillar 3306 PCNA meets this criteria. The Caterpillar engine emits approximately 46 grams of dpm per hour based on the MSHA approval test for part 7, Category A. Accordingly a 90% reduction would limit emissions to 5.0 grams an hour; and a 95% reduction would limit emissions to 2.5 grams an hour. If a filter could reduce the dpm emitted from the Caterpillar engine to these levels, it could reduce the emissions of any other permissible engine in the fleet to that level.

A number of commenters stated that they had been unable to substantiate the agency's contention that there are filters commercially available that meet such high efficiency requirements. Moreover they asserted that the only system which allegedly came close to this requirement, a system known as the DST®, was a system that would be economically infeasible to install on the entire current fleet of permissible equipment.

The DST® system is described in section 6 of Part II. Data was submitted for the record that the DST® system does indeed reduce the dpm emissions from an engine by more than 95% (*i.e.,* below 2.5 grams per hour) when tested on the ISO 8178,C1 test cycle. The engine tested with the DST® was a MWM916–6 diesel engine which emits 25.5 gm/hr based on the MSHA approval test for part 7, Category A. The system is composed of several components; a paper filter and a catalytic converter, with a heat exchanger used to reduce the temperature of the exhaust to the levels required by MSHA for permissible equipment. The low exhaust gas temperature enables the use of a paper filter without igniting the filter. Most permissible equipment uses water scrubbers to cool the exhaust temperature; hence, switching to the dry system would involve considerable expense.

The agency has reviewed the evidence to determine whether a commercially available paper type filter, mounted at the outlet of the water scrubber used to cool the exhaust of most permissible machines, can achieve comparable reductions in dpm emissions. Filter kits are readily available for most permissible machines, and the costs of equipping the fleet in this fashion is significantly lower than converting everything to a dry system.

MSHA had good reason to think that paper filters alone could do the job. In the early 1990's, equipment manufacturers along with the then Bureau of Mines installed paper filters to the exhaust of water scrubbers for dpm reduction. These systems proved to be very effective in dpm removal. Some mines have used these filters on permissible equipment successfully since the early 1980s. Anecdotal experience was also supportive. For example, a miner commented very favorably about improvement in emissions from a diesel equipped with a paper filter. The miner was referring to a dry system other than DST®. Moreover, based upon what it knows about the components of the DST® system discussed above, MSHA had reason to believe that based upon the extent to which the heat exchanger and catalytic convertor can themselves reduce dpm concentrations, that the main reason for the extensive dpm reduction of the system might well be the paper filter. However, although the record could support such a conclusion, the record contained no specific filter efficiency data. Moreover, some asserted that the DST® results were due to all of its components working together. Other commenters challenged the agency's assumption that a 95% reduction of emissions from the permissible engines that produce the highest dpm concentrations was feasible. Such a filter efficiency would be necessary to satisfy an emissions limit of 2.5 grams per hour.

In order to dispel any doubts about the matter and verify whether the addition of a paper filter alone could achieve such a significant reduction in dpm, MSHA had an analysis performed by an independent laboratory. MSHA has placed a full report of this verification analysis in the record. The analysis was performed on an engine that is representative of the permissible engines in the fleet that produce the most dpm.

The part 7 approval information indicates that three engines—the Caterpillar 3306 PCNA, 3304 PCNA, and the MWM 916–6—are basically of the same design. The Caterpillar 3306 PCNA used for the analysis is representative of the three engines' emissions performance. The Isuzu QD 100 is approved by MSHA and is used in a small number of permissible machines that can emit higher levels of dpm than the Caterpillar engine tested. This occurs when the Isuzu engine is

adjusted to the highest horsepower rating approved by MSHA. However, this engine can be derated to an existing lower horsepower MSHA approval rating which is only 5.5% lower than maximum rating. The two machines of which MSHA is aware that are currently using this engine are operated in a two entry mine through a petition for modification. The petition for modification requires these machines to be permissible. If this was not the case, the two machines that are currently using this engine would be considered light-duty equipment. In a light-duty equipment application, the lower horsepower adjustment for this engine would not be as critical as when installed in a heavy duty machine.

MSHA contracted with Southwest Research Institute (SwRI) to determine the efficiency of a paper filter when installed on a Jeffrey dry system equipped with a Caterpillar 3306 PCNA diesel engine. Jeffrey's permissible system incorporates a heat exchanger and a synthetic type filter, but no oxidation catalytic converter. For the purpose of this verification test, a paper filter was substituted for the synthetic filter. In the setup for the verification test, as described below, the paper filter efficiency was determined.

Although most permissible equipment is cooled by a water scrubber, MSHA did not ask SwRI to verify filter performance with a water scrubber system actually in place. The agency has concluded that such verification is not feasible at this time. Laboratory testing of dpm removal efficiency with a water scrubber is very difficult due to the high moisture content of the exhaust. The high moisture content would cause interference in the measurement methods using laboratory dilution tunnels. Others have attempted this type of work on a limited basis, but in most cases, were not successful or the investigators did not repeat previous attempts. Accordingly, as noted under the next heading, MSHA will assume for compliance purposes that a paper filter whose efficiency is measured with a heat exchanger will work just as well when used with a water scrubber.

The paper filter installed on the Jeffery power package was acquired from Donaldson Filter Corporation. The filter paper was a standard primary air filter media, Donaldson Part No. EN0701026. When tested by Donaldson for use as a standard primary air filter media for many applications including diesel engine intake air filter, the paper has a particle removal efficiency of 32% for 0.5 micron particles, 60% for 1.0 micron particle, and 97% for 3.0 microns particles. This information was derived from data using neutralized KCL aerosol and on a test bench which complies with SAE J1669 requirements. The test was conducted on flatsheet media at 10.5 fpm face velocity. However, since the application of this paper filter media is unique to mining, the verification tests determined the efficiency when used in the cooled diesel exhaust stream (less than 300°F) to filter whole dpm (less than 1 micorn in size). The paper filter media used had performance specifications equivalent to the paper filter used on the DST® system. Moreover, it also is the same paper media which is used on the kits sold by Jeffrey and Wagner for installation of a paper filter on the exhaust of a water scrubber.

A standard ISO 8178, C1 eight-mode emission, test which is identical to the tests required by this final, rule was performed in three component configurations. The first configuration consisted of measuring engine-out emissions with no heat exchanger or filter attached to the engine. This was considered baseline dpm emission data. The second configuration consisted of routing the engine exhaust through the heat exchanger and filter housing with no filter installed. The third configuration consisted of installing a filter into the filter housing and routing the exhaust through the heat exchanger and then through the filter. The difference between the mass of diesel particulate measured at the outlet of the filter, and the baseline dpm emissions, enabled the collection efficiency of the filter to be determined.

The results of the verification conducted by Southwest Research Institute confirmed that a paper filter, without a catalytic converter, can reduce the dpm emissions of a Caterpillar 3306PCNA by 95%, down to a machine emissions rate of 2.3 gm/hr, thus meeting the 2.5 gm/hr standard. When the efficiency of the paper filter, as determined in the Southwest verification is applied to MSHA's approval data for these three permissible engines which make up almost all of the current permissible fleet, the 2.5 gm/hr standard is met. This is illustrated in the part of Table IV–1 dealing with permissible engines.

As can be seen in that table, machines equipped with the Isuzu QD–100 engine cannot meet the standard as currently operated. However, these engines can be derated from the highest power setting to a lower power setting and, with a paper filter, meet the emissions limit as shown by the second rating for that engine in the table. Since the paper filter used in the test has the same paper media as is generally used for dpm filters, MSHA has verified that the installation of a paper type filter alone will reduce the dpm concentration on all permissible machines currently in usage in underground coal mines.

A commenter who reviewed the report of the verification test conducted by SwRI raised two issues about relying upon the results.

One issue involves the dpm reduction from the heat exchanger. The results of the SwRI test indicated that there was a 9% reduction in dpm attributable to the heat exchanger. The commenter questioned whether the 9% attributed to the heat exchanger was also reported in the 95% reduction in dpm for the disposable paper filter. The test procedures required particulate measurements be made on bare engine emissions, with the heat exchanger in-line, and with the heat exchanger and disposable paper filter in-line. Comparing the particulate measurements made with the heat exchanger and filter installed to the measurements with only the heat exchanger installed, a 95% reduction in dpm concentration was observed.

The commenter also questioned the validity of the SwRI test because the results of two tests were different with the filter installed. MSHA is aware of the minor difference in test results. However, MSHA's interest is in the efficiency of a clean filter, not a used filter. The efficiency of a used filter is typically greater than the efficiency of a clean filter. The second test was the 8-mode test using the same filter tested in the first test. The filter was exposed to dpm for approximately four hours (time incurred in running the first test). MSHA expected this second test to perform similarly. In fact, on a percentage basis, the results were close, 94% versus 96%, as shown in figure 4 of the SwRI report. However, MSHA does agree with the commenter that the results would be expected to be closer. Although not documented on the SwRI report, the raw data did show an increase in the filter weight from the first 8 mode test. SwRI and MSHA hypothesize that a ''chunk'' of dpm may have dislodged from the filter paper during the test and biased the filter weight. As with any lab testing, further studies could have been done to investigate the difference. However, as noted in the next section, MSHA intends to use the results of this test as the basis for accepting as evidence of compliance with the standard for permissible equipment the use of a paper filter like that tested; accordingly, the agency believes it can proceed without this confirmatory data.

One commenter suggested that a standard adopted by MSHA would have to be adjusted with respect to equipment used at high altitude. This commenter stated that high altitude has an extreme effect on these types of filtration systems. This commenter's experience appeared to be related to catalytic converters. The commenter did not supply any data in supporting his position.

MSHA is aware of the effect of altitude on engine performance. Engine deration must be performed on most engines to compensate for the decrease in the density of air at increasing altitudes to maintain the proper fuel-air ratio. However, the effect on aftertreatment controls specifically claimed by the commenter is not supported by any scientific principle. MSHA has experience with the former BOM on the use of paper filters on permissible machines at a high altitude mine. These were very successful tests. MSHA is not aware of any problems with other types of filters, including ceramic filters. If a self regeneration problem is noted by a mine, then the mine could use acceptable alternative regeneration devices to clean the ceramic filters. MSHA believes that the machine's dpm emission levels specified in this final rule are feasible at high altitude mines and the mine operator has many options available to meet the standards. Moreover, as discussed in the next section, if an operator is using a paper filter that is consistent with that already tested by MSHA, the agency will find the machine in compliance. There is no requirement in the final rule for an ambient air test; the laboratory test will be used.

MSHA wishes to note that it did receive comments from some in the industry acknowledging that it was appropriate for the agency to force technology; and also received some comments from filter manufacturers to the effect that they could meet whatever requirements MSHA set. Moreover, many miners commented that the costs of controlling dpm should not factor into the human cost of overexposure to dpm.

In light of these comments, and the statute, MSHA did consider whether it would be feasible for the underground coal mining industry to meet tighter requirements than the 2.5 gm/hr standard chosen. However, as discussed in Part V concerning feasibility, MSHA recognizes that the underground coal mining community has certain other relatively new standards with which to comply and others pending; moreover, the dpm exposure generated by permissible equipment is only one dpm source in many mines that needs to be addressed. Accordingly, the agency believes that an effort to force technology on paper filters at this time would not be warranted.

How the mining community can go about implementing this requirement, and how MSHA can help. As explained above, MSHA has verified that a commercially available paper filter can reduce the emissions of any permissible piece of equipment to 2.5 grams per hour, and so has set the limit at that point. But the rule itself provides flexibility of controls, and there are many aftertreatment products on the market. Thus both MSHA and operators need a way to know whether a particular combination of controls will limit emissions to 2.5 grams per hour.

The emission rate of a machine will be determined by the engine baseline dpm concentration determined during the MSHA engine approval process. The engine baseline dpm data for each MSHA approved engine is already known to the Agency. For the convenience of the mining community, the Agency is adding this information to its approval listings currently on the agency's web site. This information for permissible engines is located at http://www.msha.gov/S&HINFO/DESLREG/1907b5.HTM.

Under the final rule, an operator can purchase any commercially available aftertreatment device and would, upon a request from MSHA, have to provide evidence that the device would reduce the emissions of the machine on which it is to be installed to the emission standard. However, in a majority of cases the mine operator will not be required to submit any data nor have any aftertreatment device tested. This is because MSHA will accept as evidence of compliance the use of any paper filter which meets or exceeds the specifications of the paper filter used in the verification described above; and, as noted in the discussion of that test, it appears that *most current paper filters designed to reduce dpm use exactly the same paper as that used in the system tested.* Thus, a mine operator can add almost any current paper filter to permissible machines without additional filter tests and be in compliance with the machine emission limit.

It should be remembered, however, that the agency has established criteria for filter media intended for use on permissible equipment that go beyond filtration efficiency. These criteria were established to ensure that the addition of the filter would not compromise the permissibility features of the machine. MSHA will continue to apply these criteria in conjunction with this rule. A list of paper filters meeting the permissibility criteria and which have the required efficiency will be posted on the MSHA web site as this information becomes available.

As noted above, MSHA's verification was conducted on a system whose exhaust was cooled by a heat exchanger, not a system whose exhaust was cooled by a water scrubber. MSHA recognizes that most permissible equipment is cooled by a water scrubber, and that MSHA has not verified filter performance with a water scrubber system actually in place. For the reasons noted, the agency has concluded that such verification is not feasible at this time. Since such verification is not feasible at this time, for purposes of implementing the rule, MSHA will assume that the results achieved with a filter tested on a dry exhaust cooling system apply equally to a system in which the exhaust is cooled by a water scrubber.

The modifications required for the addition of a paper filter to the permissible machines can be made without any additional filter efficiency tests being conducted by the mine operator or machine manufacturer. The addition of a paper filter to the exhaust of the existing permissible machines would be evidence that those machines meet the 2.5 gm/hr standard. The mine operator would simply purchase a paper filter kit from the manufacturer of the permissible machine or perform a field modification to add an equivalent paper filter to the permissible machines. Since the machines are permissible, any modifications would have to be evaluated to make sure that the permissibility aspects of the diesel power package are not affected. This would normally involve evaluation of the machine's total backpressure and the addition of a high temperature exhaust gas sensor to the safety shutdown system.

The process that mine operators may elect to follow to demonstrate compliance with the dpm standard is very similar to the process MSHA established for existing permissible machines when the 1996 diesel equipment rule was implemented. MSHA had four engines tested to determine a gaseous ventilation rate and particulate index for those engines. Mine operators only needed to update the machine approval plate to show the newly determined gaseous ventilation rate to continue to operate the existing permissible machine. The machine manufacturer normally supplied the updated plate.

To demonstrate compliance with the dpm rule, the mine operator need only add a filter kit supplied by the equipment manufacturer. Filter kits which have been evaluated for permissibility are available from machine manufacturers for approximately 222 out of the 481 permissible machines that are not already equipped with filters. In the event that a kit is not available for a particular machine, the mine operator may work with the machine manufacturer to adapt an existing kit, or fabricate a special kit. MSHA will expedite the evaluation of field modifications submitted by mine operators to add such kits.

One commenter stated that MSHA has not done enough with its knowledgeable personnel and research facility, and indicated that industry would welcome the opportunity to develop with MSHA research and development programs in the area of dpm filtration. MSHA has worked with NIOSH, labor representatives, and the industry in the past and is committed to continue to work with these groups on projects which promote a safer mining environment. The Diesel Toolbox arose out of just such an effort, as described in part II. But the Agency must also act to require the use of existing technology when it determines that miners are at significant risk of a material impairment to their health.

One concern expressed by the mining community about more extensive reliance upon paper filtration systems is the increased potential for fires if, for example, water scrubbers run dry and the exhaust gases then become hot enough to ignite the paper filters. Several commenters expressed concerns about reports of fires that occurred on permissible diesel powered equipment on which paper particulate filters had been installed. Commenters told of fires on equipment in both western and eastern mines and further stated that the fires were the result of a lack of maintenance. While MSHA is concerned about all fires in underground mines, fires on permissible equipment are of particular concern because that equipment may operate in areas of the mine where methane may be present.

Shortly after particulate filters were introduced, MSHA received reports of a filter fire in an underground mine and at a surface facility of a second mine. In the latter incident, the machine operator was unaware that a filter had been installed and continued to operate the equipment on the surface without water in the water scrubber. After looking into the incidents, MSHA issued a Program Information Bulletin informing the mining community of the importance of maintaining those components of permissible diesel power packages that limit the exhaust gas temperature below 170 degrees Fahrenheit. This PIB, P92–17, was published on October 23, 1992, and was given wide distribution throughout the country.

Until the public hearings on this rule, MSHA was not aware of any additional filter fires. MSHA has no additional information concerning incidents of fires in mines involving permissible diesel equipment with particulate filters. Maintenance personnel at one mine had related that several filters had been exposed to high exhaust gas temperatures and that the filter media had started smoldering. The smoldering had been accompanied by significant amounts of smoke which alerted the equipment operators. The equipment operators removed the filters and extinguished the smoldering material before any actual fire broke out. According to mine maintenance personnel, these incidents had occurred several years ago, and since improved maintenance procedures were established and additional training had been provided, no additional problems had been noted.

MSHA has continued to investigate this matter because of the potential consequences of a filter fire underground. MSHA is aware of a filter media used in Australia for the same application on permissible diesel equipment. The media is called Filtrete and is manufactured by 3M. The media is polypropylene and when exposed to a heat source, the media reportedly melts away rather than burns. Reportedly, the filter media is as effective at removing diesel particulate as the filters currently used on diesels with water scrubber systems. MSHA is in contact with the filter manufacturer, and with Australian mine regulatory authorities, and mine operators concerning their experience with the filters. MSHA has also reviewed the flammability characteristics of the filter media used on dry type permissible diesels. One such media is a fiberglass/polyester fabric which seems to have flammability characteristics similar to the Filtrete media.

As noted by at least one commenter, observing the recent diesel equipment maintenance requirements should minimize the already small potential for any problems. Nevertheless, MSHA will continue to look at alternative media, if for no other reason that to ascertain if they perform better than paper filters in removing dpm from the engine emissions.

Although operators can comply with this requirement by using a paper filter, MSHA would like to encourage the introduction of cleaner engines in permissible equipment. The rule does not deal directly with factors which may be discouraging operators from using engines which incorporate the latest technologies to reduce dpm emissions. In order for an engine to be used in underground coal mines in permissible equipment, the engine has to be approved by MSHA for permissible applications, and this process operates at the initiative of engine manufacturers rather than mine operators. MSHA notes that even though engine manufacturers are producing significantly cleaner diesel engines, engine manufacturers have not submitted applications to MSHA to have these newer engines approved for permissible applications prior to this final rule. There are 528 permissible diesel powered machines in underground coal mines. The majority of the permissible machines use the Caterpillar 3306 PCNA, Caterpillar 3304 PCNA, or the Deutz-MWM 916–6 diesel engines as stated previously. These engines are of older technology design and produce almost 10 times the dpm emissions as modern engines. However, due to the costs of obtaining approval of an engine for permissible applications, which are borne by the applicant, and low sales volumes in underground coal for permissible machines, engine manufacturers are understandably reluctant to submit new technology engines for approval as permissible.

MSHA is developing programs that would facilitate the availability of engines that utilize the latest technologies to reduce gaseous and particulate emissions for use in permissible equipment. Current engine designs that utilize low emissions technologies are currently approved by MSHA in nonpermissible form. Particulate emissions are currently being determined by third parties testing under 30 CFR, Part 7. MSHA is in the process of purchasing an engine particulate testing system. Once this system is installed, MSHA will be able to facilitate testing and defer some of the cost of diesel engine particulate emission testing at its Approval and Testing Center. MSHA is considering a number of other programs that could aid the industry with emission tests.

One of the programs that MSHA is considering would follow the precedent established in the recently published diesel equipment rule. To facilitate compliance with this dpm rule, MSHA is considering funding the additional emissions testing needed to gain approval as permissible, certain

previously approved, non-permissible engines that utilize low emissions technology engines. Additionally, MSHA is considering waiving the normal fees that the Agency charges for the administrative and technical evaluation portion of the approval process.

Alternatively, MSHA may relax, as an interim measure, the requirement that engine approvals be issued only to engine manufacturers. This requirement, stated in part 7, is intended to ensure that the party to whom the engine approval is granted has the ability to ensure that the engine is manufactured in the approved configuration. MSHA is considering a program in which an equipment manufacturer may utilize an engine, approved by MSHA as nonpermissible, in a permissible power package. MSHA would ensure that the additional emissions tests required for permissible engines are conducted as part of the power package approval process. The use of an engine previously approved as nonpermissible is a critical element of the program. For those engines, the engine manufacturer has already made the commitment to manufacture the engine in an approved configuration. The permissible configuration would be the same as the nonpermissible configuration. Provisions of the two programs could be combined. MSHA will solicit input from the mining community as it continues to develop these program concepts.

In response to comments, MSHA also took another look at the other components added to diesel engines of permissible equipment. One such control on permissible equipment is the device used to cool the hot gases emitted by diesel engines to the temperatures required for permissible applications. Specifically, in order to use a paper filter, a means of cooling the exhaust gas must be installed upstream of the paper filter to reduce the exhaust temperature below the ignition temperature of filter media. This is accomplished on permissible machines with either a water scrubber or a heat exchanger. The water scrubber allows the water to contact the exhaust, thus cooling the exhaust to less than 170° F. The heat exchanger cools without direct contact between water and the exhaust, thus providing a dryer exhaust. Research conducted by others has shown that water scrubbers can lower dpm concentrations by 20–30%. The Southwest verification showed that a heat exchanger can remove approximately 9% of the dpm. Either cooling method would reduce dpm to some degree; however MSHA is confident, and the SwRI tests clearly showed, that the majority of the filtering comes from the paper filter.

One commenter asserted that the most important emissions control that could be placed on a piece of diesel equipment is a catalytic converter. While there is some evidence in the record suggesting that OCCs can remove up to 20% of dpm emissions, this commenter's assertions about the importance of this control appear to stem from the view that the hazards to miners from diesel emissions come primarily from diesel gases rather than the particulate emissions. As indicated in MSHA's risk assessment, the risks which MSHA is acting to prevent in this case are from particulate emissions. Catalytic converters alone could not reduce dpm emissions from permissible equipment to levels that MSHA deems necessary.

Time frames for implementation. Commenters were also concerned that the 18-month time frame established in the proposed rule to bring existing fleets into compliance would not be feasible.

In part, these concerns stemmed from technological feasibility—that controls did not yet exist which would be available by the required time. Also, these concerns related to economic feasibility. As noted above, some commenters thought they would have to replace wet systems with a dry system package in order to comply with the proposed rule; such a changeover would be expensive and, given the amount of work involved, take time. Others were concerned about the availability of filtration systems that would fit existing systems and the time necessary to develop or rig systems to fit on a variety of existing machines underground.

The evidence discussed above addresses these concerns. MSHA is not pushing technology with the proposed emissions limit; rather, the technology is already here and for many pieces of equipment already in kit form for ready installation. The costs to the industry as a whole of adding paper filter to the permissible fleet after 18 months are economically feasible as well.

Moreover, the final rule requires that a permissible piece of equipment being ''introduced'' underground for the first time 60 days after this rule is promulgated will have to be so equipped.

MSHA means by ''introduced'' any equipment added to the mine's diesel equipment inventory. That inventory, and any changes to it, must be recorded by an operator as a result of this rulemaking and be maintained pursuant to new 30 CFR 72.520. ''Introduced'' means newly purchased equipment, used equipment, or a piece of equipment receiving a replacement engine with a different serial number than the engine it is replacing, including engines or equipment coming from one mine into another. It does not include a piece of equipment whose engine was previously part of the mine's inventory and rebuilt.

As a result of the information discussed above, MSHA has determined that this requirement is both technologically and economically feasible to require any newly introduced equipment to have the filter in place (see MSHA's REA for additional information). MSHA recognizes that in some areas, longwall moving equipment may be shared among mines, and that in one or two cases a scheduled longwall move could be impacted by this effective date; however, MSHA has concluded that by working with machine manufacturers, operators who find themselves in such a situation can avoid any disruptions.

72.501 Emission Limits for Nonpermissible Heavy Duty Diesel Powered Equipment, Generators, and Compressors

Organization. MSHA proposed limits on the dpm emitted by nonpermissible heavy-duty vehicles as part of 30 CFR 72.500, but in the final rule MSHA moved these requirements to a new 30 CFR 72.501. Also, this section now contains requirements for two types of light-duty equipment whose operating characteristics produce large quantities of dpm.

Summary of final rule. In the final rule, MSHA has adopted a machine emission limit for heavy duty diesel powered equipment, as defined by § 75.1908(a), just as it is doing with permissible equipment pursuant to § 72.500 of this final rule. It also applies this limit to generators and compressors.

Paragraph (a) specifies a machine emission limit for dpm at 5.0 gm/hr for heavy-duty equipment, generators or compressors introduced into an underground area of an underground coal mine more than 60 days after the date of publication of this final rule. ''Introduced'' means any equipment added to the mine's diesel equipment inventory.

Paragraph (b) provides that the fleet of such equipment already in a mine must reach a machine emission limit for dpm at 5.0 gm/hr within 30 months.

Paragraph (c) provides that the emission limit for all such equipment is further reduced to 2.5 gm/hr after 4 years.

Paragraph (d) exempts from the requirements of the rule any generator

or compressor that discharges its exhaust directly into intake air that is coursed directly into a return air course, or discharges its exhaust directly into a return air course.

Why dpm emissions from heavy-duty equipment, generators and compressors need to be controlled.

As discussed in connection with § 72.500, MSHA determined that it could not establish a dpm concentration limit for underground coal mines, and therefore needed to focus its attention on the control of dpm emissions from specific types of equipment.

The preamble accompanying the proposed rule also explained why the agency was proposing to limit the emissions from heavy-duty equipment in particular. MSHA discussed earlier in the permissible section that engines used in permissible equipment generated large quantities of dpm. Many pieces of heavy-duty equipment utilize the same engines as permissible equipment and consequently produce similar high levels of dpm. MSHA closely examined the dpm emission rates from engines used in other heavy-duty equipment and found them to be as high as those rates found in permissible equipment. Furthermore, heavy-duty equipment is used in areas of the mine where the ventilation quantities may be less than those provided where permissible equipment is used. Equipment that moves long wall components is known to work at a high duty cycle, in close proximity to miners, and in areas of the mine where there are frequent ventilation interruptions. Numerous commenters stated that diesel emissions continue to be the cause of air quality problems during long wall moves. Even though newer engines are being added to the heavy duty fleet, additional controls are needed to further reduce the dpm levels to which miners are exposed. As shown in table IV–1, engines like the Deutz BF4M1012EC rated at 113hp and the Detroit Diesel Series 40 DDEC rated at 230 horsepower are low emission engines that have been designed to meet current EPA standards. However, the gm/hr levels are still higher than the MSHA standards and would require aftertreatment controls.

The proposed rule did not cover generators and compressors. However, the extension of the heavy duty requirements to generators and compressors stems directly from a question MSHA placed before the mining community. In reviewing alternative approaches considered by the Agency, the preamble of the proposed rule (63 FR 17564) noted that light-duty equipment does contribute to the total particulate concentration in underground coal mines, and explored the possibility of requiring light-duty equipment to be treated like permissible and heavy-duty equipment. The agency noted that it had tentatively concluded that requiring controls for the whole light duty fleet may not be feasible for the underground coal sector at this time. In this regard, it should be noted that light-duty equipment in underground coal mines makes up approximately ⅔ of the whole fleet: 2,030 engines out of the total MSHA inventory of 3121.

The Agency stated that it welcomed ''information about light-duty equipment which may be making a particularly significant contribution to dpm emissions in particular mines or particular situations, and which is likely to continue to do so after full implementation of the approval requirements of the diesel equipment rule.'' The Agency went on to say that: ''MSHA will consider including in the final rule filtration requirements that may be necessary to address any such identified problem.'' This discussion was repeated in the section by section review of the proposed rule. (63 FR 17556) The Agency reiterated its request for comments in this regard in its Questions and Answers (Q and A #10, 63 FR 17499).

As discussed below, based on the record, MSHA has concluded that generators and compressors, while considered light-duty equipment for purposes of the diesel equipment rule, in fact have operating characteristics that produce large quantities of dpm, and should be controlled in the same manner as heavy-duty equipment.

Numerous commenters spoke on the issue of whether light-duty equipment, as defined by the diesel equipment rule, should be subject to dpm emissions standards. However, the record is divided between those who asserted that this type of equipment really operates much like heavy-duty equipment—*i.e.,* works many hours during a shift at high loads—and those who asserted that the equipment is normally used at low loads and very little during the day. Very limited data was provided by proponents of either position; not enough for MSHA to make a clear determination of which position to adopt when looking at light-duty equipment as a whole.

Based on the record, MSHA believes that light-duty equipment is used in a variety of ways dependent on individual mine situations. The engine loading dependent on mine conditions can play an important role in the emissions from the diesel. Two different mining conditions with identical equipment could experience vastly different emission levels from these engines due to the engine load that must be produced to complete the work. Therefore the commenters may be correct for their individual mines where the light-duty equipment must work at higher engine loads to complete the work. However, other miners with identical equipment may not experience the same degree of engine load which could result in lower levels of exhaust emissions.

However, the situation becomes much clearer when the focus narrows to specific types of light-duty equipment. For example, one commenter noted that some light-duty equipment (such as air compressors) which was exempt from requirements in the proposed rule, emitted high levels of dpm as determined by emission analyzers. Another commenter stated that larger engines that have heavy duty loads produce more dpm per hour and should be controlled. The commenter specifically recommended an OCC, adequate ventilation, and soot (dpm) filters.

After a review of the information available, MSHA has concluded that air compressors and generators emit more dpm in the mine environment than other light-duty equipment because their engines are operated continuously under high-load conditions when they are running. Generators are designed to run under a loaded condition to produce electricity and air compressors work at full load to produce compressed air. In both cases, these engines are operating at a high load, which contributes to high dpm emissions. Based on the information provided by a commenter that the gaseous emissions levels from air compressors were high, this would correlate with high engine load and also would be related to higher dpm emissions. In addition, generators and compressors can use very large horsepower engines, *i.e.* above 200 horsepower; by comparison, permissible equipment generally does not exceed 150 horsepower. In fact, some of the highest horsepower engines in underground coal mines are in generators and compressors. For example, in Table IV–1 engines that are known to be used in generators and compressors are represented by approval numbers B018, B037, and B036 and have horsepower ratings of 500, 275, and 220, respectively. Accordingly, in the final rule MSHA requires that air compressors and the generators meet the same engine emission limits as established for heavy-duty equipment. MSHA's inventory indicates that there are 66 air

compressors and generators out of a total of 3,121 pieces of diesel-powered equipment in underground coal mines—about 3% of the 2,096 light duty units.

Why the final rule uses a machine-based emission limit instead of requiring for a high-efficiency filtration system.

The proposed rule would have required mine operators by 30 months from the date of publication of the final rule to install, on nonpermissible heavy-duty vehicles, a system capable of removing, on average, at least 95% of dpm by mass.

The use of a machine emissions limit in the final rule stems directly from an alternative which MSHA placed before the mining community in the preamble to the filter-efficiency based proposed rule. In that preamble, the Agency requested comment on an alternative approach that would establish a machine based limit on emissions in lieu of a filter efficiency requirement (see, *e.g.,* 63 FR 17556, 17563). In fact, a separate ''Question and Answer'' was included in the preamble to highlight this alternative, immediately after the description of the proposed rule. 63 FR 17501, 17653. Based on the record, MSHA has concluded that the original proposal had deficiencies (such as a credit for clean engines and a variety of filter efficiencies) which are avoided by the alternative approach.

As explained in connection with § 72.500, based on the record developed, the Agency concluded that a machine based emissions limit avoids a number of problems with the approach initially proposed. The explanation provided in that discussion as to (1) why MSHA moved to a machine based emissions limit for permissible equipment; (2) why it decided not to make adjustments for ventilation or permit an exemption for enclosed cabs; and (3) the flexibility in choice of controls provided to operators, is fully applicable for heavy-duty equipment, and accordingly is not repeated.

Why MSHA concluded that the emissions limit for heavy-duty equipment, generators and compressors should ultimately be 2.5 grams per hour. As with permissible equipment, the emissions limit for this type of equipment was determined with reference to technological and economic feasibility. As is evident from the final rule, the emissions limit is 2.5 grams/hour, the same as the permissible limit; and, like permissible equipment, 2.5 grams/hour represents a 95% reduction in the dpm emissions of the engine that produced the most dpm emission in this category.

MSHA wishes to emphasize that despite this fact, the limit in the final rule was not merely a determination to use the proposed rule in another form, or to have an equivalency between permissible equipment and this equipment. Rather, once MSHA decided to use an emissions limit approach, it reviewed the record to determine what could feasibly be achieved with the controls available for this type of equipment. Instead of using paper filters as with permissible equipment, this kind of equipment would generally be filtered by ceramic or other hot gas filters—or systems that lower the temperature of the emissions so that paper filters can be used. Ceramic filters cost more than paper filters, require regeneration, and have certain other associated costs. On the other hand, unlike the permissible fleet, the fleet of heavy-duty equipment, generators and compressors has many choices of approved engines available for use, many of them modern technology engines with significantly lower emission rates than the engines currently utilized in this equipment.

Table IV–1 shows the current dpm emissions from MSHA's inventory of heavy-duty equipment, generators and compressors based on engine approval data, and shows the filter efficiency required to reduce those emissions to the interim and final limits required by the final rule. Based on information about the current efficiencies of hot gas filters (discussed in the next section), MSHA believes that a significant percentage of the current fleet can immediately meet a limit of 2.5 grams/hour with such filters alone—and all of the current fleet, except equipment powered by the Caterpillar 3306PCTA, can move immediately to meet a limit of 5.0 grams/hour with filters of only that efficiency. And even in the highly unlikely case that filter efficiency does not continue to improve to meet new demands in Europe and for over the road hauling in the United States, operators can bring the remainder of the fleet into compliance with new engines and filters with present day performance capabilities. In fact, the only reason for the two-tiered approach adopted in the final rule is to ensure that implementation of the rule will be economically feasible.

Some commenters stated that the proposed rule is technology forcing and would require manufacturers to conduct approval tests to market new products, although some commenters who made this observation conceded that MSHA had the legal right to force technology. Another commenter stated that all heavy-duty equipment would require heat exchangers or equivalent means to allow for the use of paper filters since these, in the views of that commenter, appear at present to have higher filter efficiencies.

These comments have some credibility with respect to the original proposal, which would in essence have required the engines that produce the most dpm emission in this category to achieve a limit of 2.5 grams/hour with filters alone; although as noted above, there are already some hot gas filters that are approaching this result. However, the machine emission limits set forth in this section are clearly feasible with current technology, as cleaner, approved nonpermissible engines are available should a piece of equipment not be able to reduce dpm to the required limit with filter alone.

A number of commenters argued that MSHA should not establish a rule which might rely heavily on the availability of ceramic filters because such systems have not performed well from either a practical or efficiency standpoint. MSHA has been aware that in many cases the industry, especially the metal/nonmetal mining sector, has had problems with the use of ceramic filters. However, these problems were reported over 10 years ago when the ceramic filter technology was originally being developed for the on-highway truck engines. When the highway truck sector did not need ceramic traps to comply with the on-highway EPA regulations, significant work on these trap systems was abandoned for the on-highway sector.

More recently, the European directive requiring filters on diesels in confined areas, Canadian mines research with dpm filters, and the continued US efforts to reduce dpm emissions in the environment, have led filter manufacturers to improve the performance and reliability of ceramic filters. Some M/NM mines have reported favorably on the use of ceramic traps. Aftertreatment control vendors, mine operators and VERT have reported filter life of over 8000 hours. After a review of the information in the record in this regard, as was described in more detail in section 6 of Part II, MSHA has concluded that the more recent work with ceramic traps has shown they are feasible for use by the underground coal mining industry.

How the mining community can go about implementing this requirement, and how MSHA can help. While the rule provides flexibility of controls to reach the required limit (controls that reduce engine emissions, that is), most operators are going to utilize hot gas (ceramic) filters to comply. In some

cases, however, installation of a cleaner engine or the DST® or similar modified dry system (one without the permissibility components) may be more cost effective, and will be permitted under this machine based rule. Therefore to determine whether a particular machine is in compliance, MSHA will generally need to know the emissions from the engine in the equipment and the filtration efficiency of the filter.

The dpm emission rate of an engine will be established by the dpm concentration determined during the engine approval process. The engine baseline dpm data for each MSHA approved non-permissible engine will be posted on the MSHA homepage at http://www.msha.gov/S&HINFO/DESLREG/1909a.HTM.

Unlike the situation at present with permissible engines, in which none of the cleaner technology engines manufactured in recent years has been submitted for approval for permissible use, engine manufacturers have been submitting applications for approval of nonpermissible engines which meet EPA standards for both on road and nonroad applications. Thus, mine operators have the option of significantly reducing dpm emissions from heavy-duty equipment, generators and compressors by switching to cleaner approved engines. Moreover, MSHA is planning to accelerate the process of approving such engines so as to ensure that equipment of all sizes and shapes can utilize the cleanest engines available.

MSHA is developing a program which will streamline the procedures by which manufacturers of diesel engines intended for use in outby areas of underground coal mines can gain Agency approval. The program will draw on the EPA approval programs for engines used in off-road applications. MSHA will continue to issue approvals for mining engines, but the application process will be abbreviated. Many of the provisions of part 7 are intended to ensure that engines continue to be manufactured in the same configuration and with the same emissions as the engine tested by MSHA. Procedures within the EPA approval programs reach the same end. Additionally, EPA has the resources and the regulatory authority to conduct an extensive quality assurance program to monitor emissions from production engines.

In addition to streamlining the application process, MSHA will establish a program under which the engine emission tests conducted for EPA approval will satisfy the part 7 testing requirements. The test cycles under which emissions are tested for both MSHA and EPA are identical, and the gaseous emission results from the EPA tests can be used to establish the ventilating air quantity that appears on the engine approval plate and is referenced in mine ventilation regulations. MSHA will announce the specifics of the program when it is finalized.

As noted in the prior section, MSHA expects that most operators will turn first to hot gas filters to reach the interim or even the final limit. Technically, an operator using a commercial filtration device would, upon a request from MSHA, have to provide evidence that the device is capable of reducing the emissions of the machine on which it is to be installed to the emission standard. The procedures by which a mine operator will demonstrate compliance with the rule are described in detail in the discussion of 30 CFR 72.503 of this part. However, the particulate removal efficiency of many commercially available hot gas filters is evaluated by VERT. VERT is a joint project of several European regulatory agencies, and private companies involved in the tunneling industry. VERT maintains facilities for the testing and evaluation of diesel engine aftertreatment devices for use on equipment used in tunneling. MSHA will accept dpm filtration efficiencies determined by VERT under the provisions of 30 CFR 72.503(c) of this rule.

VERT evaluates the filtration efficiency of candidate devices using a diesel engine with an average dpm production of 0.08 gr/hp-hr. This engine produces less dpm than the majority of engines approved by MSHA. As further discussed in section 72.503, the test must be conducted on an engine that emits no more dpm than the engine that the aftertreatment device will be used on in the machine. This is to ensure that ''dirty'' engines are not used to over estimate a filter efficiency. The VERT engine used is considered a clean engine by current production standards and clean when compared to many engines in the current underground fleet. The assigned filter efficiencies from VERT would not be considered over-rated and would be consistent with expected efficiencies when used on current underground engines. Consequently, the filter efficiency determined by VERT test can be used to establish the machine dpm level in order to comply with 72.503(b)(i).

MSHA received some comments suggesting the agency could not rely upon the most recent VERT test data (listed in Table II–4) because not enough is known about how those results were derived. MSHA agrees that more information about the test data would be useful; however, given the purposes for which the agency is relying upon the data, the agency believes the information it currently has on the test data are adequate. This information is discussed in section 6 of Part II. The VERT data is generated through procedures as stringent as those MSHA is requiring in the tests which are being established in the final rule for filters not tested by such an organization. While the results noted in Table II–4 have not been incorporated into a published article and has references that are in other sources, MSHA's review of other VERT papers shows that VERT is using the same nomenclature in all their reports and the pertinent information needed from the table is available from these other VERT papers. The table shows VERT results on filters tested ''new'' and after field test. MSHA is only concerned with the ''new'' filter efficiency data for applying a filter efficiency number to the baseline engine emission data in order to determine if the machine meets the machine emission limit specified in this final rule. The range of filter efficiencies is not critical since the operator can choose a filter system based on the need for the engine for each individual machine.

MSHA will maintain a list of dpm filtration devices and their filtration efficiencies on its website at www.msha.gov to assist the mining community. Where the particulate reduction capability of an aftertreatment device is not known, the operator would have to have the system tested at a laboratory capable of performing the tests as described in 30 CFR 72.503 of this rule to obtain the necessary data. However, in a majority of cases the mine operator will not be required to submit any data nor have the aftertreatment device tested. Since ceramic filters are used in general industry and automotive applications worldwide, extensive information on filter efficiency is available and a variety of hot gas filters are commercially available.

The two tier machine emission limits provide operators with a choice when making initial control decisions—whether to select a control that will bring the equipment into compliance with the interim limit first, or whether to go ahead and purchase controls that will be required in any event by the final emissions limit. MSHA envisions that the mine operator will in most cases make a single decision as to the options to select to bring the machine into compliance. If the machine is old

and is expected to reach the end of its useful life in 4 years or less, the mine operator may choose a less costly set of options with the intention to scrap the machine when the lower emission level is effective. However, if the machine has a life expectancy beyond four years, then the mine operator may choose to install a filter system/engine combination that will meet the 2.5 gm/hr standard immediately. Moreover, MSHA has reviewed the VERT list and it identifies several filter systems that can be purchased that have sufficient efficiency ratings to meet the 2.5 gm/hr standard when matched to the majority of the MSHA approved engines in heavy-duty equipment, generators and compressors. MSHA anticipates that more such high efficiency filters will become available before the final emissions limit must be reached. Accordingly, some operators may be able to satisfy the requirements in this fashion.

Yet another alternative that can currently enable heavy-duty equipment to reach the 2.5 gm/hr final limit is the DST® system. Test data was submitted for the record showing an overall system efficiency of greater than 95%. While more costly than hot gas filters, this approach might in some cases be cheaper than a high efficiency hot gas filter and a new engine.

The final rule prohibits any piece of nonpermissible heavy duty diesel powered equipment, generator or compressor, from exceeding 5.0 grams per hour of diesel particulate emissions. MSHA believes that by working with manufacturers of aftertreatment systems, filters can be installed so that newly manufactured machines comply with this requirement. MSHA expects that new equipment, or any equipment with an expected service greater than four years will be provided with a filter capable of meeting the 2.5 gm/hr machine standard.

Section 72.502 Requirements for nonpermissible light-duty diesel powered equipment other than generators and compressors

Organization. The proposed rule did not contain specific provisions for light-duty diesel powered equipment. However, in the preamble to the rule, the agency asked the mining community if light-duty equipment should be subject to provisions that would address dpm emissions. This section is new in the final rule and is based on the large response from the mining community to that question.

Summary of final rule. Paragraph (a) of this section provides that light-duty equipment (other than generators or compressors, which are covered by 30 CFR 72.501) introduced into an underground area of an underground coal mine more than 60 days after the issuance of the final rule cannot emit more than 5.0 grams/hour of dpm. MSHA means by ''introduced'' any equipment added to the mine's diesel equipment inventory. That inventory, and any changes to it, must be recorded by an operator as a result of this rulemaking and be maintained pursuant to new 30 CFR 72.520. This includes newly purchased equipment, used equipment, or a piece of equipment receiving a replacement engine with a different serial number than the engine it is replacing, including engines or equipment coming from one mine into another, but it does not include a piece of equipment whose engine was previously part of the mine's inventory and rebuilt. MSHA will exempt newly manufactured light-duty equipment from meeting the requirements in 30 CFR 72.502, if the equipment is received after the 60 day time frame as long as a mine operator can present evidence that the equipment was ordered prior to the date of publication of this final rule.

Paragraph (b) provides that an engine will be deemed to be in compliance with this requirement if it meets or exceeds certain EPA dpm emission requirements listed in Table 72.502–1 which appears in the rule.

Paragraph (c) excludes any diesel-powered ambulance or fire fighting equipment that is being used in accordance with the mine fire fighting and evacuation plan from the requirements of this section.

Why the final rule covers newly introduced light-duty equipment. The final rule's coverage of newly introduced light-duty equipment stems directly from an alternative which MSHA placed before the mining community in the preamble to the filter-efficiency based rule that was proposed.

In reviewing alternative approaches considered by the Agency, the preamble of the proposed rule (63 FR 17564) noted that light-duty equipment does contribute to the total particulate concentration in underground coal mines, and explored the possibility of requiring light-duty equipment to be treated like permissible and heavy-duty equipment. The agency noted that it had tentatively concluded that requiring controls for the whole light duty fleet may not be feasible for the underground coal sector at this time. In this regard, it should be noted that this type of equipment in underground coal mines makes up approximately ⅔ of the whole fleet: 2096 engines out of the total MSHA inventory of 3121.

The preamble further stated that the Agency welcomed ''information about light-duty equipment which may be making a particularly significant contribution to dpm emissions in particular mines or particular situations, and which is likely to continue to do so after full implementation of the approval requirements of the diesel equipment rule''. As noted in connection with 30 CFR 72.501, the record on this point led MSHA to treat light duty generators and compressors the same way as heavy duty nonpermissible equipment in the final rule.

The preamble to the proposed rule also indicated MSHA's specific interest in exploring whether it would be feasible to require controls on just the new equipment being added to the light duty fleet. ''The Agency would also welcome comment on whether it would be feasible for this sector to implement a requirement that any new light-duty equipment added to a mine's fleet be filtered.'' The Agency further noted that limiting a filtering requirement to just this portion of the light duty fleet was a different issue in terms of economic feasibility than filtering the whole fleet. ''By way of rough cost estimate, if turnover is only 10% a year, for example, the cost of such an approach would be only about a tenth of that for filtering all light-duty outby.'' 63 FR 17564. This discussion was repeated in the section by section review of the proposed rule. (63 FR 17556) The Agency reiterated its request for comments in this regard in its Questions and Answers (Q and A #10, 63 FR 17499).

As noted in the discussion of 30 CFR 72.501 of this part, MSHA received considerable comment on whether the light duty fleet as a whole should be covered. In a significant number of mines, the light duty fleet may work under heavy loads for considerable periods of time, resulting in localized intensive exposures. But it would also appear that in other mines this is not the case; moreover, many of the experiences with localized exposures may have been due to maintenance problems, as the diesel equipment rule with its requirements for maintenance had yet to go into effect.

Also, many miners commented that large numbers of light-duty equipment were in the same area of the mine on occasion and their emissions were not adequately diluted by the ventilation air provided. MSHA believes these comments were made based on experience gained before the effective date of the ventilation requirements under the diesel equipment rule.

Section 70.1900(a)(4) of the diesel equipment rule now allows the district manager to establish areas in the mine where air quality samples for gases must be collected to identify and correct problems such as those described. Even though the focus in 30 CFR 70.1900(a)(4) is on gaseous emissions, the point is that a buildup of gaseous emissions would be an indication of a build up of diesel emissions generally and thus, of the inadequate ventilation that was the concern of the commenters.

The comments about the light duty fleet as a whole were not particularly helpful in evaluating the agency's specific request for comment on whether it would be feasible for this sector to implement a requirement that the emissions from any new light-duty equipment added to a mine's fleet be limited. Nevertheless, as noted in Part III, the best available evidence is that a significant risk of adverse health effects due to dpm exposures will remain even after this rule will be implemented. Since the Agency is under a legal obligation to eliminate significant risks to the extent feasible, the Agency determined it should conduct a further analysis of the feasibility of limiting emissions from newly introduced light-duty equipment into underground coal mines. The service life of light-duty equipment (*e.g.,* pickup trucks) is roughly ten years—much shorter than other types of equipment which is often rebuilt underground. Accordingly, if the engines in the new equipment are cleaner than the ones in the old equipment, the dpm emissions in the mine can be lowered over this period of time without the need to place controls on the existing fleet.

MSHA then examined the kinds of engines that were likely to be in new light-duty equipment, as compared with the engines in the current light duty fleet. It turns out that there is likely to be a major difference. Many of the engines in the current fleet were designed and produced before the advent of EPA emission standards. Almost all of those engines likely to be available for introduction underground in the future will be subject to such standards. Accordingly, MSHA has determined that if newly introduced light duty engines or equipment are limited to more recent models, the dpm emissions from the new light duty fleet will eventually be significantly less than from the current fleet. The service life of light-duty equipment (*e.g.,* pickup trucks) is roughly ten years—much shorter than other types of equipment which is often rebuilt underground. As explained in the next section of this discussion, MSHA determined that requiring all light-duty equipment introduced underground in the future to comply with these standards is feasible; the engines required to meet the requirement are available in all types and sizes. Accordingly, the agency decided that the record warranted adoption of the alternative it had placed before the mining community, and the final rule establishes emission standards for newly introduced light-duty equipment.

How did MSHA determine the emissions limit for newly introduced light-duty equipment? MSHA examined whether it could establish the standard for newly introduced light-duty equipment at the same level as the standard it is establishing for newly introduced heavy-duty equipment, generators and compressors. In this regard, the agency looked at two sets of existing requirements to determine what types of engines used in light-duty equipment are readily available today, and then set the standard accordingly. First, the agency looked at current MSHA approval standards, and then it looked at current EPA standards.

The record indicated that equipment in the light duty fleet may be used to the extent that the dpm emissions from these vehicles could contribute to overall mine air quality in a manner similar to heavy-duty equipment. However, an equal number of commenters stated that light-duty vehicles are not used very much except for transporting miners in, out, and around the mine on a limited basis. MSHA believes that mines utilizes their light duty fleet in various ways depending on the individual mine conditions, fleet management, and standard operating practices. Also MSHA believes that many light-duty vehicles are operated in areas of the mine where the ventilation rate exceeds the approval plate quantities. Because MSHA did not receive sufficient information to establish the need to control dpm emissions from light-duty equipment to the same degree as required for heavy duty or permissible equipment, MSHA established a new approach. MSHA determined that no action needs to be taken to modify equipment in the existing light duty fleet. However, MHSA wanted to ensure that steps be taken to limit the dpm emissions from any light-duty equipment introduced into mines. The steps would include purchasing equipment that uses engines representative of the state-of-the-art in emission control that are commercially available. These engines would be the type that are being manufactured to comply with the current EPA standards for diesel engines for both on-highway and nonroad applications. MSHA also recognized that manufacturers of mine specific vehicles currently utilize engines of older design that would not meet the EPA standards. Manufacturers of this equipment could continue to use these engines with appropriate after treatment of the exhaust to limit the dpm emissions.

In its deliberations to determine the emissions standard that was required to be met by heavy-duty equipment, MSHA also determined that engines in existing light-duty equipment could be provided with commercially available aftertreatment controls to reduce the dpm emissions to 5.0 gm/hr. In fact, some light-duty equipment with relatively low horsepower engines can meet a 5.0 gm/hr standard without any aftertreatment controls.

Some existing light-duty equipment built specifically for mine use is representative of equipment that will probably continue to be introduced into the mines. This type of light-duty equipment will continue to use engines that would not meet the EPA dpm standards. Hence for any such equipment introduced into an underground coal mine after the effective date, aftertreatment will be required.

Consequently, MSHA established the 5.0 gm/hr standard for any light-duty equipment introduced into mines after the effective date of the rule.

As stated above, part of the approach established by MSHA for light-duty equipment was to ensure that introduced light-duty equipment would be provided with engines representative of the state of the art in emission control that are commercially available. These engines would be the type that are being manufactured to comply with the current EPA standards for diesel engines for both on-highway and nonroad applications.

As noted in section 5 of Part II, the EPA emission standards are established for light-duty vehicles and trucks, heavy duty highway engines, and nonroad engines. These requirements take effect for new production runs of engines at various times depending on engine type and size. MSHA recognizes that introduced equipment provided with these engines may exceed the 5.0 gm/hr standard. However, the engines being built to meet the EPA standards represent the state of the art in emission controls that are feasible to limit diesel exhaust emissions for those sizes of engines. MSHA did not intend to require aftertreatment controls on introduced light-duty equipment. MSHA believes that as long as mine

operators purchase equipment with these new engines, the in-mine dpm concentrations will be reduced as the existing light-duty equipment fleet is replaced.

MSHA has established an exception in 30 CFR 72.502(b) that would allow mine operators to introduce equipment powered by engines that meet the EPA standards listed in Table 72.502–1 in lieu of meeting the 5.0 gm/hr standard given in 72.502(a). MSHA also knows that the EPA intends to tighten the emission standards for new diesel engines. As engines meeting these future requirements are produced, they will also become available for use in mining equipment, thus the overall contribution of dpm from the in-mine light-duty equipment should decrease even further.

MSHA has already approved engines produced by a variety of engine manufacturers in a wide range of horsepowers that meet the EPA standards listed in Table 72.502–1 of this part. These engines are shown on Table IV–1 by an asterisk (*).

Many pickup trucks used in underground coal mines use engines that would be classified by the EPA as ''heavy duty highway engines''. Consequently, if the engine was produced after 1994, it has met the EPA emissions standard of 0.1 g/bhp-hr shown in table 72.502–1. MSHA believes that the mining community is not likely to have any problem finding a pickup truck that meets the standard. Many pickup trucks can be moved from mine to mine and meet the standard.

This is basically the same for any on-highway engine the EPA classifies as a ''light-duty vehicle'' or ''light duty trucks''. If manufactured in or after model year 1994, the vehicle or truck must be limited to a dpm output of 0.1 gr/mile and meets the EPA requirement. However, there are no such vehicles currently in use in mines.

Mine operators frequently purchase equipment for use in underground coal mines that come with engines which are categorized by EPA as nonroad engines for use in underground coal mines. This includes both industrial equipment and mine specific equipment such as forklifts, rockdusters, tractors, pumps, manlifts, personnel carriers, and welders. EPA's requirements on nonroad engines vary by horsepower. As discussed in part II of this preamble, EPA originally regulated these engines at standards referred to as tier 1. The most recent standards that are scheduled to become effective for these engines are designated as tier 2 standards. Many of the engines used in this equipment will soon be meeting the EPA tier 2 dpm limits as a result of the 1998 rulemaking by that agency. MSHA chose the tier 2 standards in 30 CFR 72.502(b) of this part since they will represent the most advanced technologies for emission controls. As previously stated, some nonroad engines are already being produced which meet the tier 2 requirements and have been approved by MSHA. Approximately two-thirds of the nonpermissible MSHA approved engines meet the tier 2 standards. The exact EPA emission limits for each tier for each engine size category are listed in Table 72.502–1 of the final rule which is reproduced here in the preamble for reference:

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TABLE 72.502-1: EPA's Requirements on Nonroad Engines

EPA Requirement	EPA Category		PM Limit
40 CFR 86.094-8(a)(1)(I)(A)(*2*)	light-duty vehicle		0.1 g/mile
40 CFR 86.094-9(a)(1)(I)(A)(*2*)	light duty truck		0.1 g/mile
40 CFR 86.094-11(a)(1)(iv)(B)	heavy duty highway engine		0.1 g/bhp-hr
40 CFR 89.112(a)	Tier 2 nonroad		varies by power:
	kW<8	(hp<11)	0.80 g/kW-hr (0.60 g/bhp-hr)
	8≤kW<19	(11≤hp<25)	0.80 g/kW-hr (0.60 g/bhp-hr)
	19≤kW<37	(25≤hp<50)	0.60 g/kW-hr (0.45 g/bhp-hr)
	37≤kW<75	(50≤hp<100)	0.40 g/kW-hr (0.30 g/bhp-hr)
	75≤kW<130	(100≤hp<175)	0.30 g/kW-hr (0.22 g/bhp-hr)
	130≤kW<225	(175≤hp<300)	0.20 g/kW-hr (0.15 g/bhp-hr)
	225≤kW<450	(300≤hp<600)	0.20 g/kW-hr (0.15 g/bhp-hr)

Notes: "g" means grams "kW" means kilowatt
"hp" means horsepower "g/kW-hr" means grams/kilowatt-hour
"g/bhp-hr" means grams/brake horsepower-hour

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In this final rule, operators have the option to meet the requirements of the standard by installing filters on newly introduced light-duty equipment. For example, an operator wishing to take an existing piece of light-duty equipment whose emissions exceed 5.0 grams/hour from one mine and use it in another mine could do so if the machine is equipped with a filter or catalytic converter efficient enough to bring the emissions down to 5.0 grams/hour. MSHA anticipates that the majority of mine operators will choose to purchase equipment with MSHA approved engines meeting the EPA dpm standards. Some models of small utility equipment might be difficult to filter, so the mine operator will probably choose to introduce this type of equipment with an engine that meets EPA requirements. However in some cases where an engine which complies with the 5.0 g/hr standard or the EPA requirements is too expensive or hard to use for a specific machine application, a filter system can be designed in during the construction of the vehicle instead of a retrofit.

The Agency wishes to emphasize that it is not barring operators from introducing used equipment into an underground coal mine simply because it is used. As noted in the examples above, many of these EPA requirements have been in place for a while, so operators should have a wide choice of equipment from which to choose, and in other cases there are MSHA approved engines that will meet the standards.

MSHA will undertake other actions to further facilitate compliance with this standard. As noted above, MSHA is enabling operators to comply with this standard by selecting engines or equipment that comply with various EPA standards. However, under the diesel equipment rule, all engines used underground have to be approved by MSHA. Accordingly, MSHA is reviewing actions that could be taken to facilitate the approval process when an engine meets EPA standards.

As was described earlier in the discussion of the heavy-duty equipment requirements, MSHA is developing a program which will streamline the procedures by which manufacturers of diesel engines intended for use in outby areas of underground coal mines can gain Agency approval. The program will draw on the EPA testing procedures (currently used only in the certification program for nonroad engines). MSHA will announce the specifics of the program when it is finalized. This program, when implemented, will assure mine operators and mining equipment manufacturers of the availability of low emissions engines, approved by both MSHA and EPA, in a wide range of horsepowers with which they can easily comply with the dpm requirements for light-duty equipment.

Exemption for ambulances and fire fighting equipment. Paragraph (c) of this section excludes from these requirements diesel powered ambulance and fire fighting equipment being used in accordance with the mine fire fighting and evacuation plan under 30 CFR 75.1101–23. This is done in the same manner as MSHA excluded this type of equipment in the diesel equipment rule. This exclusion ensures consistency between this rule and the diesel equipment rule.

Section 72.503 Determination of Emissions; Filter Maintenance

Organization. This section is added to the final rule to specify the means to determine and maintain compliance with the machine emission limits established in this part. The requirements of this section revise and refine provisions included in the proposal under 72.500(c) and (d). The requirements have been moved to a separate section because they are relevant to the requirements of several other sections—30 CFR 72.500, 72.501 and 72.502.

Engine emissions. Section 72.503(a) of the final rule specifies that the amount of dpm emitted by a particular engine shall be determined from the engine approval pursuant to 30 CFR 7.89(a)(9)(iii)(B) or 7.89(a)(9)(iv)(A), except for those engines in light-duty equipment deemed to be in compliance with the requirements of this rule pursuant to 30 CFR 72.502(b).

This approach using part 7 engine approval data was inherent in the requirements of proposed 30 CFR 70.500(d). The current formulation refines the requirement to make it more clear and extends coverage to the EPA approval program.

MSHA currently lists all part 7 engine approvals on the Internet. The web addresses have been previously listed in this section. To assist mine operators in complying with the provisions of this rule, MSHA will add the dpm grams per hour number for each approved engine based on the approval test data. This number is calculated from the equations in 30 CFR 7.89(a)(9)(iii)(B) or 7.89(a)(9)(iv)(A) which are direct results of tests conducted for determination of the particulate index. This value will be used as an engine's baseline dpm concentration; the efficiency of the filter will then be multiplied by this baseline dpm number to establish compliance with the machine's emission limit under the appropriate section of this rule. MSHA will use the gm/hr data obtained from the MSHA approval data and not the gm/hr data determined from other filter tests that determine the efficiency of the filter being tested. Results from different engine configurations or different laboratories could give results that could prevent the mine operator from showing compliance. The data could also be different if the tests were run differently from the approval test.

Laboratory test procedures for testing aftertreatment devices; MSHA acceptance of results of other organizations. Section 72.503(b) of this final rule provides that the efficiency of an aftertreatment device is to be established by a laboratory test with a device representative of that to be used—and not by an actual test at the mine site on a particular filter. The test of the aftertreatment device is to be on an approved engine that emits no more dpm than the engine in the machine on which the aftertreatment device is to be used. If the filter test were run on an engine with higher emissions, the filter is likely to be rated as having a higher efficiency than it does when installed on an engine that produces lower emissions. This is consistent with the views of those commenters who objected to the proposal to establish a 95% efficient filter standard on the grounds that they would not be able to maintain such an efficiency as cleaner engines are introduced. The engine is to be run on the same test cycle used for MSHA approvals. The test procedure to follow must be appropriate to the filter media being tested. Furthermore the test is to be done by a laboratory capable of testing engines in accordance with MSHA approval requirements, to ensure consistency among testing and results.

Although these requirements provide the specifications for filter efficiency tests, MSHA does not believe that many filter tests will need to be run in order for mine operators to comply with the requirements of this rule. A key reason is that 30 CFR 72.503(c) allows the Secretary to accept the results of tests conducted or certified by an organization whose testing standards are deemed by the Secretary to be as rigorous as those set forth in 30 CFR 72.503(b). Also, the Secretary may accept the results of tests for one aftertreatment device as evidencing the efficiency of another aftertreatment device which the Secretary determined to be essentially identical to the one tested.

With respect to hot gas filters, the agency has already indicated (in the discussion of 30 CFR part 72.501) its intention to accept the efficiency results of any filter tested by VERT—

notwithstanding their use of somewhat different test procedures. MSHA will provide additional information on how mine operators can easily obtain the filter efficiency data from VERT in the compliance guide for this rule.

Moreover, the record of this rulemaking contains data establishing the efficiency of both the DST® system and paper filters. Both of these were tested by SwRI in tests meeting the requirements of this section. MSHA has indicated (in the discussion of proposed section 72.500 of this part) that it will accept as having the same efficiency as the paper filter it tested, any filter using the same or equivalent media. Such filter paper appears to be used for the production of a variety of filters. Consequently, effective filters will be readily available.

The filter efficiency test procedure stated in this final rule is basically the same as that procedure specified in the proposal. This test procedure follows the test cycle specified in part 7, subpart E, for determination of the particulate index. This test is similar to the test procedure used by VERT. VERT has streamlined their test procedure to minimize testing time but retained the main dpm producing modes on the steady state test cycle. The MSHA test procedures in part 7, subpart E were originally adapted from the ISO 8178 procedures. VERT actually follows the test procedures in ISO 8178.

Several commenters questioned whether the ISO 8178 is an appropriate test for performing the filter efficiency tests, but offered no suggestions as to a cycle which should be used. Other commenters stated that the ISO 8178 is the best test at this point in time for conducting the filter efficiency test since no other cycle is available. Because ISO 8178 is an internationally accepted test cycle for evaluating diesel engine emissions, MSHA is retaining the ISO 8178 test procedure in this final rule. However the rule does allow the Secretary to accept data from tests.

MSHA will maintain a list (posted on its web site) of additional sources from which mine operators and inspectors can obtain the necessary information, including aftertreatment manufacturers who follow testing procedures MSHA deems meet its requirements. Mine operators will have to show evidence that for each particular machine, the engine baseline data multiplied by the filter efficiency will meet the appropriate standard. Any questions on acceptance of a filter manufacturer should be made prior to purchasing of the filter media. The mine operator may want to contact MSHA's approval and certification center located at Triadelphia, WVA to determine that the filter efficiency data is acceptable prior to purchasing, especially if the filter data is not from VERT or from a source listed by MSHA.

One commenter stated that industry was concerned that laboratory tests of filters may give invalid indication of filter efficiency. MSHA believes that the filter test should be appropriate to the media; that is the aftertreatment device should be tested with the contaminant that is being controlled. The aftertreatment industry has been testing filters in the laboratory for many years in development of their products. In the case of ceramic type filters, MSHA is not aware of any types of tests performed on ceramics that does not use dpm from the diesel exhaust. Aftertreatment control manufacturers that build dpm control devices test their systems for various applications worldwide, through both laboratory and field work.

Other types of filter media (*e.g.,* paper) have been developed by the mining industry for use on permissible equipment which is specific to mining. General industry does not use paper for dpm reduction due to the high exhaust gas temperatures from diesels. Paper filters are mainly produced as intake air cleaners and industry test standards for determining air cleaner efficiency are followed. Since these filters are mainly used for intake air filters, MSHA believes that industry standard intake air filter tests could be representative tests for this type of filter media when used for dpm reduction. MSHA would compare the paper specifications to determine equivalency. If the papers were equivalent, then air filter type tests would be acceptable to the Secretary for this type of media.

Aftertreatment device maintenance requirements. Section 72.503(d) of this rule states that any aftertreatment device installed on a piece of diesel equipment, upon which the operator relies to remove dpm, shall be maintained in accordance with manufacturer specifications and shall be free of observable defects. Except for the last phrase, which was added by MSHA in order to clarify the requirement for the mining community, this requirement was specified in the proposal under section 72.500(d).

One commenter requested that MSHA also require an on board engine performance and diagnostic system. MSHA is aware that some permissible machines have added electronic type shut down systems and electronic controlled fire suppression systems. On some newer nonpermissible engines, especially larger engines, engine manufacturers use electronic controls to regulate the engine's fuel injection timing and governing. Engines equipped with these electronic devices typically have complete diagnostic capability. MSHA believes as engine technologies develop, more engines will have diagnostic systems built in from the manufacturer. MSHA is not requiring in this final rule on board engine performance and diagnostic systems on equipment. However, MSHA will work with engine manufacturers under the part 7 approval process to evaluate new electronic controls, especially for permissible engines.

Other commenters stated that maintenance is part of the toolbox approach, and therefore ought not to be specifically included. MSHA has a requirement in the current diesel equipment rule to maintain diesel powered equipment in approved and safe condition or be removed from service. This final rule is extending the requirements for maintenance specifically to aftertreatment controls added to the machines to reduce dpm.

Section 72.510 Miners Health Training

Paragraph (a) of this section requires annual hazard awareness training of underground coal miners who can reasonably be expected to be exposed to dpm. Paragraph (b) includes provisions on records retention, access and transfer.

Section 72.510(a) of this rule would require any underground coal miner ''who can reasonably be expected to be exposed to diesel emissions'' be trained annually in: (1) The health risk associated with exposure to diesel particulate matter; (2) the methods used in the mine to control diesel particulate matter concentrations; (3) identification of the person responsible for maintaining those controls; and (4) actions miners must take to ensure the controls operate as intended. The final rule is the same as that proposed.

The purpose of these requirements is to promote miner awareness. Exposure to diesel particulate is associated with a number of harmful effects as discussed in Part III of this preamble, and the safe level is unknown. Miners who work in mines where they are exposed to this risk must be reminded of the dpm hazard to make them active and committed partners in implementing actions that will reduce that risk.

Several commenters expressed concern about which miners will be required to be trained. MSHA believes the rule is clear on this issue. The training need only be provided to underground miners who can reasonably be expected to be exposed to

dpm at the mine. The training is to be provided by the operator; hence, it is to be without cost to the miner.

The rule places no constraints on how the operator should conduct this training. MSHA believes that the required training can be provided with minimal cost and with minimal disruption. This final rule does not require any special qualifications for instructors, nor does it specify the hours of instruction.

One-on-one discussions that cover the required topics is one approach that can be used. Alternatively, instruction could take place at safety meetings before the shift begins. Several of the training requirements can be covered by simply providing miners with a copy of MSHA's ''toolbox.'' Operators may determine how the ''toolbox'' can be used at their mine.

The Agency requested comments concerning inclusion of dpm training in the required part 48 training plan. The only comment received suggested that this training be included in the part 48 training and removed from this rule. MSHA considered whether the requirements of part 48 were adequate to ensure the training required under the final diesel particulate standard. After careful consideration, MSHA concluded that available information provided to miners under current part 48 training would be inadequate to fully convey information under the diesel particulate final rule. MSHA will, however, accept part 48 training for compliance with diesel particulate training requirements under this section, provided mine operators fully integrate the requirements of diesel particulate training into their existing program.

Section 115 of the Federal Mine Safety and Health Act of 1977 and 30 CFR part 48, ''Training and Retraining of Miners,'' requires operators to submit to MSHA and obtain its approval of training plans under which miners are provided training, primarily through initial and annual refresher training courses. Part 48, among other things, also specifies qualifications for training instructors, minimum training hours for miners and instruction on particular topics which must be covered within the specified minimum training time. Existing section 48.8(a) establishes a minimum of eight hours of annual refresher training for underground miners. Section 48.8(b), specifies that underground miners must be trained on a minimum of eleven different subjects, none of which MSHA believes would cover the specific requirements for diesel particulate training.

Nevertheless, MSHA believes compliance with this proposal can in many cases be fulfilled at the same time as scheduled part 48 training. The Agency, however, does not believe special language is required in this final rule to permit this action under part 48. If incorporated into part 48, mine operators would, however, be required to submit a revised training plan to the appropriate MSHA district office for approval. Some mine operators, however, may not be able to incorporate these topics in their part 48 plans. MSHA has endeavored to make the training requirements as simple as possible. If conducted separately from part 48 training, there are no specifications on trainer qualifications, no minimal training time, nor any training plans. If, however, the training is incorporated into part 48, then all applicable part 48 requirements will have to be met.

A commenter expressed concerns about individual MSHA inspectors determining their own set of health risks for training purposes and then trying to cite a company for not training on those health risks. They also suggested that the Agency develop a ''Question and Answer'' document to address this problem. To address the mine operators concern about the training requirements, MSHA intends to develop an instruction outline that mine operators can use as a guide for training personnel. Instruction materials will also be provided with the outline. MSHA believes this will not only provide guidance to the mining industry but also to MSHA inspectors.

The final rule does not require the mine operator to separately certify the completion of the dpm training, but some evidence that the training took place would have to be produced upon request. A serial log with the employee's signature is an acceptable practice.

Section 72.510(a)(1) of this rule requires the operator to train underground miners who can reasonably be expected to be exposed to diesel emissions in the health risk associated with dpm exposure. Several commenters disagreed with this requirement. They do not believe the health risks associated with exposures to diesel emissions have been sufficiently identified. ''If the health effects have not been identified, how can effective training be provided to the effected miners?'' MSHA disagrees with this comment. MSHA believes, as throughly discussed in Part III of this preamble, that the health effects associated with diesel emissions have been well documented. Comments received during this rulemaking further support MSHA's position concerning health effects associated with diesel emissions. Therefore, the requirements for training underground miners who can be reasonably be expected to be exposed to diesel emissions have been retained in the final rule.

Section 72.510(a)(3) of this rule requires the operator to identify personnel responsible for maintaining the methods used to control dpm in the mine. Some commenters suggested removing this provision from the rule. These commenters objected to identifying the personnel responsible for maintaining the methods used to control dpm. Because they were concerned about having the employee, ''singled out from the remaining workforce.'' Another commenter, asked how MSHA wanted the operator to identify the employee responsible for maintaining dpm controls; is the name to be posted, made available to interested persons, put in the training plan, etc? While there is no provision in this final rule for posting the information on the mine bulletin board or in any other location, this information is required to be presented to any underground miner who can reasonably be expected to be exposed to diesel emissions. The final rule requires this information to be presented at least annually but does not specify any specific method for presenting the information. The operator has the option of presenting this information orally or in written form.

The Agency believes this provision is consistent with the requirements contained in 30 CFR 75.1915(c). 30 CFR 75.1915(c) requires the operator to maintain a record of persons qualified to perform maintenance, repairs, examinations and tests on diesel-powered equipment. The operator is also required by § 75.1915(c) to include a copy of the training program used to qualify persons to perform maintenance, repairs, examinations and tests in their records. Section 75.1915(c) also requires the operator to make this record available for inspection by an authorized representative of the Secretary of Labor. All records that would need to be maintained concerning the qualification of personnel responsible for maintaining dpm controls are contained in § 75.1915(c). The individuals identified by § 75.1915(c) would also be the individuals identified in § 72.510(a)(3). The requirement to identify personnel qualified to perform specialized tasks is not a novel approach. Therefore, § 72.510(a)(3) has not been changed or deleted from the final rule.

Section 72.510(b)(1) of this rule requires that any log or record produced signifying that the training has taken place would be retained for one year. A commenter stated other records are not required to be maintained and should not be required by this rule. Numerous training records are required to be maintained for a variety of training requirements throughout 30 CFR, and MSHA believes that retention of the record for one year is important for documentation purposes. Therefore, § 72.510(b)(1) of this rule was not changed from the proposed rule and is incorporated in this final rule.

The training records need to be where an inspector can view them during the course of an inspection, as the information in the record may determine how the inspection proceeds. If the mine site has a fax machine or computer terminal, MSHA would permit the record to be maintained elsewhere so long as they are readily accessible. This approach is consistent with the Office of Management and Budget Circular A–130 and 30 CFR 75.1915(c).

Paragraph (b)(2) of section 72.510 of this rule requires mine operators to provide prompt access to the training records upon request from an authorized representative of the Secretary of Labor, the Secretary of Health and Human Services, or from an authorized representative of the miners. If an operator ceases to do business, all training records of employees are expected to be transferred to any successor operator. The successor operator is expected to maintain those training records for the required one year period unless the successor operator has undertaken to retrain the employees. There were no comments received concerning the maintenance of records by a successor operator. Therefore, the final rule has adopted the wording as published in the proposed rule.

Section 72.520 Diesel Equipment Inventory

Proposed § 75.371(qq) would have required, ''A list of diesel-powered units used by the mine operator together with information about any unit's emission control or filtration system.'' One commenter stated that the proposal was vague and overly burdensome. The commenter also stated that exhaustive, detailed technical specifications were not needed in the approved ventilation plan. MSHA agrees with the comments and has changed the final rule to reflect what MSHA believes is necessary information to help evaluate the effectiveness of dpm controls in underground coal mines. By specifying the information required, MSHA has provided uniform guidance to the mining community as to the information required to be submitted in the diesel equipment inventory.

Another commenter suggested the information be provided and posted at the mine and made available to a representative of the Secretary and other interested person. Another commenter was concerned with the time delay in submitting an addendum to the ventilation plan and the approval of the plan. The commenter stated that this was not required of other equipment used underground and should not be required of diesel-powered equipment. Concerns were raised by several commenters about delays in the approval of revisions to the ventilation plan.

MSHA has taken these comments into consideration and in the final rule has removed the diesel equipment inventory provision from the Approved Ventilation Plan and established it as a separate requirement § 72.520. There was no intent to require that the inventory be approved, but rather to require the information to be provided to MSHA and the representatives of the miners. The final rule requires each mine operator to prepare and submit a diesel equipment inventory to the District Manager. It also clarifies the information that must be included in the inventory. This information must be accurate so that the appropriate emission controls can be matched with an engine and to ensure that the required emission rates during the phase-in period are met. If there are modifications to the inventory, such as equipment being added or deleted, or changes to emission control systems, these modification must be submitted to the District Manager within 6 months. If no changes to the inventory are made, there is no need to update the diesel equipment inventory. The final rule also requires that mine operators provide a copy the diesel equipment inventory to the representative of the miners within 3 days.

Effective Dates

The final rule provides that unless otherwise specified, its provisions take effect 60 days after the date of promulgation. Some provisions of the final rule contain delayed effective dates that provide more time for technical assistance to the operators. Table I–1 presents the effective dates of various provisions of the final rule is reproduced below for convenience.

BILLING CODE 4510–43–P

Table I-1

Type of Equipment	Emissions Limit	When Applicable (from date final rule published)
Permissible		
newly introduced	2.5 grams per hour	60 days
existing fleet	2.5 grams per hour	18 months
Heavy duty nonpermissible		
newly introduced	5.0 grams per hour	60 days
existing fleet (interim)	5.0 grams per hour	30 months
existing fleet (final)	2.5 grams per hour	4 years
Generators and compressors	same as heavy duty	same as heavy duty
Other light duty nonpermissible		
newly introduced	5.0 grams per hour (or listed EPA standards)	60 days
existing fleet	no requirements	

BILLING CODE 4510–43–C

The final rule stipulates that any piece of diesel-powered equipment introduced into an underground coal mine 60 days after the promulgation date of this final rule is required to meet specific emission limits. For equipment that is currently used in underground coal mines, the compliance dates vary with regards to the type of diesel-powered equipment used in underground coal mines. MSHA includes in the category of equipment currently in use in underground coal mines any equipment that is ordered on or before the promulgation date of this final rule, even if the delivery date is more that 60 days from the promulgation date. By treating equipment on order as equipment already in use, the Agency is allowing the operator to use the equipment as delivered by the equipment supplier. A valid purchase order would be required of the operator as evidence that the diesel-powered equipment was ordered on or before the promulgation date of the final rule.

The time frame of 60 days after the promulgation date of the final rule also applies to newly introduced diesel-powered equipment as a result of explicit effective dates in 30 CFR 72.500, 72.501, and 72.502 of this rule. Diesel-powered equipment that is introduced in an underground coal mine 60 days after the promulgation date of the final rule must emit no more than 2.5 grams per hour of dpm. The term ''introduced'' is defined in § 72.503(e) and is explained in the appropriate Section-by-Section discussion in this preamble.

Section 72.500(b) of this rule allows the operator 18 months from the promulgation date of the final rule to meet emission limits for permissible diesel-powered equipment currently in use in underground coal mines. Several commenters stated the 18 month time frame was insufficient to comply with the proposed rule. They suggested increasing the effective date to between 2 and 4 years from the promulgation date of the final rule. The proposed rule would have required, in part, a system capable of removing, on average, at least 95% of diesel particulate matter by mass. The only system reportedly available that achieved the filtration efficiency necessary, was the DST® system. As discussed elsewhere in this preamble, the final rule sets emission limits on diesel-powered equipment and allows the operator to use whatever diesel particulate reducing technologies available to meet the limits. Information submitted during the rule making process and verification testing conducted for MSHA, has identified that readily available paper filters can achieve the emission limits set for permissible diesel-powered equipment. Therefore, MSHA has retained the 18 month effective date for diesel-powered equipment currently in use in underground coal mines.

Section 72.501 of this rule addresses emission limits for nonpermissible heavy-duty diesel-powered equipment, generators and compressors. There are 3 time tables associated with these pieces of diesel-powered equipment. As with permissible diesel-powered equipment, all nonpermissible heavy-duty diesel powered equipment, generators and compressors introduced into an underground coal mine 60 days from the promulgation date of the final rule would be required to meet a specific dpm emission limit. As stated the final rule differs from the proposed rule, however, the compliance date for newly introduced diesel-powered equipment has not been changed.

The final rule allows 30 months from the promulgation date for the operator to reduce the emission levels to the levels required for newly introduced diesel-powered equipment. Some commenters believe this time frame should be increased to 3 to 4 years.

Another commenter stated the time frame for complying with the standard should be shortened. Based upon information obtained during the rule making process, MSHA believes the 30 month time table is adequate and reasonable to install the necessary particulate controls to comply with the required emission limits.

Section 72.501(c) of this final rule requires all nonpermissible heavy-duty diesel-powered equipment, generators and compressors to meet a stricter emission limit within 4 years after promulgation of the final rule. The proposed rule would have allowed 6 years to achieve these stricter limits. After reviewing the record, particularly information submitted by aftertreatment device manufacturers, MSHA has concluded that these stricter standards can be met in a shorter time frame. Discussions on these emission limits are covered in greater detail elsewhere in this preamble. Therefore, the effective date for the stricter emission limits was reduced from 6 years to 4 years.

Section 72.503 of this final rule addresses nonpermissible light-duty diesel-powered equipment other than generators and compressors. The proposed rule did not address nonpermissible light-duty diesel-powered equipment. As discussed earlier in the preamble, nonpermissible light-duty diesel-powered equipment has been included in this final rule. The final rule only addresses nonpermissible light-duty diesel-powered equipment that is introduced 60 days after the promulgation date of this final rule. Equipment currently in use in underground coal mines is excluded from meeting emission limits. Based upon information gathered during the rule making process, MSHA believes 60 days after the promulgation date of the final rule is reasonable and this requirement has been added to the final rule.

V. Adequacy of Protection and Feasibility of Final Rule; Alternatives Considered

The Mine Act requires that in promulgating a standard, the Secretary, based on the best available evidence, shall attain the highest degree of health and safety protection for the miner with feasibility a consideration.

Overview. This part begins with a summary of the pertinent legal requirements, followed by a general profile of the economic health and prospects of the coal mining industry.

The discussion then turns to the main component of the rule being promulgated by the Agency for underground coal mines. MSHA is requiring that mine operators limit the emissions of dpm to defined quantities for various categories of diesel equipment underground. This part evaluates the rule to ascertain if, as required by the statute, it achieves the highest degree of protection for underground coal miners that is both technologically and economically feasible for mine operators.

About half a dozen regulatory alternatives to the final rule were also reviewed by MSHA in light of the record. After considerable study, the Agency has concluded that compliance with these alternatives either provide less protection than the feasible approach being adopted, or are not technologically or economically feasible for the underground coal mining industry as a whole at this time.

Pertinent Legal Requirements. Section 101(a)(6)(A) of the Federal Mine Safety and Health Act of 1977 (Mine Act) states that the Secretary of Labor (Secretary) in promulgating mandatory standards dealing with toxic materials or harmful physical agents under the Act, shall set standards when most:

> * * * [A]dequately assure, on the basis of the best available evidence, that no miner will suffer material impairment of health or functional capacity even if such miner has regular exposure to the hazards dealt with by such standard for the period of his working life.

The Mine Act also specifies that the Secretary, in promulgating these mandatory standards, must base such standards upon:

> * * * [R]esearch, demonstrations, experiments, and such other information as may be appropriate. In addition, to the attainment of the highest degree of health and safety protection for the miner, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws. Whenever practicable, the mandatory health or safety standard promulgated shall be expressed in terms of objective criteria and of the performance desired. [Section 101(a)(6)(A)].

Thus, the Mine Act requires that the Secretary, in promulgating a standard, based on the best available evidence, attain the highest degree of health and safety protection for the miner with feasibility a consideration.

In relation to feasibility, the legislative history of the Mine Act states that:

> * * * This section further provides that ''other considerations'' in the setting of health standards are ''the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws.'' While feasibility of the standard may be taken into consideration with respect to engineering controls, this factor should have a substantially less significant role. Thus, the Secretary may appropriately consider the state of the engineering art in industry at the time the standard is promulgated. However, as the circuit courts of appeal have recognized, occupational safety and health statutes should be viewed as ''technology-forcing'' legislation, and a proposed health standard should not be rejected as infeasible when the necessary technology looms in today's horizon. *AFL–CIO* v. *Brennan,* 530 F.2d 109 (1975); *Society of the Plastics Industry* v. *OSHA,* 509 F.2d 1301, *cert. denied,* 427 U.S. 992 (1975).

Similarly, information on the economic impact of a health standard which is provided to the Secretary of Labor at a hearing or during the public comment period, may be given weight by the Secretary. In adopting the language of [this section], the Committee wishes to emphasize that the agency rejects the view that cost benefit ratios alone may be the basis for depriving miners of the health protection which the law was intended to insure. S. Rep. No. 95–181, 95th Cong., 1st Sess. 21 (1977).

Court decisions have clarified the meaning of feasibility. The Supreme Court, in *American Textile Manufacturers' Institute* v. *Donovan* (OSHA Cotton Dust), 452 U.S. 490, 101 S.Ct. 2478 (1981), defined the word ''feasible'' as ''capable of being done, executed, or effected.'' The Court stated that a standard would not be considered economically feasible if an entire industry's competitive structure was threatened. According to the Court, the appropriate inquiry into a standard's economic feasibility is whether the standard is capable of being achieved.

Courts do not expect hard and precise predictions from agencies regarding feasibility. Congress intended for the ''arbitrary and capricious standard'' to be applied in judicial review of MSHA rulemaking (S.Rep. No. 95–181, at 21.) Under this standard, MSHA need only base its predictions on reasonable inferences drawn from the existing facts. MSHA is required to produce a reasonable assessment of the likely range of costs that a new standard will have on the industry. The agency must also show that a reasonable probability exists that the typical firm in the industry will be able to develop and install controls that will meet the standard. See, *Citizens to Preserve Overton Park* v. *Volpe,* 401 U.S. 402, 91 S.Ct. 814 (1971); *Baltimore Gas & Electric Co.* v. *NRDC,* 462 U.S. 87 103 S.Ct. 2246, (1983); *Motor Vehicle Manufacturers Assn.* v. *State Farm Mutual Automobile Insurance Co.,* 463

U.S. 29, 103 S.Ct. 2856 (1983); *International Ladies' Garment Workers' Union* v. *Donovan,* 722 F.2d 795, 232 U.S. App. D.C. 309 (1983), *cert. denied,* 469 U.S. 820 (1984); *Bowen* v. *American Hospital Assn.,* 476 U.S. 610, 106 S.Ct. 2101 (1986).

In developing a health standard, MSHA must also show that modern technology has at least conceived some industrial strategies or devices that are likely to be capable of meeting the standard, and which industry is generally capable of adopting. *United Steelworkers of America* v. *Marshall,* 647 F.2d 1189, 1272 (1980). If only the most technologically advanced companies in an industry are capable of meeting the standard, then that would be sufficient demonstration of feasibility (this would be true even if only some of the operations met the standard for some of the time). *American Iron and Steel Institute* v. *OSHA,* 577 F. 2d 825, (3d Cir. 1978); see also, *Industrial Union Department, AFL–CIO* v. *Hodgson,* 499 F. 2d 467 (1974).

Industry Profile. The industry profile provides background information describing the structure and economic characteristics of the coal mining industry. This information was considered by MSHA in reaching its conclusions about the economic feasibility of various regulatory alternatives.

MSHA divides the mining industry into two major segments based on commodity: (1) coal mines and (2) metal and nonmetal (M/NM) mines. These segments are further divided based on type of operation (*e.g.,* underground mines or surface mines). MSHA maintains its own data on mine type, size, and employment.

MSHA also collects data on the number of independent contractors and contractor employees by major industry segment.

MSHA categorizes mines by size based on employment. For the past 20 years, for rulemaking purposes, MSHA has consistently defined a small mine to be one that employs fewer than 20 workers and a large mine to be one that employs 20 or more workers. To comply with the requirements of the Small Business Regulatory Enforcement Fairness Act (SBREFA) amendments to the Regulatory Flexibility Act (RFA), however, an agency must use the Small Business Administration's (SBA's) criteria for a small entity—for mining, 500 or fewer employees—when determining a rule's economic impact.

Table V–1 presents the total number of small and large coal mines and the corresponding number of miners, excluding contractors, for the coal mining segment. This table uses three mine size categories based on the number of employees: (1) fewer than 20 employees (MSHA's traditional definition of small), (2) 20 to 500 employees (small according to SBA's definition) and (3) more than 500 employees. Table V–1 further disaggregates data by surface mines and underground mines, as well as (for employees) office workers. Table V–2 presents corresponding data on the number of independent contractors and their employees working in the coal mining segment.

Although this particular rulemaking does not apply to the surface coal sector, information about surface coal mines is provided here in order to give context for the discussions on underground mining.

TABLE V–1.—DISTRIBUTION OF COAL MINE OPERATIONS AND EMPLOYMENT (EXCLUDING CONTRACTORS) BY MINE TYPE AND SIZE [a]

Size of coal mine [b]		Mine type			
		Underground	Surface	Office workers	Total coal
Fewer Than 20 Employees	Mines	382	1,058	.....	1,438
	Employees	3,751	6,491	487	10,729
20 to 500 Employees	Mines	522	492	.....	1,014
	Employees	39,566	31,731	3,389	74,692
Over 500 Employees	Mines	6	1	.....	7
	Employees	3,459	510	189	4,158
All Coal Mines	Mines	910	1,549	.....	2,459
	Employees	46,776	38,738	4,065	89,579

[a] Source: U.S. Department of Labor, Mine Safety and Health Administration, Office of Standards, Regulations, and Variances based on 1998 MS data, CM441/CM935LA cycle 1998/198. Data for Total Office workers from Mine Injury and Worktime Quarterly (1997 Closeout Edition) Table 1, p. 5.

[b] Based on MSHA's traditional definition, large mines include all mines with 20 or more employees. Based on SBA's definition, as required by SBREFA, large mines include only mines with over 500 employees.

TABLE V–2.—DISTRIBUTION OF CONTRACTORS AND CONTRACTOR EMPLOYMENT BY SIZE OF OPERATION [a]

Size of contractor [b]		Contractors			
		Underground	Surface	Office workers	Total
Fewer Than 20 Employees	Mines	1,077	2,403	.....	3,480
	Employees	4,078	9,969	1,064	15,111
20 to 500 Employees	Mines	79	242	.....	321
	Employees	4,131	11,618	1,192	16,941
Over 500 Employees	Mines	.....	.....	.....	.....
	Employees	.....	.....	.....	.....
Total Contractors	Mines	1,156	2,645	.....	3,801
	Employees	8,209	32,052	2,256	30,052

[a] Source: U.S. Department of Labor, Mine Safety and Health Administration, Office of Standards, Regulations, and Variances based on 1998 MS data, CT441/CT935LA cycle 1998/198. Data for Total Office workers from Mine Injury and Worktime Quarterly (1998 Closeout Edition) Table 5, p. 20.

[b] Based on MSHA's traditional definition, large mines include all mines with 20 or more employees. Based on SBA's definition, as required by SBREFA, large mines include only mines with over 500 employees.

Agency data (Table V–1) indicate that there were about 2,459 coal mines in 1998. When applying MSHA's definition of a small mine (fewer than 20 workers), 1,438 (about 58%) were small mines and 1,021 (about 42%) were large.[82] Using SBA's definition, only 7 coal mines (0.3 percent) were large. These data show that employment at coal mines in 1998 was about 89,600, of which (by MSHA's definition) about 10,700 (12 percent) worked at small mines and 78,900 (88 percent) worked at large mines.[83] Using SBA's definition, 95 percent of coal miners worked at small mines and 5 percent worked at large mines. Using MSHA's definition, small coal mine average 7 employees, and large coal mines average 77 employees. Using SBA's definition, there are, on average, 35 employees in each small coal mine and 594 employees in each large coal mine. MSHA classifies the U.S. coal mining segment into two major commodity groups: bituminous and anthracite. About 92 percent of total coal production is bituminous. The remaining 8 percent is the product of lignite and anthracite mines.[84]

Mines east of the Mississippi accounted for about 49% of coal production in 1998. For the period 1949 through 1998, coal production east of the Mississippi River fluctuated relatively little, from a low of 395 million tons in 1954 to a high of 630 million tons in 1990; 1998 production was estimated at 571 million tons. Coal production west of the Mississippi, by contrast, increased each year from a low of 20 million tons in 1959 to a record high of 548 million tons in 1998.[85] The growth in western coal has been due, in part, to environmental concerns that led to increased demand for low-sulfur coal, which is abundant in the West.

In addition, surface mining, with its higher average productivity, is much more prevalent in the West. Surface mining methods for coal, which include drilling and blasting, are also practiced in surface mines for other commodity types. Most surface mines use front-end loaders, bulldozers, shovels, or trucks for haulage.

The U.S. coal sector produced a record 1.12 billion short tons of coal in 1998, at an average price of $17.58 per ton. The total value of U.S. coal production in 1998 was estimated as $19.7 billion. Small mines (by MSHA's definition) produced about 4 percent (40 million tons) of domestic coal production valued at $0.7 billion, and large mines (by MSHA's definition) produced about 96 percent (1.08 billion tons) valued at $19.0 billion.[86]

The U.S. coal industry enjoys a fairly constant domestic demand. Over 90 percent of U.S. coal demand was accounted for by electric utilities in 1998.[87] Due to the high conversion costs of changing a fuel source, MSHA does not expect a substantial change in coal demand by utility power plants in the near future.[88]

Adequacy of Miner Protection Provided by the Rule for Underground Coal Mines. In evaluating the protection provided by the rule, it should be noted that MSHA has measured dpm concentrations in production areas and haulageways of underground coal mines which exceed 2500_{DPM} μg/m³ with a mean concentration of 644_{DPM} μg/m³. See Table III–1 and Figure III–1 in part III of this preamble. As discussed in detail in part III of this preamble, these concentrations place underground coal miners at significant risk of material impairment of their health, and the evidence supports the proposition that reducing the exposure reduces the risk.

The final rule would require operators to limit the emissions of dpm emitted by various categories of equipment in underground coal mines—permissible, heavy duty (and compressors and generators), and other light duty. Equipment added to a mine's inventory more than 60 days after the rule is promulgated (or equipment already in the inventory but equipped with a new engine after that time), would have to comply with the appropriate standard. In addition, operators would have 18 months to bring the existing fleet of permissible diesel equipment into compliance with a 2.5 gr/hr emission standard. Operators would have an additional year (30 months from date of promulgation) to bring the existing fleet of heavy duty equipment (and generators and compressors) into compliance with a 5.0 gr/hr emission standard, and up to 4 years in all to bring that fleet down to a standard of 2.5 gr/hr.

As an example of how these emission standards can reduce dpm concentration levels in a section of an underground coal mine, take the case of a single-section mine with three Ramcars (94hp, indirect injection) and a section airflow of 45,000 cfm. MSHA measured concentrations of dpm in this mine at 610_{DPM} μg/m³. Of this amount, 25_{DPM} μg/m³ was coming from the intake to the section, and the remaining 585 $_{DPM}$ μg/m³ was emitted by the engines. Reducing the engine emissions by 95% through the use of commercially available paper filters would reduce the dpm emitted to 29_{DPM} μg/m³. With an intake amount of 25_{DPM} μg/m³, the ambient concentration would be about 54_{DPM} μg/m³. Similarly, dramatic results can be achieved in almost any situation by adding high efficiency aftertreatment filters or by replacing current engines in the fleet with a more recent generation.

While the reductions in section concentration from the controls required by the final rule can be significant, it is important to recognize that the actual reductions in a section will vary depending upon a number of factors.

In the first place, unlike the proposed rule, the final rule does not require current dpm emissions from each machine to be reduced by 95%. While the existing permissible fleet, and much of the existing heavy duty fleet, will need to reduce engine emissions significantly to come into compliance with the final standard, this will be feasible in many cases with a less efficient filter. A detailed table illustrating by how much the emissions from each current engine in the inventory must be reduced to achieve compliance is shown in table IV–1.

Second, while aftertreatment filters currently available are capable in laboratory tests of achieving a very significant reduction in dpm mass, and this has been confirmed in some field tests, the Agency has not tested filter efficiency under a variety of actual mining conditions. Therefore, actual performance may be different in the field due to individual mining

[82] U.S. Department of Labor, MSHA, 1998 Final MIS data CM441 cycle 1998/198.

[83] U.S. Department of Labor, MSHA, 1998 Final MIS data CM441 cycle 1998/198.

[84] U.S. Department of Energy, Energy Information Administration, *Annual Energy Review 1998*, July 1999, p. 191.

[85] U.S. Department of Energy, Energy Information Administration, *Annual Energy Review 1998*, July 1999, p. 191.

[86] U.S. Department of Energy, Energy Information Administration, *Annual Energy Review 1998*, July 1999, p. 203, U.S. Department of Energy, Energy Information Administration, *Coal Industry Annual 1997*, December 1998, pp. ix and 154, and U.S. Department of Labor, Mine Safety and Health Administration, Division of Mining Information Systems, 1998 Final MIS data (quarter 1–quarter 4) CM441 cycle 1998/198.

[87] U.S. Department of Energy, Energy Information Administration, *Annual Energy Review 1998*, July 1999, p. 187.

[88] U.S. Department of Energy, Energy Information Administration, *Annual Energy Outlook 2000*, p. 68.

conditions (*e.g.,* ventilation changes, changes of the equipment due to maintenance, and the type of engine used).

Third, the impact on a mine section of reduced emissions from a particular machine depends upon the ventilation rate and the ambient dpm intake into the section. If ventilation levels drop below the requirements established to control gaseous emissions, or if many pieces of equipment throughout the mine create a high ambient level of dpm, implementation of the rule may not bring concentrations down as effectively as suggested in the prior example. On the other hand, if the ventilation rate is maintained at a higher level, the emissions would be better diluted and the ambient concentration could offset any decrease in control efficiency under actual mining conditions. The intake of dpm to any section depends on what emissions are upstream. In this regard, it should be noted that the final rule does not require controls on the existing fleet of light-duty equipment, except for generators and compressors; hence, mines with significant light duty equipment will have this exhaust as an ''intake'' in such calculations.

Table V–3 summarizes information from a series of simulations designed to illustrate some of these variables. The simulations were performed using MSHA's ''Estimator''—a computerized spreadsheet designed to calculate dpm ambient levels from given equipment, and the impact of various controls on those ambient levels. (The Estimator was discussed in detail in an Appendix to the preamble to the proposed rule and has since been published (Haney and Saseen, April 2000)). The example simulated here involves a mine section with a 94 horsepower engine, with a 0.3 gm/hp-hr dpm emission rate and a nameplate airflow, 5500 cfm. The engine was operated during an eight hour shift. The Estimator was used to calculate the section concentrations with a paper filter at full laboratory efficiency (95%) and two lower filter efficiencies. The same results would be obtained for multiple pieces of equipment provided that the nameplate airflow is additive for each piece of equipment.

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Table V-3: Section DPM Concentrations for Various Airflow Rates, Afterfilter Efficiencies and Intake DPM Concentrations

Airflow	Intake DPM (µg/m³)	Resulting Section DPM Concentration (µg/m³)		
		85 Percent	90 Percent	95 Percent
		After-filter	After-filter	After-filter
1.0 x Nameplate Airflow	0	452	302	151
2.0 x Nameplate Airflow	0	226	151	75
3.0 x Nameplate Airflow	0	151	101	50
4.0 x Nameplate Airflow	0	113	75	38
1.0 x Nameplate Airflow	25	477	327	176
2.0 x Nameplate Airflow	25	251	176	100
3.0 x Nameplate Airflow	25	176	126	75
4.0 x Nameplate Airflow	25	138	100	63
1.0 x Nameplate Airflow	50	502	352	201
2.0 x Nameplate Airflow	50	276	201	125
3.0 x Nameplate Airflow	50	201	151	100
4.0 x Nameplate Airflow	50	163	125	88
1.0 x Nameplate	75	527	377	226
2.0 x Nameplate Airflow	75	301	226	150
3.0 x Nameplate Airflow	75	226	176	125
4.0 x Nameplate Airflow	75	188	150	113

* Emission rate - 0.3 gm/hp-hr
Airflow - 5500 cfm

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In Table V–3, the intake dpm (second column) increases after every fourth row. Within each group of four rows, the ventilation (first column) increases

from one row to the next. The last 3 columns display the ambient dpm concentration with a particular filter efficiency.

The first four rows represent a situation where there is no intake dpm. If the mine is ventilated with four times the nameplate airflow (row 4), the ambient dpm concentration using a filter operating at 95% (last column) is reduced to 38_{DPM} μg/m³. If the filter in this situation only works in practice at 85% efficiency in removing dpm, the ambient dpm concentration is only reduced to 113_{DPM} μg/m³. And if the ventilation is reduced to the nameplate airflow (first column) and the filter is only 85% efficient, the ambient dpm climbs to 452_{DPM} μg/m³.

The last four rows display the parallel situation but with an ambient intake concentration to the section of 75_{DPM} μg/m³. In this situation, depending on ventilation and filter effectiveness, the ambient dpm concentration ranges from 113_{DPM} to 527_{DPM} μg/m³.

In the example discussed above—a single section mine with three 94 hp Ramcars—the airflow of 45,000 cfm represents three times the current nameplate requirements. Many underground coal mines may use more than the nameplate ventilation to lower methane concentrations at the face. But if this airflow were reduced to the current nameplate requirements, the ambient dpm would have been 1620_{DPM} μg/m³, and would have been reduced by 95% effective filters to 105_{DPM} μg/m³.

Based on its experience as to the general effects of mining conditions on the expected efficiency of equipment, and on ventilation rates, MSHA has concluded that the rule for this sector will substantially reduce the concentrations of dpm to which underground coal miners are exposed.

Alternatives considered. In order to ensure that the maximum protection that is feasible for the underground mining industry as a whole is provided, the Agency has considered some alternatives. Most are discussed elsewhere in this preamble, but are briefly repeated here and illustrate the extensive thought MSHA gave to this issue.

(1) *Establish a Concentration Limit.* MSHA considered establishing a dpm concentration limit for this sector, as it is doing for underground metal and nonmetal mines. A concentration limit provides operators with flexibility to select any combination of controls that keep ambient dpm concentrations below the limit.

The agency has concluded that it is not yet technologically feasible to establish a dpm concentration limit for underground coal mines. The problem is that significant questions remain as to whether there is a sampling and analytical system that can provide consistent and accurate measurements of dpm in areas of underground coal mines where there is a heavy concentration of coal dust. The Agency is continuing to work on the technical issues involved, and should it determine that these technological problems have been resolved, it will notify the mining community and proceed accordingly.

(2) *95% Filters on Defined Categories of Equipment.* This is what the agency initially proposed for this sector. It has the advantage of ensuring that all controlled equipment is filtered, which some assert is easier to keep in proper shape through observation, and others believe provides more protection against nanoparticles. On the other hand, such an approach may quickly become technologically infeasible as newer, cleaner engines are introduced underground; removing 95% (or any defined percentage) of the lower emissions of these engines is likely to prove much more difficult. Moreover, this approach could act as a disincentive to introduce cleaner engines underground, and thus slow the reduction of dpm that such a replacement fleet might make possible. Finally, the Agency determined that at this time, there is not enough evidence about the risks of nanoparticles to regulate on that basis. Accordingly, the agency rejected this approach in order to avoid the problems associated with its implementation over the long term.

(3) *A machine-based emissions limit with credit for extra ventilation used in the mine.* Under this approach, if the bench test of the combined engine and filter package was conducted at the approval plate ventilation, a mine's use of more than that level of ventilation would be factored into the calculation of what package would be acceptable. So if, for example, an engine equipped with a ceramic filter can reduce emissions to 5.0 grams/hour in a test using the approval plate ventilation, and the mine actually ventilates at twice the name plate ventilation, the system would be deemed to reach 2.5 grams/hour under that circumstance. This alternative, however, is less protective than the rule adopted by the agency, as it would not require dpm emissions to be reduced as much. Accordingly, since the more protective alternative is feasible as well, it would be inappropriate under the law for the agency to adopt this alternative.

(4) *Adjust the Time-Frame for Implementation of the Final Rule.* The final rule will not be fully implemented for several years. The existing permissible fleet is given a full 18 months to comply, even though the agency has determined that there are readily available paper filters which can bring this equipment into compliance. The implementation schedule for the existing heavy duty fleet (and compressors and generators) extends for 4 years from the date of promulgation, even though the agency has concluded that there are hot gas filters readily available which can bring most of this equipment into compliance with the final emissions limit. Accordingly, the agency has considered whether a faster implementation schedule is feasible.

Cutting the 18 month time-frame for permissible equipment does not appear to be practicable for the industry. Eighteen months to obtain and install a relatively new technology is a reasonable time. Time is needed for operators to familiarize themselves with this technology. Also, mine personnel have to be trained in how to maintain control devices in working order. Moreover, MSHA needs time to work with the mining community to develop a revised approach to approving engines for use in permissible equipment in order to accelerate the introduction of a cleaner generation of engines into the permissible fleet.

With respect to the heavy duty fleet, the four years permitted to meet the final emissions limit is actually two years faster than originally proposed by the agency when 95% filters were being proposed. As indicated in section 6 of Part II of this preamble, the development of high efficiency hot gas filters has proceeded much faster than expected, so that it is technologically feasible to comply more quickly with this requirement than originally proposed. Moreover, MSHA has determined that the cost differential to the industry of reaching the final 2.5 micrograms/hour emission limit in 4 years instead of 6 is minor (see REA). However, MSHA has concluded that moving up the timeline further would create unwarranted difficulties for operators in terms of installing the required engines and filters, and accordingly has determined that further acceleration of this schedule would be infeasible.

(5) *Require Machine Emission Limits on all Diesel Equipment in Underground Coal Mines.* The final rule would not immediately apply to more than 60% of the fleet—light-duty equipment other than generators and compressors. Over time, the final rule would have an impact on the remaining light duty fleet through controls on any new equipment introduced underground, but it will take

many years before mine workers get the benefits of this approach. By contrast, the Commonwealth of Pennsylvania has recently adopted legislation for universal high-efficiency filtration based on an agreement in the mining community of that state. The Pennsylvania law requires that all diesel-powered equipment introduced into underground coal mines in that state (essentially all equipment, given the past ban), meet an emissions limit requirement (as well as a separate filter requirement).

One reason asserted for not covering all light duty equipment is that this equipment may run only intermittently, and under light loads, hence producing less dpm than other kinds of equipment. This proposition was supported by industry representatives during the rulemaking, and disputed by miners during the rulemaking proceedings. The Agency has not been able to draw any conclusions based on the mixed evidence as to the light duty fleet as a whole; as noted previously, it has carved out the 3% of the light duty fleet that clearly works like heavy duty equipment, and is covering them in this rule (generators and compressors).

A second issue is costs. The Agency decided to consider what it would take to bring the rest of the industry up to the standard established under the Pennsylvania agreement of universal coverage. MSHA has calculated that such a requirement would cost the underground coal industry an additional $9.7 to $17.4 million a year. This would be an increase of 135–240% of the cost of the rule for the underground coal mining industry. Since drawing conclusions concerning the level of dpm actually produced by light duty equipment in underground coal mines is difficult, the Agency has decided to take the approach of phasing in emission controls for light duty outby equipment over a period of five years. This approach significantly reduces the cost of the rule. Eventually, dpm exposures will be reduced for all miners in all areas of the mine.

(6) *Requiring certain engines to meet defined particulate emission standards.* As discussed in part II of this preamble, the Mine Safety and Health Advisory Committee on Standards and Regulations for Diesel-Powered Equipment in Underground Coal Mines recommended the establishment of a particulate index (PI), and MSHA did so in its diesel equipment rule. Under that rule, the PI establishes the amount of air required to dilute the dpm produced by an engine (as determined during its approval test under subpart E of part 7) to 1000 $\mu g/m^3$.

In the preamble of the diesel equipment rule, MSHA noted that mine operators and machine manufacturers would find it useful to consider the engine PI in selecting and purchasing decisions. The agency explicitly deferred until this rulemaking the question of whether to require engines used in mining environments to meet a particular PI.

In its final rule, the Agency is, in fact, using a significant portion of the concepts embodied in the particulate index. The determination of the quantity of dpm emitted from the machine is based on the information from the engine approval tests in 30 CFR 7.89 as was used to establish the particulate index. Both means of expressing the dpm characteristics of the machine begin with determining the total amount of dpm, expressed in grams/hour, produced by the engine over the test cycle described in ISO 8178. The particulate index is determined by calculating the quantity of air required to dilute that particulate to a concentration of 1 mg/m^3. The quantity of dpm emitted from the machine is determined by multiplying the quantity of dpm emitted from the engine by the filtration efficiency of the aftertreatment device.

Had the agency been able to utilize a concentration limit in this sector, the particulate index could have been used directly to compute an estimated level of dpm that could be achieved with various quantities of ventilation air. As noted above, however, that approach was found to be infeasible.

Feasibility of final rule for underground coal mining sector. The Agency has carefully considered both the technological and economic feasibility of the rule for the underground coal mining sector as a whole.

Although some doubts were expressed about this during the rulemaking proceedings, it is clear now that the technology exists to implement the final rule's requirements. As this preamble explains in overview in section 6 of Part II, and reiterates in connection with the specific requirements of the rule in Part IV, there are available emission controls which can bring all existing and contemplated future diesel equipment into compliance with the requirements of the rule. Paper filters have now been verified to reduce emissions from the dirtiest permissible engines to the required limit of 2.5 grams per hour. Ceramic filters have been certified by VERT to have the efficiency required to reduce emissions from the dirtiest heavy duty engines to the interim limit of 5.0 grams/hour, and for all but one engine to the final limit of 2.5 grams/hour. Approved engines that meet the emissions limit for newly introduced light duty equipment are available for all categories. And as MSHA and the mining industry work together to address aspects of the approval process that may be inhibiting the introduction of the newer generations of engines into underground mines, there should be no technological nor practical barriers to further emission limit reductions.

The economic feasibility of this rule has also been carefully considered by MSHA. The total for the final rule for underground coal mines will be about $7 million per year. The costs per dieselized mine are expected to be about $48,000 a year. MSHA has calculated that the costs of the final rule amount to less than one-quarter of one percent (0.23 percent) of the annual revenues of the dieselized underground coal mining sector. (The methodology for this calculation is discussed in Chapter IV of the Agency's REA). After reviewing the economic profile of that sector, and taking into account the cost of implementing the related diesel equipment rule, MSHA has concluded that the rule is economically feasible for this sector as a whole.

Conclusion: Underground Coal Mines. Based on the best evidence available to it at this time, the Agency has concluded that the final rule for the underground coal sector meets the statutory requirement that it attain the highest degree of health and safety protection for the miners in that sector, with feasibility a consideration.

VI. Regulatory Impact Analyses

This part of the preamble reviews several impact analyses which the Agency is required to provide in connection with its final rulemaking. The full text of these analyses can be found in the Agency's Regulatory Economic Analysis (REA).

(A) Costs and Benefits: Executive Order 12866

In accordance with Executive Order 12866, MSHA has prepared a Regulatory Economic Analysis (REA) of the estimated costs and benefits associated with the final rule for the underground coal sector.

The key conclusions of the REA are summarized, together with cost tables, in part I of this preamble (see Item number 7). The complete REA is part of the record of this rulemaking, and is available from MSHA.

The Agency considers this rulemaking ''significant'' under section 3(f) of Executive Order 12866, and has so

designated the rule in its semiannual regulatory agenda (RIN 1219–AA74). However, based upon the REA, MSHA has determined that the final rule does not constitute an ''economically significant'' regulatory action pursuant to section 3(f)(1) of Executive Order 12866.

(B) Regulatory Flexibility Certification.

The Regulatory Flexibility Act (RFA) requires regulatory agencies to consider a rule's economic impact on small entities. Under the RFA, MSHA must use the Small Business Administration's (SBA's) criterion for a small entity in determining a rule's economic impact unless, after consultation with the SBA Office of Advocacy, MSHA establishes an alternative definition for a small mine and publishes that definition in the **Federal Register** for notice and comment. For the mining industry, SBA defines ''small'' as a mine with 500 or fewer workers. MSHA traditionally has considered small mines to be those with fewer than 20 workers. To ensure that the final rule conforms with the RFA, MSHA has analyzed the economic impact of the final rule on mines with 500 or fewer workers (as well as on those with fewer than 20 workers).

MSHA has determined that the final rule would not have a significant economic impact on small mines, whether a small mine is defined as one with 500 or fewer workers or one with fewer than 20 workers.

Using the Agency's traditional definition of a small mine, which is one employing fewer than 20 workers, the estimated yearly cost of the final rule on small underground coal mines will be about $7,400. This estimated annualized cost for small mines compares to estimated annual revenues of approximately $9.1 million for the class of small underground coal mines.

Using SBA's definition of a small mine, which is one employing 500 or fewer workers, the estimated yearly cost of the final rule for all small underground coal mines would be about $6.1 million. This estimated cost for small mines compares to estimated annual revenues of approximately $2.95 billion for small underground coal mines, using SBA's criteria.

Based on its analysis, MSHA has determined that the final rule would not have a significant economic impact on a substantial number of small mines. MSHA has so certified these findings to the Small Business Administration. The factual basis for this certification is discussed in Chapter V of the REA for this rule.

(C) Unfunded Mandates Reform Act of 1995

For purposes of the Unfunded Mandates Reform Act of 1995, the final rule does not include any Federal mandate that may result in increased expenditures by State, local, or tribal governments, or increased expenditures by the private sector of more than $100 million.

(D) Paperwork Reduction Act of 1995

The final rule contains information collections which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA95). The final rule will impose paperwork burden hours on underground coal mine operators that use diesel powered equipment and on manufacturers of diesel powered equipment. For mine operators that use diesel powered equipment, the final rule imposes two types of burden hours. First, there are burden hours that will occur *only* in the first year the rule is in effect (hereafter known as first year burden hours). Second, there are burden hours that will occur *every* year that the rule is in effect, starting with the first year (hereafter known as ''annual'' burden hours). Manufacturers of diesel equipment that are affected by this rule, will incur only first year burden hours.

Mine Operators

First Year Burden Hours

In the first year that the rule takes effect, mine operators will incur 997 burden hours, which is composed of 349 first year burden hours (from Table VI–1) and 648 annual burden hours (from Table VI–1(a)). The related costs to mine operators will be $33,049, of which $12,627 is related to first year burden hours (from Table VI–1) and $20,422 is related to annual burden hours (from Table VI–1(a)).

Burden Hours After the First Year

Beginning in the second year the rule takes effect and continuing every year thereafter, mine operators will incur 648 burden hours and related costs of $20,422 (from Table VI–1(a)).

Manufacturers

First Year Burden Hours

In the first year that the rule is in effect, manufacturers will incur 700 burden hours and related costs of $35,000 (from Table VI–2). After the first year, manufacturers will not incur any burden hours or related costs.

TABLE VI–1.—MINE OPERATORS—FIRST YEAR BURDEN HOURS

Detail	<20 emp.		20 to 500 emp.		>500 emp.		Total	
	Hrs.	Costs	Hrs.	Costs	Hrs.	Costs	Hrs.	Costs
75.1915/72.503	1.0	$28	50	$1,299	1.0	$14	52	$1,341
72.510	0.6	29	11	568	0.1	4	12	602
72.520	9.0	399	267	10,027	9.0	257	285	10,684
Total	11.0	456	329	11,895	10.0	276	349	12,627

TABLE VI–1(a).—MINE OPERATORS—ANNUAL BURDEN HOURS

Detail	<20 emp.		20 to 500 emp.		>500 emp.		Total	
	Hrs.	Costs	Hrs.	Costs	Hrs.	Costs	Hrs.	Costs
72.510	5.0	$167	563	$17,971	28.0	$922	597	$19,061
72.1915/72.503	0	0	4	76	0.3	5	4	82
72.520	0.3	8	43	1,177	3.5	94	47	1,279
Total	5.0	176	610	19,225	32.0	1,021	648	20,422

TABLE VI–2.—MANUFACTURERS—ANNUAL BURDEN HOURS

Detail	Hrs.	Costs
Amended Applications	700	$35,000

The paperwork provisions for the proposed rule were approved under OMB Control Number 1219–0124. Our paperwork submission summarized above is explained in detail in the final REA. The REA includes the estimated costs and assumptions for each final paperwork requirement related to this final rule. A copy of the REA is available from us. This final rule is being submitted to OMB under the same control number. Respondents are not required to respond to any collection of information unless it displays a current valid OMB control number.

(E) National Environmental Protection Act

The National Environmental Policy Act (NEPA) of 1969 requires each Federal agency to consider the environmental effects of final actions and to prepare an Environmental Impact Statement on major actions significantly affecting the quality of the environment. MSHA has reviewed the final rule in accordance with NEPA requirements (42 U.S.C. 4321 *et seq.*), the regulations of the Council of Environmental Quality (40 CFR Part 1500), and the Department of Labor's NEPA procedures (29 CFR Part 11). As a result of this review, MSHA has determined that this rule will have no significant environmental impact.

(F) Executive Order 12360 Governmental Actions and Interference With Constitutionally Protected Property Rights

This final rule is not subject to Executive Order 12360, Governmental Actions and Interference with Constitutionally Protected Property Rights, because it does not involve implementation of a policy with takings implications.

(G) Executive Order 13045 Protection of Children from Environmental Health Risks and Safety Risks

In accordance with Executive Order 13045, MSHA has evaluated the environmental health and safety effects of the final rule on children. The Agency has determined that the rule will not have an adverse impact on children.

(H) Executive Order 12988 Civil Justice Reform

The Agency has reviewed Executive Order 12988, Civil Justice Reform, and determined that the final rule will not unduly burden the Federal court system. The rule has been written so as to provide a clear legal standard for affected conduct, and has been reviewed carefully to eliminate drafting errors and ambiguities.

(I) Executive Order 13084 Consultation and Coordination with Indian Tribal Governments

MSHA certifies that the final rule will not impose substantial direct compliance costs on Indian tribal governments.

(J) Executive Order 13132 Federalism

MSHA has reviewed the final rule in accordance with Executive Order 13132 regarding federalism and has determined that it does not have ''federalism implications.'' The final rule does not ''have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

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List of Subjects in 30 CFR Part 72

Coal, Health standards, Mine safety and health, Underground mines, Diesel particulate matter.

Dated: January 8, 2001.

Robert A. Elam,

Acting Assistant Secretary for Mine Safety and Health.

Chapter I of Title 30 of the Code of Federal Regulations is hereby amended as follows:

PART 72—[AMENDED]

1. The authority citation for Part 72 continues to read as follows:

Authority: 30 U.S.C. 811, 813(h), 957, 961.

2. Part 72 is amended by adding Subpart D to read as follows:

Subpart D—Diesel Particulate Matter—Underground Areas of Underground Coal Mines

72.500 Emission limits for permissible diesel-powered equipment.
72.501 Emission limits for nonpermissible heavy-duty diesel-powered equipment, generators and compressors.
72.502 Requirements for nonpermissible light-duty diesel-powered equipment other than generators and compressors.
72.503 Determination of emissions; filter maintenance; definition of ''introduced''.
72.510 Miner health training.
72.520 Diesel equipment inventory.

Subpart D—Diesel Particulate Matter—Underground Areas of Underground Coal Mines

§ 72.500 Emission limits for permissible diesel-powered equipment.

(a) Each piece of permissible diesel-powered equipment introduced into an underground area of an underground coal mine after March 20, 2001 must not emit no more than 2.5 grams per hour of diesel particulate matter.

(b) As of July 19, 2002, each piece of permissible diesel-powered equipment operated in an underground area of an underground coal mine must not emit no more than 2.5 grams per hour of diesel particulate matter.

§ 72.501 Emission limits for nonpermissible heavy-duty diesel-powered equipment, generators and compressors.

(a) Each piece of nonpermissible heavy-duty diesel-powered equipment (as defined by § 75.1908(a) of this part), generator or compressor introduced into an underground area of an underground coal mine after March 20, 2001 must not emit no more than 5.0 grams per hour of diesel particulate matter.

(b) As of July 21, 2003, each piece of nonpermissible heavy-duty diesel-powered equipment (as defined by § 75.1908(a) of this part), generator or compressor operated in an underground area of an underground coal mine must not emit no more than 5.0 grams per hour of diesel particulate matter.

(c) As of January 19, 2005, each piece of nonpermissible heavy-duty diesel-powered equipment (as defined by § 75.1908(a) of this part), generator or compressor operated in an underground area of an underground coal mine must not emit no more than 2.5 grams per hour of diesel particulate matter.

(d) Notwithstanding the other provisions of this section, a generator or compressor that discharges its exhaust directly into intake air that is coursed directly to a return air course, or discharges its exhaust directly into a return air course, is not subject to the applicable requirements of this section.

§ 72.502 Requirements for nonpermissible light-duty diesel-powered equipment other than generators and compressors.

(a) Each piece of nonpermissible light-duty diesel-powered equipment (as defined by § 75.1908(b) of this part), other than generators and compressors, introduced into an underground area of an underground coal mine after March 20, 2001 must not emit no more than 5.0 grams per hour of diesel particulate matter.

(b) A piece of nonpermissible light-duty diesel-powered equipment must be deemed to be in compliance with the requirements of paragraph (a) of this section if it utilizes an engine which meets or exceeds the applicable particulate matter emission requirements of the Environmental Protection Administration listed in Table 72.502–1, as follows:

TABLE 72.502–1

EPA requirement	EPA category	PM limit
40 CFR 86.094–8(a)(1)(I)(A)(2)	light duty vehicle	0.1 g/mile.
40 CFR 86.094–9(a)(1)(I)(A)(2)	light duty truck	0.1 g/mile.
40 CFR 86.094–11(a)(1)(iv)(B)	heavy duty highway engine	0.1 g/bhp-hr.
40 CFR 89.112(a)	Tier 2 nonroad	Varies by power:
	kW< (hp<11)	0.80 g/kW-hr (0.60 g/bhp-hr).
	8≤kW<19 (11≤hp<25)	0.80 g/kW-hr (0.60 g/bhp-hr).
	19≤kW<37 (25≤hp<50)	0.60 g/kW-hr (0.45 g/bhp-hr).
	37≤kW<75 (50≤hp<100)	0.40 g/kW-hr (0.30 g/bhp-hr).
	75≤kW<130 (100≤hp<175)	0.30 g/kW-hr (0.22 g/bhp-hr).
	130≤kW<225 (175≤hp<300)	0.20 g/kW-hr (0.15 g/bhp-hr).
	225≤kW<450 (300≤hp<600)	0.20 g/kW-hr (0.15 g/bhp-hr).

Notes: ''g'' means grams; ''kW'' means kilowatt; ''hp'' means horsepower; ''g/kW-hr'' means grams/kilowatt-hour; ''g/bhp-hr'' means grams/brake horsepower-hour.

(c) The requirements of this section do not apply to any diesel-powered ambulance or fire fighting equipment that is being used in accordance with the mine fire fighting and evacuation plan under § 75.1101–23.

§ 72.503 Determination of emissions; filter maintenance; definition of ''introduced''.

(a) MSHA will determine compliance with the emission requirements established by this part by using the amount of diesel particulate matter emitted by a particular engine determined from the engine approval pursuant to § 7.89(a)(9)(iii)(B) or § 7.89(a)(9)(iv)(A) of this title, with the exception of engines deemed to be in compliance by meeting the EPA requirements specified in Table 72.502–1 (§ 72.502(b)).

(b) Except as provided in paragraph (c) of this section, the amount by which an aftertreatment device can reduce engine emissions of diesel particulate matter as determined pursuant to paragraph (a) must be established by a laboratory test:

(1) on an approved engine which MSHA has determined, pursuant to paragraph (a) of this section, to emit no more diesel particulate matter than the engine being used in the piece of diesel-powered equipment in question;

(2) using the test cycle specified in Table E–3 of § 7.89 of this title, and following a test procedure appropriate for the filtration system, by a laboratory capable of testing engines in accordance with the requirements of Subpart E of part 7 of this title; and

(3) with an aftertreatment device representative of that being used on the piece of diesel-powered equipment in question.

(c) In lieu of the laboratory tests required by paragraph (b), the Secretary may accept the results of tests conducted or certified by an organization whose testing standards are deemed by the Secretary to be as rigorous as those set forth by paragraph (b) of this section; and further, the Secretary may accept the results of tests for one aftertreatment device as evidencing the efficiency of another aftertreatment device which the Secretary determines to be essentially identical to the one tested.

(d) Operators must maintain in accordance with manufacturer specifications and free of observable defects, any aftertreatment device installed on a piece of diesel equipment upon which the operator relies to remove diesel particulate matter from diesel emissions.

(e) For purposes of §§ 72.500(a), 72.501(a) and 72.502(a), the term ''introduced'' means any piece of equipment whose engine is a new addition to the underground inventory of engines of the mine in question, including newly purchased equipment, used equipment, and equipment receiving a replacement engine that has a different serial number than the engine it is replacing. ''Introduced'' does not include a piece of equipment whose engine was previously part of the mine inventory and rebuilt.

§ 72.510 Miner health training.

(a) Operators must provide annual training to all miners at a mine who can reasonably be expected to be exposed to diesel emissions on that property. The training must include—

(1) The health risks associated with exposure to diesel particulate matter;

(2) The methods used in the mine to control diesel particulate matter concentrations;

(3) Identification of the personnel responsible for maintaining those controls; and

(4) Actions miners must take to ensure the controls operate as intended.

(b)(1) An operator must keep a record of the training at the mine site for one year after completion of the training. An

operator may keep the record elsewhere if the record is immediately accessible from the mine site by electronic transmission.

(2) Upon request from an authorized representative of the Secretary of Labor, the Secretary of Health and Human Services, or from the authorized representative of miners, mine operators must promptly provide access to any such training record. Whenever an operator ceases to do business, that operator must transfer the training records, or a copy, to any successor operator who must maintain them for the required period.

§ 72.520 Diesel equipment inventory.

(a) The operator of each mine that utilizes diesel equipment underground, shall prepare and submit in writing to the District Manager, an inventory of diesel equipment used in the mine. The inventory shall include the number and type of diesel-powered units used underground, including make and model of unit, type of equipment, make and model of engine, serial number of engine, brake horsepower rating of engine, emissions of engine in grams per hour or grams per brake horsepower-hour, approval number of engine, make and model of aftertreatment device, serial number of aftertreatment device if available, and efficiency of aftertreatment device.

(b) The mine operator shall make changes to the diesel equipment inventory as equipment or emission control systems are added, deleted or modified and submit revisions, to the District Manager, within 7 calendar days.

(c) If requested, the mine operator shall provide a copy of the diesel equipment inventory to the representative of the miners within 3 days of the request.

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DEPARTMENT OF LABOR

Mine Safety and Health Administration

30 CFR Part 57

RIN 1219–AB11

Diesel Particulate Matter Exposure of Underground Metal and Nonmetal Miners

AGENCY: Mine Safety and Health Administration (MSHA), Labor.

ACTION: Final rule.

SUMMARY: This rule establishes new health standards for underground metal and nonmetal mines that use equipment powered by diesel engines.

This rule is designed to reduce the risks to underground metal and nonmetal miners of serious health hazards that are associated with exposure to high concentrations of diesel particulate matter (dpm). DPM is a very small particle in diesel exhaust. Underground miners are exposed to far higher concentrations of this fine particulate than any other group of workers. The best available evidence indicates that such high exposures put these miners at excess risk of a variety of adverse health effects, including lung cancer.

The final rule for underground metal and nonmetal mines would establish a concentration limit for dpm, and require mine operators to use engineering and work practice controls to reduce dpm to that limit. Underground metal and nonmetal mine operators would also be required to implement certain ''best practice'' work controls similar to those already required of underground coal mine operators under MSHA's 1996 diesel equipment rule. These operators would also be required to train miners about the hazards of dpm exposure.

By separate notice, MSHA has published a rule to reduce dpm exposures in underground coal mines.

DATES: The provisions of the final rule are effective March 20, 2001. However, §57.5060 (a) will not apply until July 19, 2002 and §57.5060 (b) will not apply until January 19, 2006.

FOR FURTHER INFORMATION CONTACT: David L. Meyer, Director, Office of Standards, Regulations, and Variances, MSHA, 4015 Wilson Boulevard, Arlington, VA 22203–1984. Mr. Meyer can be reached at dmeyer@msha.gov (Internet E-mail), 703–235–1910 (voice), or 703–235–5551 (fax). You may obtain copies of the final rule in alternative formats by calling this number. The alternative formats available are either a large print version of the final rule or the final rule in an electronic file on computer disk. The final rule also is available on the Internet at http://www.msha.gov/REGSINFO.HTM.

SUPPLEMENTARY INFORMATION:

I. Overview of the Final Rule

This Part: (1) Summarizes the key provisions of the final rule; and (2) summarizes MSHA's responses to some of the fundamental questions raised during the rulemaking proceeding—the need for the rule, the ability of the agency to accurately measure diesel particulate matter (dpm) in underground metal and nonmetal mine environments, and the feasibility of the requirements for this sector of the mining industry.

(1) Summary of Key Provisions of the Final Rule

The final rule applies only to underground areas of underground metal and nonmetal mines.

The final rule requires operators: (A) To observe a concentration limit where miners normally work or travel by the application of engineering controls, with certain limited exceptions, compliance with which will be determined by MSHA sampling; (B) to observe a set of best practices to minimize dpm generation; (C) to limit engines newly introduced underground to those meeting basic emissions standards; (D) to provide annual training to miners on dpm hazards and controls; and (E) to conduct sampling as often as necessary to effectively evaluate dpm concentrations at the mine. A list of effective dates for the provisions of the rule follows this summary.

(A) Observe a limit on the concentration of dpm in all areas of an underground metal or nonmetal mine where miners work or travel, with certain specific exceptions. The rule would limit dpm concentrations to which miners are exposed to about 200 micrograms per cubic meter of air—expressed as 200_{DPM} μg/m^3. However, the rule expresses the limit so as to reflect the measurement method MSHA will be using for compliance purposes to determine dpm concentrations. That method is specified in the rule itself. As discussed in detail in response to Question 2, the method analyzes a dust sample to determine the amount of total carbon present. Total carbon comprises 80–85% of the dpm emitted by diesel engines. Accordingly, using the lower boundary of 80%, a concentration limit of 200_{DPM} μg/m^3 can be achieved by restricting total carbon to 160_{TC} μg/m^3. This is the way the standard is expressed:

> After January 19, 2006 any mine operator covered by this part shall limit the concentration of diesel particulate matter to which miners are exposed in underground areas of a mine by restricting the average eight-hour equivalent full shift airborne concentration of total carbon, where miners normally work or travel, to 160 micrograms per cubic meter of air (160_{TC} μg/m^3).

All underground metal and nonmetal mines would be given a full five years to meet this limit, which is referred to in this preamble as the ''final'' concentration limit. However, starting July 19, 2002, underground metal and nonmetal mines have to observe an ''interim'' dpm concentration limit—expressed as a restriction on the

concentration of total carbon of 400 micrograms per cubic meter (400_{TC} μg/m^3). The interim limit would bring the concentration of whole dpm in underground metal and nonmetal mines to which miners are exposed down to about 500 micrograms per cubic meter. No limit at all on the concentration of dpm is applicable for the first eighteen months following promulgation. Instead, this period would be used to provide compliance assistance to the metal and nonmetal mining community to ensure it understands how to measure and control diesel particulate matter concentrations in individual operations.

In general, a mine operator has to use engineering or work practice controls to keep dpm concentrations below the applicable limit. The use of administrative controls (*e.g.,* the rotation of miners) is explicitly barred. The use of personal protective equipment (*e.g.,* respirators) is also explicitly barred except in two situations noted below. An operator can filter the emissions from diesel-powered equipment, install cleaner-burning engines, increase ventilation, improve fleet management, or use a variety of other readily available controls; the selection of controls is left to the operator's discretion.

Special extension. The rule provides that if an operator of a metal or nonmetal mine can demonstrate that there is no combination of controls that can, due to technological constraints, be implemented by January 19, 2006, MSHA may approve an application for an additional extension of time to comply with the dpm concentration limit. Such a special extension is available only once, and is limited to 2 years. To obtain a special extension, an operator must provide information in the application adequate for MSHA to ensure that the operator will: (a) Maintain concentrations at the lowest limit which is technologically achievable; and (b) take appropriate actions to minimize miner exposure (*e.g.,* provide suitable respiratory protection during the extension period).

It is MSHA's intent that primary responsibility for analysis of the operator's application for a special extension will rest with MSHA's district managers. District managers are the most familiar with the conditions of mines in their districts, and have the best opportunity to consult with miners as well. At the same time, MSHA recognizes that district managers may need assistance with respect to the latest technologies and solutions being used in similar mines elsewhere in the country. Accordingly, the Agency intends to establish within its Technical Support directorate in Arlington, Va., a special panel to consult on these issues, to provide assistance to district managers, and to give final approval of any application for a special extension.

Special rule for employees engaged in inspection, maintenance or repair activities. The final rule provides that with the advance approval of the Secretary, employees engaged in such activities may work in concentrations of dpm exceeding the applicable concentration limit. However, the Secretary may only approve such work under three circumstances: when the activities are to be conducted are in areas where miners work or travel infrequently or for brief periods of time; when the miners work exclusively inside enclosed and environmentally controlled cabs, booths and similar structures with filtered breathing air; or when the miners work in shafts, inclines, slopes, adits, tunnels and similar workings that are designated as return or exhaust air courses and that are used for access into the mine or egress from the mine. Moreover, to approve such an exception, the Secretary must determine that it is not feasible to reduce the concentration of dpm in these areas, and that adequate safeguards (including personal protective equipment) will be employed to minimize the dpm exposure of the miners involved.

An operator plan providing such details must be submitted; it is MSHA's intent to review these in the same manner as applications for a special extension. Such plans can only be approved for one year, but may be resubmitted each year.

Compliance determinations with concentration limit. Measurements to determine noncompliance with the dpm concentration limit will be made directly by MSHA, rather than having the Agency rely upon operator samples. Under the rule, a single Agency sample, using the sampling and analytical method prescribed by the rule, is explicitly deemed adequate to establish a violation.

The rule requires that if an underground metal or nonmetal mine exceeds the applicable limit on the concentration of dpm, a diesel particulate matter control plan must be established and remain in effect for 3 years. The purpose of such plans is to ensure that the mine has instituted practices that will demonstrably control dpm levels thereafter. Reflecting current practices in this sector, the plan does not have to be preapproved by MSHA. The plan must include information about the diesel-powered equipment in the mine and applicable controls. The rule requires operator sampling to verify that the plan is effective in bringing dpm levels down below the applicable limit, using the same sampling and analytical methods as MSHA, with the records kept at the mine site with the plan to facilitate review. Failure of an operator to comply with the requirements of the dpm control plan or to conduct adequate verification sampling is a violation of the rule; MSHA is not be required to sample to establish such a violation.

(B) *Observe best practices.* The rule requires that operators observe the following best practices to minimize the dpm generated by diesel-powered equipment in underground areas:

- Only low-sulfur (0.05% or less) diesel fuel may be used. The rule does not at this time require the use of ultra-low sulfur fuel by the mining community. MSHA is aware that the Environmental Protection Agency issued final regulations addressing emissions standards (December 2000) for new model year 2007 heavy-duty diesel engines and the low-sulfur fuel rule. The regulations require ultra-low sulfur fuel be phased in during 2006–2010.
- Only EPA-approved fuel additives may be used.
- Approved diesel engines have to be maintained in approved condition; the emission related components of non-approved engines have to be maintained in accordance with manufacturer specifications; and any installed emission devices have to be maintained in effective operating condition.
- Equipment operators are authorized and required to tag equipment with potential emissions-related problems, and tagged equipment has to be promptly referred for a maintenance check by persons qualified by virtue of training or experience to perform the maintenance.

(C) *Limit newly introduced engines to those meeting basic emission standards.* The rule requires that, with the exception of diesel engines used in ambulances and fire-fighting equipment, any diesel engines added to the fleet of an underground metal or nonmetal mine after January 19, 2001 must either be an engine approved by MSHA under Part 7 or Part 36, or an engine meeting certain EPA requirements on particulate matter specified in the rule. Since not all engines are MSHA approved, this ensures a wide variety of choice in meeting the engine requirements of this rule.

(D) *Provide annual training to miners on dpm hazards and controls.* Mines using diesel-powered equipment must annually train miners exposed to dpm

in the hazards associated with that exposure, and in the controls being used by the operator to limit dpm concentrations. An operator may propose including this training in the Part 48 training plan.

(E) *Conduct sampling as often as necessary to effectively evaluate dpm concentrations at the mine.* The purpose of this requirement is to assure that operators are familiar with current dpm concentrations so as to be able to protect miners. Since mine conditions vary, MSHA is not requiring a specific schedule for operator sampling, nor a specific sampling method. The Agency will evaluate compliance with this sampling obligation by reviewing evidence of operator compliance with the concentration limit, as well as information retained by operators about their sampling. Consistent with the statute, the rule requires that miners and their representatives have the right to observe any operator monitoring—including any sampling required to verify the effectiveness of a dpm control plan.

Summary of Effective Dates. As of March 20, 2001, operators must comply with the requirement that new engines added to a mine's inventory be either MSHA approved or meet the listed EPA standards.

As of March 20, 2001, underground metal and nonmetal mine operators must comply with the requirement to provide basic hazard training to miners who are exposed underground to dpm and the best practice requirements listed above under (B).

As of July 19, 2002, underground metal and nonmetal mine operators must also comply with the interim dpm concentration limit of 400 micrograms of total carbon per cubic meter of air.

Finally, as of January 19, 2006, all underground metal and nonmetal mines have to comply with a final dpm concentration limit.

MSHA intends to provide considerable technical assistance and guidance to the mining community before the various requirements go into effect, and be sure MSHA personnel are fully trained in the requirements of the rule. A number of actions have already been taken toward this end. The Agency held workshops on this topic in 1995 which provided the mining community an opportunity to share advice on how to control dpm concentrations. The Agency has published a ''toolbox'' of methods available to mining operators to achieve reductions in dpm concentration, often referred to during the rulemaking proceedings. MSHA also developed a computer spreadsheet template which allows an operator to model the application of alternative engineering controls to reduce dpm, which it has published in the literature and disseminated to the mining community. The Agency is committed to issuing a compliance guide for mine operators providing additional advice on implementing the rule.

A note on surface mines. Surface areas of underground mines, and surface mines, are not covered by this rule. In certain situations the concentrations of dpm at surface mines may be a cause for concern: *e.g.,* production areas where miners work in the open air in close proximity to loader-haulers and trucks powered by older, out-of-tune diesel engines, shops, or other confined spaces where diesel engines are running. The Agency believes, however, that these problems are currently limited and readily controlled through education and technical assistance. The Agency would like to emphasize, however, that surface miners are entitled to the same level of protection as other miners; and the Agency's risk assessment indicates that even short-term exposures to concentrations of dpm like those observed may result in serious health problems. Accordingly, in addition to providing education and technical assistance to surface mines, the Agency will also continue to evaluate the hazards of diesel particulate exposure at surface mines and will take any necessary action, including regulatory action if warranted, to help the mining community minimize any hazards.

(2) Summary of MSHA's Responses to Several Fundamental Questions About This Rule

During the rulemaking proceeding, the mining community raised some fundamental questions about: (A) The need for the rule; (B) the ability of the agency to accurately measure diesel particulate matter (dpm) in underground metal and nonmetal mine environments; and (C) the feasibility of the requirements for this sector of the mining industry. MSHA gave serious considerations to these questions, has made some adjustments in the final rule and its economic assessment as a result thereof, and has provided detailed responses in this preamble. These responses are briefly summarized here.

(A) *The need for the rule.* MSHA has to act in accordance with the requirements of the Mine Safety and Health Act. Section 101(a)(6)(A) of the Act specifies that any health standard must:

> * * * [A]dequately assure, on the basis of the best available evidence, that no miner will suffer material impairment of health or functional capacity even if such miner has regular exposure to the hazards dealt with by such standard for the period of his working life.

The Mine Act also specifies that the Secretary of Labor (Secretary), in promulgating mandatory standards pertaining to toxic materials or harmful physical agents, base such standards upon:

> * * * [R]esearch, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the miner, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws. Whenever practicable, the mandatory health or safety standard promulgated shall be expressed in terms of objective criteria and of the performance desired. [Section 101(a)(6)(A)].

Thus, the Mine Act requires that the Secretary, in promulgating a standard, based on the best available evidence, attain the highest degree of health and safety protection for the miner with feasibility a consideration. (More information about what constitutes ''feasibility'' is discussed below in item C).

In proposing this rule, MSHA sought comment on its risk assessment, which it published in full as part of the preamble to the proposed rule. In that risk assessment, the agency carefully laid out the evidence available to it, including shortcomings inherent in that evidence. Although not required to do so by law, MSHA had this risk assessment independently peer reviewed, and incorporated the reviewers recommendations. The reviewers stated that:

> * * * principles for identifying evidence and characterizing risk are thoughtfully set out. The scope of the document is carefully described, addressing potential concerns about the scope of coverage. Reference citations are adequate and up to date. The document is written in a balanced fashion, addressing uncertainties and asking for additional information and comments as appropriate. (Samet and Burke, Nov. 1997).

Based on the information in that risk assessment, the agency made some tentative conclusions. First, its tentative conclusion that miners are exposed to far higher concentrations of dpm than anybody else. The agency noted that median concentrations of dpm had been observed in individual dieselized metal and nonmetal underground mines up to 180 times as high as average environmental exposures in the most heavily polluted urban areas and up to 8 times as high as median exposures estimated for the most heavily exposed

workers in other occupational groups. Moreover, MSHA noted its tentative conclusion that exposure to high concentrations of dpm can result in a variety of serious health effects. These health effects include: (i) Sensory irritations and respiratory symptoms serious enough to distract or disable miners; (ii) premature death from cardiovascular, cardiopulmonary, or respiratory causes; and (iii) lung cancer. After a review of all the evidence, MSHA tentatively concluded that:

(1) The best available evidence is that the health effects associated with exposure to dpm can materially impair miner health or functional capacity.

(2) At levels of exposure currently observed in underground mining, many miners are presently at significant risk of incurring these material impairments over a working lifetime.

(3) The reduction in dpm exposures that is expected to result from implementation of the rule proposed by the agency for underground metal and nonmetal mines would substantially reduce the significant risks currently faced by underground metal and nonmetal miners exposed to dpm.

During the hearings and in written comments, some representatives of the mining industry raised a number of objections to parts of MSHA's proposed risk assessment, thus questioning the scientific basis for this rulemaking. It has been asserted that MSHA's observations of dpm concentrations in underground metal and nonmetal mines do not accurately represent exposures in the industry. It has been asserted that if dpm concentrations are not this high in general, or only on an intermittent basis, then the agency is incorrect in determining that the conditions in these mines put miners at significant risk of material impairment of their health. Moreover it has been asserted that there is insufficient evidence to establish a causal connection between dpm exposure and significant adverse health effects, that the agency has no hard evidence that reducing exposures to a particular level will in fact reduce the risks, and that it has no rational basis for selecting the concentration limit it did. In addition, it has been asserted that the risks of dpm exposure at any level are not well enough established to provide the basis for regulation at this time, and that action should be postponed pending the completion of various studies now underway that might shed more light on these risks.

MSHA has carefully evaluated all of these comments, and the evidence submitted in support of these positions. The agency's risk assessment has been modified as a result.

Exposures of underground metal and nonmetal miners. MSHA has clarified the charts of exposure measurements in Part III of this preamble to ensure that they fully reflect all studies in the record.

MSHA has not and does not claim that the actual exposure measurements in the record are a random or fully representative sample of the industry. What they do show is that exposures far higher than those which have been observed in other industries can and do occur in an underground mining environment.

Moreover, MSHA also placed into the record of the proposed rule several studies it had recently conducted in which dpm concentrations for several underground metal and nonmetal mines were estimated based upon the actual equipment and dpm controls currently available in those mines. Those simulations were performed using a software tool known as the Estimator (described in detail in an appendix to Part V of the preamble of the proposed rule, and since published in the literature (Haney and Saseen, April 2000). These studies of specific mines demonstrated that the type of equipment found in such mines, even after the application of current ventilation and controls, can be expected to produce localized high concentrations of dpm. The agency acknowledged that these simulations were conducted in mines that were not typical for the industry (they were chosen because the agency thought dpm concentrations might be particularly difficult to control in these mines, which turned out not to be the case); nevertheless, they indicate what is likely to be the case in at least some sections of many underground metal and nonmetal mines. To the extent that an individual mine has no covered mining areas with concentrations higher than those observed in other industries, it will not be impacted by the concentration limit established through this rulemaking. That is because the rule does not eliminate exposures, or even to reduce them to a safe level, but only to reduce them to the levels observed in other industries.

The nature of risks associated with dpm exposure. Although there were some commenters who suggested that symptoms reported by miners working around diesel equipment might be due to the gases present rather than dpm, there was nothing in the comments that changed MSHA's conclusions about the health problems associated with dpm exposure.

There are a number of studies quantifying significant adverse health effects—as measured by lost work days, hospitalization and increased mortality rates—suffered by the general public when exposed to concentrations of fine particulate matter like dpm far lower than concentrations to which some miners are exposed. The evidence from these fine particulate studies was the basis for recent rulemaking by the Environmental Protection Agency [1] to further restrict the exposure of the general public to fine particulates, and the evidence was given very widespread and close scrutiny before that action was made final. Of particular interest to the mining community is that these fine particulate studies indicate that smokers and those who have pre-existing pulmonary problems are particularly at risk. Many individual miners in fact have such pulmonary problems and are especially susceptible to the adverse health effects of inhaling fine particles.

Although no epidemiological study is flawless, numerous epidemiological studies have shown that long term exposure to diesel exhaust in a variety of occupational circumstances is associated with an increased risk of lung cancer. With only rare exceptions, involving relatively few workers and/or observation periods too short to reliably detect excess cancer risk, the human studies have consistently shown a greater risk of lung cancer among workers exposed to dpm than among comparable unexposed workers. When results from the human studies are combined, the risk is estimated to be 30–40 percent greater among exposed workers, if all other factors (such as smoking habits) are held constant. The consistency of the human study results, supported by experimental data establishing the plausibility of a causal connection, provides strong evidence that chronic dpm exposure at high levels significantly increases the risk of lung cancer in humans.

Moreover, all of the occupational studies indicating an increased frequency of lung cancer among workers exposed to dpm involved exposure levels estimated, on average, to be far below levels observed in underground mines. Except for miners, the workers

[1] The basis for the $PM_{2.5}$ NAAQS was a large body of scientific data indicating that particles in this size range are responsible for the most serious health effects associated with particulate matter. The evidence was thoroughly reviewed by a number of scientific panels through an extended process. The proposed rule resulted in considerable public attention, and hearings by Congress, in which the scientific evidence was further discussed. Moreover, challenges to the EPA's determination that this size category warranted rulemaking were rejected by a three-judge panel of the DC Circuit Court. (ATA v. EPA, 175 F.3d 1027, D.C. Circuit 1999).

included in these studies were exposed to average dpm levels below the limit established by this rule.

As noted in Part III, MSHA views extrapolations from animal experiments as subordinate to results obtained from human studies. However, it is noteworthy that dpm exposure levels recorded in some underground mines have been of the same order of magnitude that produced tumors in rats.

Based on the scientific data available in 1988, the National Institute for Occupational Safety and Health (NIOSH) identified dpm as a probable or potential human carcinogen and recommended that it be controlled. Other organizations have made similar recommendations. Most recently, the National Toxicology Program listed dpm as ''reasonably anticipated to be a human carcinogen'' in the Ninth Edition (Year 2000) of the National Report on Carcinogens.

The relationship between exposures and risks. Commenters noted MSHA's caution about trying to define a quantitative relationship between dpm exposure and particular health outcomes. They roundly attacked the agency's benefit analysis and a NIOSH paper reviewing quantification efforts as implying that such a relationship could be established in a valid way.

As MSHA acknowledged in the preamble to the proposed rule, the scientific community has not yet widely accepted any exposure-response relationship between the amount of dpm exposure and the likelihood of adverse health outcomes (63FR 58167). There are, however, two lung cancer studies in the record that show increasing risk of lung cancer with increasing levels of dpm exposure. Quantitative results from these studies, both conducted specifically on underground miners, can be used to estimate the reduction in lung cancer risk expected when dpm exposure is reduced in accordance with this rule. Depending on the study and method of statistical analysis used, these estimates range from 68 to 620 lung cancer deaths prevented, over an initial 65-year period, per 1000 affected miners with lifetime (45-year) exposure to dpm.

NIOSH and the National Cancer Institute (NCI) are collaborating on a cancer mortality study designed to provide additional information in this regard. The study is projected to take about seven years.

Notwithstanding this situation, MSHA believes the Agency is required under its statute to take action now to protect miners' health. As noted by the Supreme Court in an important case on risk involving the Occupational Safety and Health Administration, the need to evaluate risk does not mean an agency is placed into a ''mathematical straightjacket.'' *Industrial Union Department, AFL–CIO* v. *American Petroleum Institute,* 448 U.S. 607, 100 S.Ct. 2844 (1980). The Court noted that when regulating on the edge of scientific knowledge, absolute scientific certainty may not be possible, and:

> so long as they are supported by a body of reputable scientific thought, the Agency is free to use conservative assumptions in interpreting the data * * * risking error on the side of overprotection rather than underprotection. (Id. at 656).

This advice has special significance for the mining community, because a singular historical factor behind the enactment of the current Mine Act was the slowness of the mining community in coming to grips with the harmful effects of other respirable dust (coal dust).

It is worth noting that while the cohort selected for the NIOSH/NCI study consists of underground miners (specifically, underground metal and nonmetal miners), this choice is in no way linked to MSHA's regulatory framework or to miners in particular. This cohort was selected for the study because it provides the best population for scientists to study. For example, one part of the study would compare the health experiences of miners who have worked underground in mines with long histories of diesel use with the health experiences of similar miners who work in surface areas where exposure is significantly lower. Since the general health of these two groups is very similar, this will help researchers to quantify the impacts of diesel exposure. No other population is likely to be as easy to study for this purpose. But as with any such epidemiological study, the insights gained are not limited to the specific population used in the study. Rather, the study will provide information about the relationship between exposure and health effects that will be useful in assessing the risks to any group of workers in a dieselized industry.

Because of the lack of a generally accepted dose-response relationship, some commenters questioned the agency's rationale in picking a particular concentration limit: 160_{TC} μg/m³ or around 200_{DPM} μg/m³. Capping dpm concentrations at this level will eliminate the worst mining exposures, and bring miner exposures down to a level commensurate with those reported for other groups of workers who use diesel-powered equipment. The proposed rule would not bring concentrations down as far as the proposed ACGIH TLV[R] of 150_{DPM} μg/m³. Nor does MSHA's risk assessment suggest that the proposed rule would completely eliminate the significant risks to miners of dpm exposure.

In setting the concentration limit at this particular value, the Agency is acting in accord with its statutory obligation to attain the highest degree of safety and health protection for miners that is feasible. The Agency's risk assessment supports reduction of dpm to the lowest level possible. But feasibility considerations dictated proposing a concentration limit that does not completely eliminate the significant risks that dpm exposure poses to miners.

The Agency specifically explored the implications of requiring mines in this sector to comply with a lower concentration limit than that being adopted. The results, discussed in Part V of this preamble, indicate that although the matter is not free from question, it still may not be feasible at this time for the underground metal and nonmetal mining industry as a whole to comply with a significantly lower limit than that being adopted. The Agency notes that since this rulemaking was initiated, the efficiency of hot gas filters has improved significantly, the dpm emissions from new engines continue to decline under EPA requirements, and the availability of ultra-low sulfur fuel should make controls even more efficient than at present.

The agency also explored the idea of bridging the gap between risk and feasibility by establishing an ''action level''. In the case of MSHA's noise rule, for example, MSHA adopted a ''permissible exposure level'' of a time-weighted 8-hour average (TWA_8) of 90 dBA (decibels, A-weighted), and an ''action level'' of half that amount—a TWA_8 of 85 dBA. In that case, MSHA determined that miners are at significant risk of material harm at a TWA_8 of 85 dBA, but technological and feasibility considerations preclude the industry as a whole, at this time, below a TWA_8 of 90 dBA. Accordingly, to limit miner exposure to noise at or above a TWA_8 of 85 dBA, MSHA requires that mine operators must take certain actions that are feasible (*e.g.,* provide hearing protectors).

MSHA considered the establishment of a similar ''action level'' for dpm—probably at half the proposed concentration limit, or 80_{TC} μg/m³. Under such an approach, mine operators whose dpm concentrations are above the ''action level'' would be required to implement a series of ''best practices''—*e.g.,* limits on fuel types,

idling, and engine maintenance. Only one commenter supported the creation of an Action Level for dpm. However, this commenter suggested that such an Action Level be adopted in lieu of a rule incorporating a concentration limit requiring mandatory compliance. The agency determined it is feasible for the entire underground mining community to implement these best practices to minimize the risks of dpm exposure without the need for a trigger at an Action Level.

Some of the comments suggesting that the agency had no rational basis for setting the exposure limit at 160_{TC} µg/m³ seem to suggest that the statute itself does not provide the Agency with adequate guidance in this regard. The Agency recognizes that the Supreme Court has scheduled argument on a case that raises the question of how specific a regulatory statute must be with respect to how an agency must make standards determinations in order to be deemed a constitutional delegation of authority from the Congress. A decision is not expected until 2001. However, unless and until determined otherwise, MSHA presumes the Mine Act does pass constitutional muster in this regard, consistent with the existing case law concerning the very similar Occupational Safety and Health Act.

(B) The ability of the agency to accurately measure diesel particulate matter (dpm) in underground metal and nonmetal mine environments. As MSHA noted in the preamble to the proposed rule, there are a number of methods which can measure dpm concentrations with reasonable accuracy when it is at high concentrations and when the purpose is exposure assessment. Measurements for the purpose of compliance determinations must be more accurate, especially if they are to measure compliance with a dpm concentration of 200_{DPM} µg/m³ or lower. Accordingly, MSHA noted that it needed to address a number of questions as to whether such any existing method could produce accurate, reliable and reproducible results in the full variety of underground mines, and whether the infrastructure (samplers and laboratories) existed to support such determinations. (See 63 FR 58127 *et seq.*).

MSHA concluded that there was no method suitable for such compliance measurements in underground coal mines, due to the inability of the available methods to distinguish between dpm and coal dust. Accordingly, the agency developed a rule for the coal mining sector that does not depend upon ambient dpm measurements.

By contrast, the agency tentatively concluded that by using a sampler developed by the Bureau of Mines, and an analytical method developed by the National Institute for Occupational Safety and Health (NIOSH) to detect the total amount of carbon in a sample, MSHA could accurately measure dpm levels at the required concentrations in underground metal and nonmetal mines. While not requiring operators to use this method for their own sampling, MSHA did commit itself through provisions of the proposed rule to use this approach (or a method subsequently determined by NIOSH to provide equal or improved accuracy) for its own sampling. Moreover the agency proposed that MSHA sampling be the sole basis upon which determinations would be made of compliance by metal and nonmetal mine operators with applicable compliance limits, and that a single sample would be adequate for such purposes. Specifically, proposed § 57.5061 provided as follows:

§ 57.5061 Compliance Determinations

(a) A single sample collected and analyzed by the Secretary in accordance with the procedure set forth in paragraph (b) of this section shall be an adequate basis for a determination of noncompliance with an applicable limit on the concentration of diesel particulate matter pursuant to § 57.5060.

(b) The Secretary will collect and analyze samples of diesel particulate matter by using the method described in NIOSH Analytical Method 5040 and determining the amount of total carbon, or by using any method subsequently determined by NIOSH to provide equal or improved accuracy in mines subject to this part.

This part of MSHA's proposed rule received considerable comment. Some commenters challenged the accuracy, precision and sensitivity of NIOSH Analytical Method 5040. Some challenged whether the amount of total carbon determined by the method is a reliable way to determine the amount of dpm. Others questioned whether the sampler developed by the Bureau of Mines would provide an accurate sample to be analyzed, and whether such samplers and analytical procedures would be commercially available. Commenters also questioned the use of a single sample as the basis for a compliance determination, and the use of area sampling in compliance determinations. These comments are addressed elsewhere in this preamble (section 3 of Part II, and in connection with section 5061 in Part IV).

Here, MSHA summarizes its views on the most common assertion made by commenters: that the sampling and analytical methods the agency proposed to use are not able to distinguish between dpm and various other substances in the atmosphere of underground metal and nonmetal mines—carbonates and carbonaceous minerals, graphitic materials, oil mists and organic vapors, and cigarette smoke.

Interferences: what MSHA said in preamble to proposed rule. In the preamble to the proposed rule, MSHA recognized that there might be some interferences from other common organic carbon sources in underground metal and nonmetal mines: specifically, oil mists and cigarette smoke. The agency noted it had no data on oil mists, but had not encountered the problem in its own sampling. With respect to cigarette smoke, the agency noted that: ''Cigarette smoke is under the control of operators, during sampling times in particular, and hence should not be a consideration.'' (63FR 58129)

The agency also discussed the potential advantages and disadvantages of using a special device on the sampler—a submicron impactor—to eliminate certain other possible interferences (See Figure I–1). The submicron impactor stops particles larger than a micron from being collected by the sampler, while allowing the smaller dpm to be collected. Thus, an advantage of using the impactor would be to ensure that the sampler was not inadvertently collecting materials other than dpm. However MSHA pointed out that while samples in underground metal and nonmetal mines could be taken with a submicrometer impactor, this could lead to underestimating the total amount of dpm present (63FR 58129). This is because the fraction of dpm particles greater than 1 micron in size in the environment of noncoal mines can be as great as 20% (Vuk, Jones, and Johnson, 1976).

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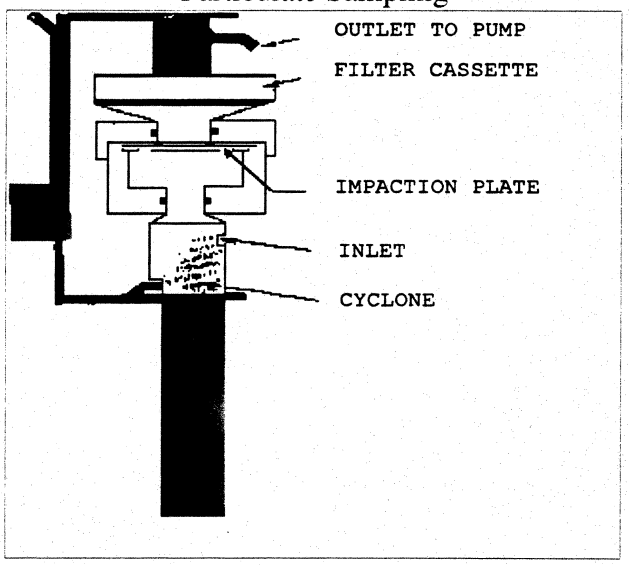
Figure II- 3
Personal Sampler For Submicrometer Particulate Sampling



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Interferences: comments and MSHA efforts to verify. Many commenters asserted that no matter how it is performed in underground metal and nonmetal mines, the sampling and analysis proposed by MSHA to determine the amount of diesel particulate present would suffer from one or more of the aforementioned interferences. A number asserted that their own measurements using this approach provided clear evidence of such interferences. Although MSHA repeatedly asked for actual data and information about the procedures used to verify these assertions, very little was provided. Nevertheless, rather than conclude that these assertions were baseless, MSHA decided to attempt to verify these assertions itself. Accordingly, appropriate field and laboratory measurements were conducted toward this end, the results written up in appropriate fashion, and added to the record of this rulemaking. The agency has taken those results into account in ascertaining what weight to give to the assertions made by commenters and how to deal with those assertions supported by its measurements.

As described in detail in section 3 of Part II, MSHA's verifications demonstrate that the submicron impactor can eliminate any interferences from carbonates, carbonaceous minerals, and graphitic ores. Accordingly, although use of the impactor will result in an undercount of dpm, the final rule provides that MSHA will always use the submicron impactor in compliance sampling.

MSHA's verifications also demonstrated that oil mists as well as cigarette smoke, can in fact, under certain circumstances, create interferences even with the use of the impactor. MSHA presumes the same would happen with organic vapors. The verifications demonstrated that the problems occur in the immediate vicinity of the interferent (*e.g.,* close to a drill or smoker). However, the verifications also demonstrated that the interference dissipates when the sampling device is located a certain distance away from the interferent.

Accordingly, as detailed in the discussion of section 5061 in Part IV of this preamble, MSHA's sampling strategy for dpm will take these problems into account. For example, if a miner works in an enclosed cab all day and smokes, MSHA will not place a sampler in that cab or on that miner. If a miner works part of a day drilling, MSHA will not place a sampler on that miner. But MSHA can, for example, take an area sample in an area of a mine where drilling is being performed without concern about interferences from oil mists if it locates the sampler far enough away from the drill. MSHA's compliance manual will provide specific instructions to inspectors on how to avoid interferences.

The organic interferences (diesel mist, smoking) could be avoided by only analyzing a sample for elemental carbon, pursuant to the NIOSH method. As it indicated in the preamble to the proposed rule, however, MSHA does not at this time know the ratio between the amount of elemental carbon and the amount of dpm. Accordingly, rather than deal with the uncertainties in all samples which this approach would present, MSHA is going to use a method (i.e., sampling and analyzing for both organic carbon and elemental carbon) that, if properly applied, provides accurate results.

(C) The feasibility of the requirements for this sector of the mining industry. The Mine Act generally requires MSHA to set the standard that is most protective of miner health while still being technologically and economically feasible. In addition, consistent with the Regulatory Flexibility Act, the agency pays particular attention to the impact of any standard on small mining operations.

(1) Technological feasibility of the rule. It has been clear since the beginning of this rulemaking that if technological feasibility was an issue, it would be in the context of requiring all underground metal and nonmetal mines to meet a particular limit. While the Mine Act does not require that each mine be able to meet a standard for it to be considered technologically feasible—only that the standard be feasible for the industry as a whole—the extent to which various mines might have a problem complying is the evidence upon which this conclusion must be based.

Accordingly, MSHA evaluated the technological feasibility of the concentration limit in the underground

metal and nonmetal sector by evaluating whether it was possible, using a combination of existing control approaches, to reach the concentration limit even in situations in which the Agency's engineers determined that compliance might be the most difficult. In this regard, the Agency examined how emissions generated by the actual equipment in four different underground mining operations could be controlled. The mines were very diverse—an underground limestone mine, an underground (and underwater) salt mine, and an underground gold mine. Yet in each case, the analysis revealed that there are available combinations of controls that can bring dpm concentrations down to well below the final limit—even when the controls that needed to be purchased were not as extensive as those which the Agency is assuming will be needed in determining the costs of the final rule. (The results of these analyses are discussed in Part V of the preamble, together with the methodology used in modeling the results—just as they were discussed in the preamble accompanying the proposed rule.) As a result of these studies, the Agency has concluded that there are engineering and work practice controls available to bring dpm concentrations in all underground metal and nonmetal mines down to the required levels.

The best actions for an individual operator to take to come into compliance with the interim and final concentration limits will depend upon an analysis of the unique conditions at the mine. The final rule provides 18 months after it is promulgated for MSHA to provide technical assistance to individual mine operators. It also gives all mine operators in this sector an additional three and a half years to bring dpm concentrations down to the proposed final concentration limit—using an interim concentration limit during this time which the Agency is confident every mine in this sector can timely meet. And the rule provides an opportunity for a special extension for an additional two years for mines that have unique technological problems meeting the final concentration limit.

As noted during 1995 workshops co-sponsored by MSHA on methods for controlling diesel particulate, many underground metal and nonmetal mine operators have already successfully determined how to reduce diesel particulate concentrations in their mines. MSHA has disseminated the ideas discussed at these workshops to the entire mining community in a publication, ''Practical Ways to Control Exposure to Diesel Exhaust in Mining—a Toolbox''. The control methods are divided into eight categories: use of low emission engines; use of low sulfur fuel; use of aftertreatment devices; use of ventilation; use of enclosed cabs; diesel engine maintenance; work practices and training; fleet management; and respiratory protective equipment. Moreover, MSHA designed a model in the form of a computer spreadsheet that can be used to simulate the effects of various controls on dpm concentrations. (This model is discussed in Part V of the preamble.) This makes it possible for individual underground mine operators to evaluate the impact on diesel particulate levels of various combinations of control methods, prior to making any investments, so each can select the most feasible approach for his or her mine.

(2) Economic Feasability of the Rule. The underground metal and nonmetal industry uses a lot of diesel-powered equipment, and it is widely distributed. Accordingly, MSHA recognizes that the costs of bringing mines into compliance with this rule will be widely felt in this sector (although, unlike underground coal mines, this sector did not have to comply with MSHA's 1996 diesel equipment rule).

In summary, the costs per year to the underground metal and nonmetal industry are about $25.1 million. The cost for an average underground metal and nonmetal mine is expected to be about $128,000 annually.

The Agency's initial cost estimates of $19.2 million a year were challenged during the rulemaking proceeding. As a result, the Agency reconsidered the costs.

In its initial estimate of the costs for the industry to comply with the concentration limit, MSHA assumed that a variety of engineering controls, such as low emission engines, ceramic filters, oxidation catalytic converters, and cabs would be needed on diesel powered equipment. Most of the engineering controls would be needed on diesel equipment used for production, while a small amount of diesel equipment that is used for support purposes would need engineering controls. In addition to these controls, MSHA assumed that some underground metal and nonmetal mines would need to make ventilation changes in order to meet the proposed concentration limits.

Specifically, in the PREA, MSHA assumed that: (1) the interim standard would be met by replacing engines, installing oxidation catalytic converters, and improving ventilation; and (2) the final standard would be met by adding cabs and filters. Comments on the PREA and data collected by the Agency since publication of the proposed rule indicate that engine replacement is more expensive than originally thought and filters are more effective relative to engine replacement. The revised compliance strategy, upon which MSHA bases its revised estimates of compliance costs, reverses the two most widely used measures. MSHA now anticipates that: (1) the interim standard will be met with filters, cabs, and ventilation; and (2) the final standard will be met with more filters, ventilation, and such turnover in equipment and engines as will have occurred in the baseline. This new approach uses the same toolbox and optimization strategy that was used in the PREA. Since relative costs are different, however, the tools used and cost estimated are different.

(3) Impact on small mines. As required by the Regulatory Flexibility Act, MSHA has performed a review of the effects of the proposed rule on ''small entities''.

The Small Business Administration generally considers a small mining entity to be one with less than 500 employees. MSHA has traditionally defined a small mine to be one with less than 20 miners, and has focused special attention on the problems experienced by such mines in implementing safety and health rules. Accordingly, MSHA has separately analyzed the impact of the rule on three categories of mines: large mines (more than 500 employees), middle size mines (20–500 employees), and small mines (those with less than 20 miners).

As required by law, MSHA has also developed a preliminary and final regulatory flexibility analysis. The Agency published its preliminary Regulatory Flexibility Analysis with its proposed rule and specifically requested comments thereon; the agency's final Regulatory Flexibility Analysis is included in the Agency's REA. In addition to a succinct statement of the objectives of the rule and other information required by the Regulatory Flexibility Act, the analysis reviews alternatives considered by the Agency with an eye toward the nature of small business entities.

In promulgating standards, MSHA is required to protect the health and safety of all the Nation's miners and may not include provisions that provide less protection for miners in small mines than for those in larger mines. But MSHA does consider the impact of its standards on even the smallest mines when it evaluates the feasibility of various alternatives. For example, a major reason why MSHA concluded it

needed to stagger the effective dates of some of the requirements in the rule is to ensure that it would be feasible for the smallest mines to have adequate time to come into compliance.

MSHA recognizes that smaller mines may need particular assistance from the agency in coming into compliance with this standard. Before the dpm concentration goes into effect in 18 months, the Agency plans to provide extensive compliance assistance to the mining community. The metal and nonmetal community will also have an additional three and a half years to comply with the final concentration limit, which in many cases means these mines may have a full five years of technical assistance before any engineering controls are required. MSHA intends to focus its efforts on smaller operators in particular—training them in measuring dpm concentrations, and providing technical assistance on available controls. The Agency will also issue a compliance guide, and continue its current efforts to disseminate educational materials and software.

(4) Benefits of the final rule Benefits of the rule include reductions in lung cancer. In the long run, as the mining population turns over, MSHA estimates that a minimum of 8.5 lung cancer deaths will be avoided per year.[2]

Benefits of the rule will also include reductions in the risk of death from cardiovascular, cardiopulmonary, or respiratory causes and in sensory irritation and respiratory symptoms. MSHA does not believe that the available data can support reliable or precise quantitative estimates of these benefits. Nevertheless, the expected reductions in the risk of death from cardiovascular, cardiopulmonary, or respiratory causes appear to be significant, and the expected reductions in sensory irritation and respiratory symptoms appear to be rather large.

II. General Information

This part provides the context for this preamble. The nine topics covered are:

(1) The role of diesel-powered equipment in underground metal and nonmetal mining in the United States;

(2) The composition of diesel exhaust and diesel particulate matter (dpm);

(3) The sampling and analytical techniques for measuring ambient dpm in underground metal and nonmetal mines;

(4) Limiting the public's exposure to diesel and other final particulates—ambient air quality standards;

(5) The effects of existing standards—MSHA standards on diesel exhaust gases (CO, CO_2, NO, NO_2, and SO_2), and EPA diesel engine emission standards—on the concentration of dpm in underground metal and nonmetal mines;

(6) Methods for controlling dpm concentrations in underground metal and nonmetal mines;

(7) MSHA's approach to diesel safety and health in underground coal mines and its effect on dpm;

(8) Information on how certain states are restricting occupational exposure to dpm; and

(9) A history of this rulemaking.

Material on these subjects which was available to MSHA at the time of the proposed rulemaking was included in Part II of the preamble that accompanied the proposed rule. (63 FR 58123 et seq). Portions of that material relevant to underground metal and nonmetal mines is reiterated here (although somewhat reorganized), and the material is amended and supplemented where appropriate as a result of comments and additional information added to the record since the proposal was published.

(1) The Role of Diesel-Powered Equipment in Underground Metal and Nonmetal Mining in the United States

Diesel engines, first developed about a century ago, now power a full range of mining equipment in underground metal and nonmetal mines, and are used extensively in this sector. This sector's reliance upon diesel engines to power equipment in underground metal and nonmetal mines appears likely to continue for some time.

Historical Overview of Diesel Power Use in Mining. As discussed in the notice of proposed rulemaking, the diesel engine was developed in 1892 by the German engineer Rudolph Diesel. It was originally intended to burn coal dust with high thermodynamic efficiency. Later, the diesel engine was modified to burn middle distillate petroleum (diesel fuel). In diesel engines, liquid fuel droplets are injected into a prechamber or directly into the cylinder of the engine. Due to compression of air in the cylinder the temperature rises high enough in the cylinder to ignite the fuel.

The first diesel engines were not suited for many tasks because they were too large and heavy (weighing 450 lbs. per horsepower). It was not until the 1920's that the diesel engine became an efficient lightweight power unit. Since diesel engines were built ruggedly and had few operational failures, they were used in the military, railway, farm, construction, trucking, and busing industries. The U.S. mining industry was slow, however, to begin using these engines. Thus, when in 1935 the former U.S. Bureau of Mines published a comprehensive overview on metal mine ventilation (McElroy, 1935), it did not even mention ventilation requirements for diesel-powered equipment. By contrast, the European mining community began using these engines in significant numbers, and various reports on the subject were published during the 1930's. According to a 1936 summary of these reports (Rice, 1936), the diesel engine had been introduced into German mines by 1927. By 1936, diesel engines were used extensively in coal mines in Germany, France, Belgium and Great Britain. Diesel engines were also used in potash, iron and other mines in Europe. Their primary use was in locomotives for hauling material.

It was not until 1939 that the first diesel engine was used in the United States mining industry, when a diesel haulage truck was used in a limestone mine in Pennsylvania, and not until 1946 was a diesel engine used in a coal mine. Today, however, diesel engines are used to power a wide variety of equipment in all sectors of U.S. mining. Production equipment includes vehicles such as haultrucks and shuttle cars, front-end loaders, hydraulic shovels, load-haul-dump units, face drills, and explosives trucks. Diesel engines are also used in support equipment including generators and air compressors, ambulances, fire trucks, crane trucks, ditch diggers, forklifts, graders, locomotives, lube units, personnel carriers, hydraulic power units, longwall component carriers, scalers, bull dozers, pumps (fixed, mobile and portable), roof drills, elevating work platforms, tractors, utility trucks, water spray units and welders.

Current Patterns of Diesel Power Use in Underground Metal and Nonmetal Mining. Table II–1 provides information on the current utilization of diesel equipment in underground metal and nonmetal mines.

[2] This lower bound figure could significantly underestimate the magnitude of the health benefits. For example the estimate based on the mean value of all the studies examined is 49 lung cancer deaths avoided per year.

TABLE II–1.—DIESEL EQUIPMENT IN UNDERGROUND METAL AND NONMETAL MINES

Mine size	Number of underground mines [A]	Number of mines with diesels [B]	Number of Engines [B]
Small [C]	134	77	584
Large	130	119	3,414
All	264	196	3,998

(A) Number of underground mines is based on those reporting operations for FY1999 (preliminary data).
(B) Number of mines using diesels are based on January 1998 count, by MSHA inspectors, of underground metal and nonmetal mines that used diesel powered equipment, and the number of engines (the latter rounded to the nearest 25) was determined in the same count with reference to equipment normally in use.
(C) A ''small'' mine is one with less than 20 miners.

As noted in Table II–1, a majority of underground metal and nonmetal mines use diesel-powered equipment.

Diesel engines in metal and nonmetal underground mines, and in surface coal mines, range up to 750 HP or greater, although equipment size, and thus the size of the engine, can be limited by production requirements, the dimensions of mine openings, and other factors. By contrast, in underground coal mines, the average engine size is less than 150 HP. The reason for this disparity is the nature of the equipment powered by diesel engines. In underground metal and nonmetal mines, and surface mines, diesel engines are widely used in all types of equipment—both the equipment used under the heavy stresses of production and the equipment used for support. In underground metal and nonmetal mines, of the approximate 4,000 pieces of diesel equipment normally in use, about 1,800 units are used for loading and hauling. By contrast, the great majority of the diesel usage in underground coal mines is in support equipment.

This fact is significant for dpm control in underground metal and nonmetal mines. As the horsepower size of the engine increases, the mass of dpm emissions produced per hour increases. (A smaller engine may produce the same or higher levels of particulate emissions per volume of exhaust as a large engine, but the mass of particulate matter increases with the engine size). Accordingly, as engine size increases, control of emissions may require additional efforts.

Another factor relevant to control of dpm emissions in this sector is that fewer than 15 underground metal and nonmetal mines are required to use Part 36 permissible equipment because of the possibility of the presence of explosive mixtures of methane and air. The surface temperature of diesel powered equipment in underground metal and nonmetal mines classified as gassy must be controlled to less than 400°F. Such mines must use equipment approved as permissible under Part 36 if the equipment is utilized in areas where permissible equipment is required. These gassy metal and nonmetal mines have been using the same permissible engines and power packages as those approved for underground coal mines. (MSHA has not certified a diesel engine exclusively for a Part 36 permissible machine for the metal and nonmetal sector since 1985 and has certified only one permissible power package; however, that engine model has been retired and is no longer available as a new purchase to the industry). As a result, engine size (and thus dpm production of each engine) is more limited in these mines, and, as explained in section 6 of this part, the exhaust from these engines is cool enough to add a paper type of filtration device directly to the equipment.

By contrast, since in nongassy underground metal and nonmetal mines mine operators can use conventional construction equipment in their production sections without the need for modifications to the machines, they tend to do so. Two examples are haulage vehicles and front-end loaders. As a result, these mines can and do use engines with larger horsepower and hot exhaust. As explained in section 6 of this part, the exhaust from such engines must be cooled by a wet or dry device before a paper filter can be used, or high temperature filters (*e.g.,* ceramics) must be used.

At this time, diesel power faces little competition from other power sources in underground metal and nonmetal mines. As can be seen from the chart, there are some small metal and nonmetal mines (less than 20 employees) which do not use diesel-powered equipment; most of these used compressed air for drilling and battery-powered rail equipment for haulage.

It is unclear at this time, how quickly new ways to generate energy to run mobile vehicles will be available for use in a wide range of underground metal and nonmetal mining activities. New hybrid electric automobiles are being introduced this year by two manufacturers (Honda and Toyota); such vehicles combine traditional internal combustion power sources (in this case gasoline) with electric storage and generating devices that can take over during part of the operating period. By reducing the time the vehicle is directly powered by combustion, such vehicles reduce emissions. Further developments in electric storage devices (batteries), and chemical systems that generate electricity (fuel cells) are being encouraged by government-private sector partnerships. For further information on recent developments, see the Department of Energy alternative fuels web site at http://www.afdc.doe.gov/altfuels.html, and ''The Future of Fuel Cells'' in the July 1999 issue of *Scientific American.* Until such new technologies mature, are available for use in large equipment, and are reviewed for safe use underground, however, MSHA assumes that the underground metal and nonmetal mining community's significant reliance upon the use of diesel-power will continue.

(2) The Composition of Diesel Exhaust and Diesel Particulate Matter (DPM)

The emissions from diesel engines are actually a complex mixture of compounds, containing gaseous and particulate fractions. The specific composition of the diesel exhaust in a mine will vary with the type of engines being used and how they are used. Factors such as type of fuel, load cycle, engine maintenance, tuning, and exhaust treatment will affect the composition of both the gaseous and particulate fractions of the exhaust. This complexity is compounded by the multitude of environmental settings in which diesel-powered equipment is operated. Nevertheless, there are a few basic facts about diesel emissions that are of general applicability.

The gaseous constituents of diesel exhaust include oxides of carbon, nitrogen and sulfur, alkanes and alkenes (*e.g.,* butadiene), aldehydes (*e.g.,* formaldehyde), monocyclic aromatics (*e.g.,* benzene, toluene), and polycyclic aromatic hydrocarbons (*e.g.,*

phenanthrene, fluoranthene). The oxides of nitrogen (NO_X) are worth particular mention because in the atmosphere they can precipitate into particulate matter. Thus, controlling the emissions of NO_X is one way that engine manufacturers can control particulate production indirectly. (See section 5 of this part).

The particulate components of the diesel exhaust gas include the so-called diesel soot and solid aerosols such as ash particulates, metallic abrasion particles, sulfates and silicates. The vast majority of these particulates are in the invisible sub-micron range of 100nm.

The main particulate fraction of diesel exhaust is made up of very small individual particles. These particles have a solid core mainly consisting of elemental carbon. They also have a very surface-rich morphology. This surface absorbs many other toxic substances, that are transported with the particulates, and can penetrate deep into the lungs. There can be up to 1,800 different organic compounds adsorbed onto the elemental carbon core. A portion of this hydrocarbon material is the result of incomplete combustion of fuel; however, the majority is derived from the engine lube oil. In addition, the diesel particles contain a fraction of non-organic adsorbed materials. Figure II–1 illustrates the composition of dpm.

Diesel particles released to the atmosphere can be in the form of individual particles or chain aggregates (Vuk, Jones, and Johnson, 1976). In underground coal mines, more than 90% of these particles and chain aggregates are submicrometer in size (i.e., less than 1 micrometer (1 micron) in diameter). Dust generated by mining and crushing of material—*e.g.,* silica dust, coal dust, rock dust—is generally not submicrometer in size. Figure II–2 shows a typical size distribution of the particles found in the environment of a mine that uses equipment powered by diesel engines (Cantrell and Rubow, 1992). The vertical axis represents relative concentration, and the horizontal axis the particle diameter. As can be seen, the distribution is bimodal, with dpm generally being well less than 1 μm in size and dust generated by the mining process being well greater than 1 μm.

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Figure II-1
DPM components

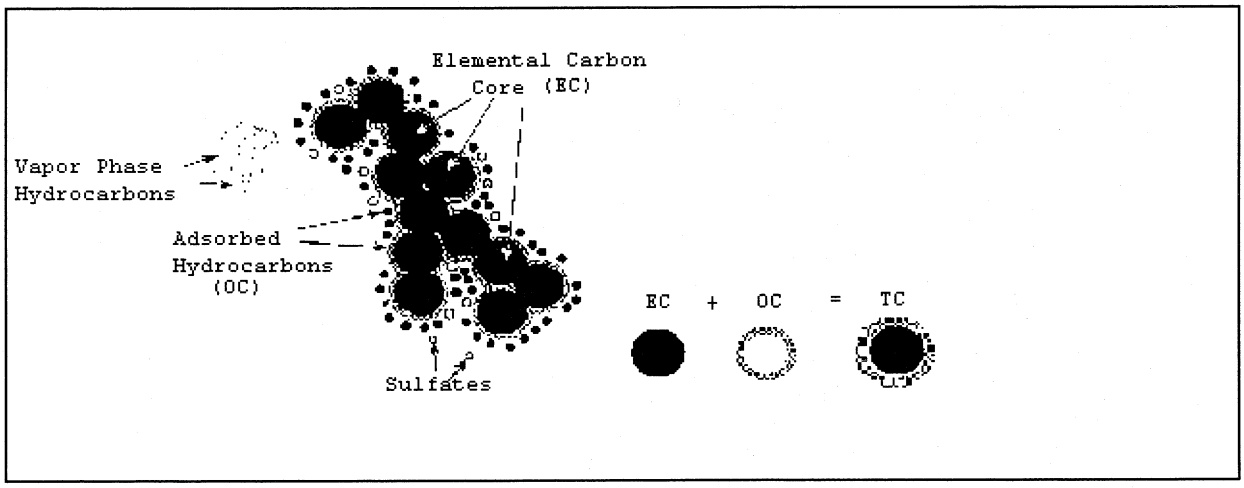


Figure II-2 -Typical distribution of dpm relative to distribution of other mining particulates.

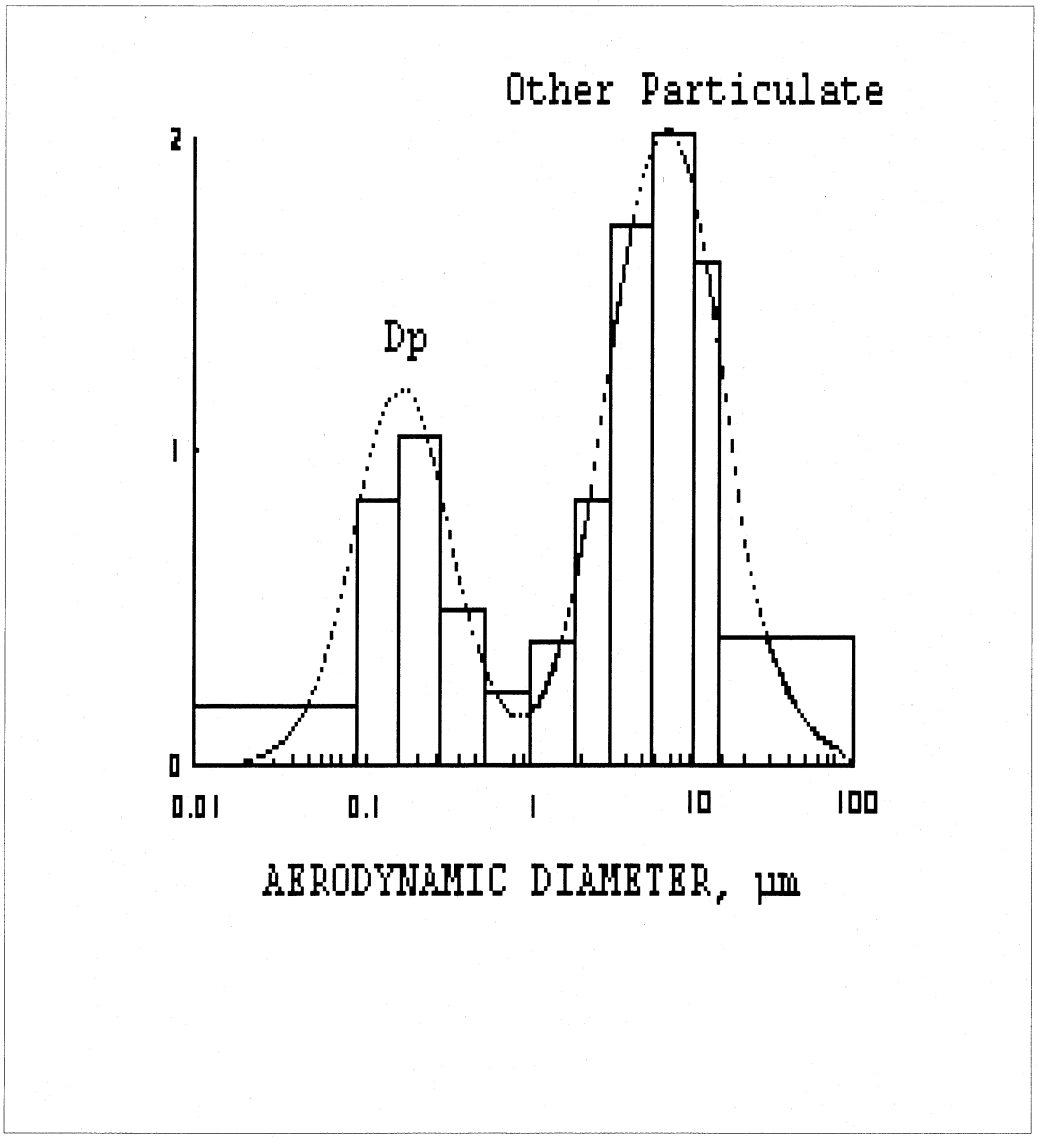
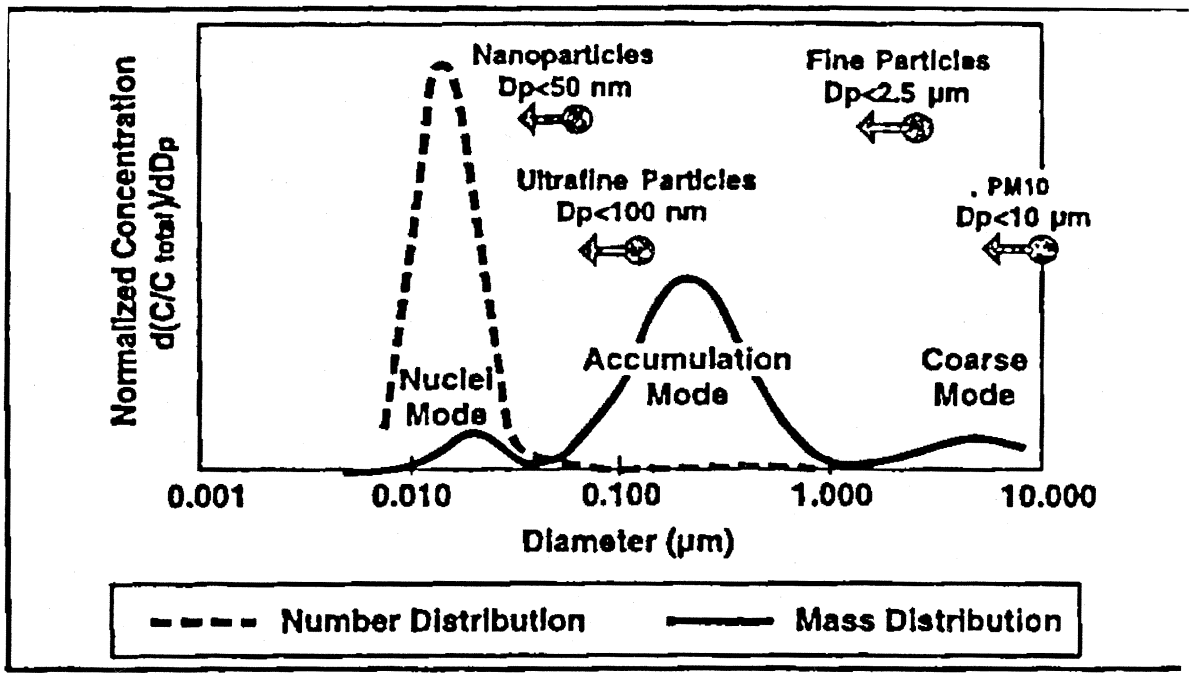


Figure II-3



Diesel particulate size distribution.

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As shown on Figure II–3 (Majewski, W. Addy, Diesel Progress June, 1998) diesel particulates have a bimodal size distribution which includes small nuclei mode particles and larger accumulation mode particles. As further shown, most of diesel particle mass is contained in the accumulation mode but most of the particle number can be found in the nuclei mode.

The particles in the nuclei mode, also known as nanoparticles, are being investigated as to their health hazard relevance. The interest in these particles has been sparked by the finding that newer ''low polluting engines emit higher numbers of small particles than the old technology engines. Although the exact composition of diesel nanoparticles is not known, it was found that they may be composed of condensates (hydrocarbons, water, sulfuric acid). The amount of these condensates and the number of nanoparticles depends very significantly on the particulate sampling conditions, such as dilution ratios, which were applied during the measurement.

Both the maximum particle concentration and the position of the nuclei and accumulation mode peaks, however, depend on which representation is chosen. In mass distributions, the majority of the particulates (*i.e.,* the particulate mass) is found in the accumulation mode. The nuclei mode, depending on the engine technology and particle sampling technique, may be as low as a few percent, sometimes even less than 1%. A different picture is presented when the number distribution representation is used. Generally, the number of particles in the nuclei mode contributes to more than 50% of the total particle count. However, sometimes the nuclei mode particles represent as much as 99% of the total particulate number. The topic of nanoparticles is discussed further in section 5 of this Part.

(3) The Sampling and Analytical Techniques for Measuring Ambient dpm in Underground Metal and Nonmetal Mines

As MSHA noted in the preamble to the proposed rule, there are a number of methods which can measure dpm concentrations with reasonable accuracy when it is at high concentrations and when the purpose is exposure assessment. Measurements for the purpose of compliance determinations must be more accurate, especially if they are to measure compliance with a dpm concentration as low as 200 µg/m^3 or lower. Accordingly, MSHA noted that it needed to address a number of questions as to whether any existing method could produce accurate, reliable and reproducible results in the full variety of underground mines, and whether the samplers and laboratories existed to support such determinations. (See 63 FR 58127 *et.seq*).

MSHA concluded that there was no method suitable for such compliance measurements in underground coal mines, due to the inability of the available methods to distinguish between dpm and coal dust. Accordingly, the agency developed a rule for the coal mining sector that does not depend upon ambient dpm measurements.

By contrast, the agency concluded that by using a sampler developed by the former Bureau of Mines, and an analytical method developed by the National Institute for Occupational Safety and Health (NIOSH), MSHA could accurately measure dpm levels at the required concentrations in underground metal and nonmetal mines. While not requiring operators to use this method for their own sampling, MSHA did commit itself to use this approach (or a method subsequently determined by NIOSH to provide equal or improved accuracy) for its own sampling. Moreover the agency proposed that MSHA sampling be the sole basis for determining compliance by metal and nonmetal mine operators with applicable compliance limits, and that a single sample would be adequate for such purposes. Specifically, proposed § 57.5061 would have provided:

Section 57.5061 Compliance determinations.

(a) A single sample collected and analyzed by the Secretary in accordance

with the procedure set forth in paragraph (b) of this section shall be an adequate basis for a determination of noncompliance with an applicable limit on the concentration of diesel particulate matter pursuant to § 57.5060.

(b) The Secretary will collect and analyze samples of diesel particulate matter by using the method described in NIOSH Analytical Method 5040 and determining the amount of total carbon, or by using any method subsequently determined by NIOSH to provide equal or improved accuracy in mines subject to this part.

This part of MSHA's proposed rule received considerable comment. Some commenters challenged the accuracy, precision and sensitivity of NIOSH Analytical Method 5040. Some challenged whether the amount of total carbon determined by the method is a reliable way to determine the amount of dpm. Others questioned whether the sampler developed by the former Bureau of Mines would provide an accurate sample to be analyzed. Many commenters asserted that the analytical method would not be able to distinguish between dpm and various other substances in the atmosphere of underground metal and nonmetal mines—carbonates and carbonaceous minerals, graphitic materials, oil mists and organic vapors, and cigarette smoke. (It should be noted that commenters also questioned the use of a single sample as the basis for a compliance determination, and the use of area sampling in compliance determinations; these comments are reviewed and responded to in Part IV of this preamble in connection with the discussion of § 57.5061.)

The agency has carefully reviewed the information and data submitted by commenters. Where necessary to verify the validity of comments, MSHA collected additional information which it has placed in the record, and which in turn were the subject of an additional round of comments.

Background. As discussed in section 2 of this part, diesel particulate consists of a core of elemental carbon (EC), adsorbed organic carbon (OC) compounds, sulfates, vapor phase hydrocarbons and traces of other compounds. The method developed by NIOSH provides for the collection of a sample on a quartz fiber filter. As originally conceived, the filter is mounted in an open face filter holder that allows for the sample to be uniformly deposited on the filter surface. After sampling, a section of the filter is analyzed using a thermal-optical technique (Birch and Cary, 1996). This technique allows the EC and OC species to be separately identified and quantified. Adding the EC and OC species together provides a measure of the total carbon concentration in the environment.

Studies have shown that the sum of the carbon (C) components (EC + OC) associated with dpm accounts for 80–85% of the total dpm concentration when low sulfur fuel is used (Birch and Cary, 1996). Therefore, in the preamble to the proposed rule, MSHA asserted that since the TC:DPM relationship is consistent, it provides a method for determining the amount of dpm. MSHA noted that the method can detect as little as 1 $\mu g/m^3$ of TC. Moreover, NIOSH has investigated the method and found it to meet NIOSH's accuracy criterion (NIOSH, 1995)—i.e., that measurements come within 25 percent of the true TC concentration at least 95 percent of the time.

In the preamble to the proposed rule, MSHA recognized that there might be some interferences from other common organic carbon sources in underground metal and nonmetal mines: specifically, oil mists and cigarette smoke. The agency noted it had no data on oil mists, but had not encountered the problem in its own sampling. With respect to cigarette smoke, the agency noted that: ''Cigarette smoke is under the control of operators, during sampling times in particular, and hence should not be a consideration.'' (63 FR 58129).

The agency also discussed the potential advantages and disadvantages of using a special device on the sampler to eliminate certain other possible interferences. NIOSH had recommended the use of a submicron impactor when taking samples in coal mines to filter out particles more than one micron in size. See Figure III–3. The idea is to ensure that a sample taken in a coal mine does not include significant amounts of coal dust, since the analytical method would capture the organic carbon in the coal dust just like the carbon in dpm. Coal dust is generally larger than one micron, while dpm is generally smaller than one micron. However, MSHA pointed out that while samples in underground metal and nonmetal mines could be taken with a submicrometer impactor, this could lead to underestimating the total amount of dpm present. This is because the fraction of dpm particles greater than 1 micron in size in the environment of noncoal mines can be as great as 20%.

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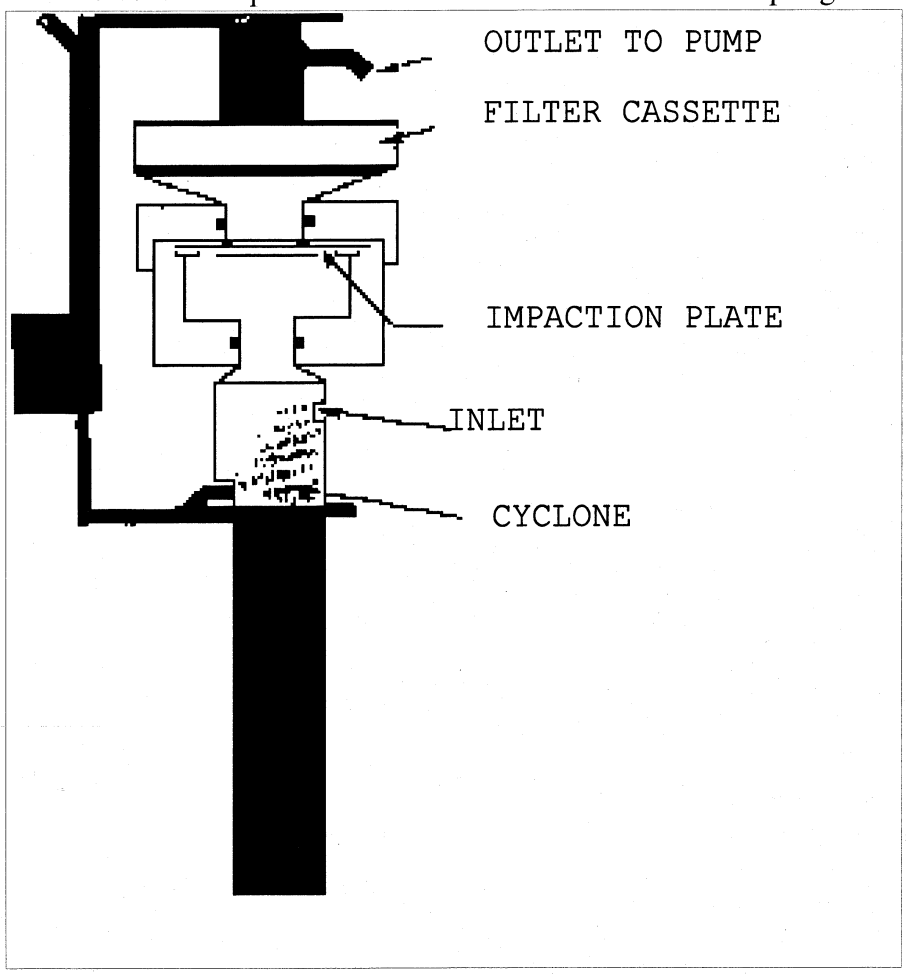
Figure II- 3
Personal Sampler For Submicrometer Particulate Sampling



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MSHA also noted that while NIOSH Method 5040 requires no specialized equipment for collecting a dpm sample, the sample would most probably require analysis by a commercial laboratory. The agency noted it did not foresee the availability of qualified testing facilities as a problem. The agency likewise discussed the availability of the sampling device, and noted steps that were underway to develop a disposable sampler. (63 FR 58130)

Sample Collection Methods. Some commenters raised questions about how dpm samples should be taken: using open face sampling, respirable sampling and submicron sampling. All three are discussed in NIOSH Analytical Method 5040. Because diesel particulate matter is primarily submicron in size any of the three sampling methods could be used.

The choice of sample collection method considers the cost and potential interferences that the method can contribute. Regardless of the sampling method, the sampling media (filter) must be one that does not interfere with the analysis. For this reason a pre-fired quartz fiber filter has been chosen. The quartz fiber filter is capable of withstanding the temperatures from the analytical procedure. The filter is pre-fired to remove residual carbon, attached to the filter during manufacturing.

Total Dust Sampling. Total dust sampling is the least expensive method to collect an airborne dust sample. It is commonly used to collect a sample that is representative of all the dust in the environment; i.e., the particles are not preclassified during the collection process. Total dust sampling can be performed using a filter cassette that allows the whole face of the filter to be exposed during collection of the sample (open face) or using a filter cassette with a small inlet opening (referred to as a closed face filter cassette). The latter method is used by MSHA for compliance sampling for total dust in the metal and nonmetal sector. Because the sample collected is representative of all the particulate matter in the environment, there is the potential for interference from mineral contaminants when sampling for diesel particulate matter. While in many cases the analytical results can be corrected for these interferences, in some instances the interferences may be so large that they can not be quantified with the analytical procedure, thus preventing the analytical result to be corrected for the interference.

Additionally, MSHA has noted that in some cases when using the total dust sampler with the small inlet hole, distribution of the collected sample on the filter is not uniform. The distribution of sample is concentrated in the center of the filter. This can result in the effect of an interference being magnified. As a result, MSHA considers that total dust sampling is not an appropriate sampling method for the mining industry to use when sampling diesel particulate matter.

Respirable Dust Sample Collection. Respirable dust sampling is commonly used when a size selective criteria for dust is required. The mining industry is familiar with size selective sampling for the collection of coal mine dust samples in coal mines and for collecting respirable silica samples in metal and nonmetal mines. For respirable dust sampling MSHA uses a 10 millimeter, Dorr Oliver nylon cyclone as a particle classifier to separate the respirable fraction of the aerosol from the total aerosol sampled. The use of this particle classifier would be suitable when sampling diesel particulate, provided significant amounts of interfering minerals are not present. This is because 90 percent of the diesel particulate is typically less than 1 micrometer in size. Particles less than 1 micrometer in size pass through the cyclone and are deposited on the filter. While in many cases, these interferences could be removed during the analytical procedures, the analytical procedures alone can not be assured to remove the interferences when large amounts of mineral dust are present.

Additionally, MSHA has observed that in some sampling equipment the cyclone outlet hole has been reduced when interfacing it with the filter capsule. MSHA has further observed that where this has occurred, the distribution of sample on the collection filter may not be uniform. In this circumstance the sample is also concentrated in the center of the filter which can result in the effect of a mineral interference being magnified. As a result, MSHA considers that respirable dust sampling is not a universally applicable sampling method for the mining industry to use for sampling diesel particulate matter.

Submicron Dust Sample Collection. Since only a small fraction of a mineral dust aerosol is less than 1 micrometer in size, a submicrometer impactor (Cantrell and Rubow, 1992) was developed to permit the sampling of diesel particulate without sampling potential mineral interferences. The submicrometer impactor was initially developed to remove the interference from coal mine dust when sampling diesel particulate in coal mines. It was designed to remove the carbon coal particles, that are greater than 0.8 micrometer in size, when sampling for diesel particulate matter at a pump flowrate of 2.0 liters per minute. As a result the submicrometer impactor cleans potentially interfering mineral dust from the sample.

As noted in the preamble to the proposed rule, use of this method to measure dpm does result in the exclusion of that portion of dpm that is not submicron in size, and this can be significant. On the other hand, this method avoids problems associated with the other methods described above. Moreover, as discussed in more detail below under the topic of ''interferences'', the submicron impactor can eliminate certain substances that in metal and nonmetal mines would otherwise make it difficult for the analytical method to be used for compliance purposes.

Accuracy of Analytical Method, NIOSH Method 5040. Commenters challenged the accuracy, precision and sensitivity of the analytical method (NIOSH Method 5040) used for the diesel particulate analysis. MSHA has carefully reviewed these concerns, and has concluded that provided a submicron impactor is used with the sampling device in underground metal and nonmetal mines, NIOSH Method 5040 does provide the accuracy, precision and sensitivity necessary to use in compliance sampling for dpm in such mines.

As noted above, NIOSH Method 5040 is an analytical method that is used to determine elemental and organic carbon content from an airborne sample. It is more versatile than other carbon analytical methods in that it differentiates the carbon into its organic and elemental carbon components. The method accomplishes this through a thermal optical process. An airborne sample is collected on a quartz fiber filter. A portion of the filter, (approximately 2 square centimeters in area) is placed into an oven. The temperature of the oven is increased in increments. At certain oven temperature and atmospheric conditions (helium, helium-oxygen), carbon on the filter is oxidized into carbon dioxide. The carbon dioxide gas is then passed over a catalyst and reduced to methane. The methane concentration is measured and carbon content is determined. Separation of different types of organic carbon is accomplished through temperature and atmospheric control. The instrument is programmed to increase temperature in steps over time. This step by step increase in temperature allows for differentiation between various types of organic carbon.

A laser is used to differentiate the organic carbon from the elemental carbon. The laser penetrates the filter and when the laser transmittance reaches its initial value this determines when elemental carbon begins to evolve. The computer software supplied with the instrumentation indicates this separation by a vertical line. The separation point can be adjusted by the analyst. As a result, there may be small differences in the determination of organic and elemental carbon between analysts, but the total carbon (sum of elemental and organic carbon) does not change. The software also allows the analyst to identify and quantify the different types of organic carbon using identifiable individual peaks. This permits the mathematical subtraction of a particular carbon peak. This feature is particularly useful in removing contributions from carbonates or other carbonaceous minerals. In other total carbon methods, samples have to be acidified to remove carbonate interference. A thermogram is produced with each analysis that shows the temperature ramps, oven atmospheric conditions and the amount of carbon evolved during each step.

A range of five separate sucrose standards between 10–100 $\mu g/cm^2$ carbon are initially analyzed to check the linearity of the internal calibration determined using a constant methane concentration. This constant methane concentration is injected at the end of each analysis. To monitor this methane constant, sucrose standards are analyzed several times during a run to determine that this constant does not deviate by more than 5–10%.

The method has the sensitivity to analyze environmental samples containing 1 to 10 $\mu g/m^3$ of elemental carbon. The method will be used in mining applications to determination total carbon contamination where the diesel particulate concentration will be limited to 400 $\mu g/m^3_{TC}$ and 160 $\mu g/m^3_{TC}$. NIOSH has reported that the lower limit of detection for the method is 0.1 $\mu g/cm^2$ elemental carbon for an oven pre-fired filter portion and 0.5 $\mu g/cm^2$ organic carbon for an oven pre-fired filter portion. For a full shift sample, this detection limit represents approximately 1 and 5 $\mu g/m^3$ of elemental and organic carbon, respectively. Additionally, NIOSH has conducted a round robin program to assess interlaboratory variability of the method. This study indicated a relative standard deviation for total carbon, of less than 15 percent.

A typical diesel particulate thermogram is shown in Figure II–4. The thermogram generally contains five or six carbon peaks, one for each temperature ramp on the analyzer. The first four peaks (occurring during a helium atmosphere ranging from a temperature of 210C to 870C) are associated with organic carbon determination and the fifth and/or sixth peak (occurring during a helium/oxygen atmosphere ranging in temperature from 610C to 890C) is the elemental carbon determination.

The fourth peak (temperature ~750C) is also where carbonate and other carbonaceous minerals are evolved in the analysis. For a diesel particulate sample without interferences present, this fourth peak is usually minimal as it is attributed to heavy distillant organics not normally associated with diesel operations in underground mining applications. If this peak is due to carbonate, the carbonate interference can be verified by analyzing a second portion of the sample after acidification as described in the NIOSH 5040 method. If the fourth peak is caused by some other carbonaceous mineral, the acidification process may not completely remove the interference and may, on occasion cause a positive bias to elemental carbon.

As explained below in the discussion of interferences, these analytical interferences from carbonaceous materials can be corrected by using the submicron impactor preceded by a cyclone (respirable classifier) to collect diesel particulate matter samples, since nearly all the particles of these minerals are greater than 1 micrometer in size. Accordingly, MSHA has determined it should utilize a submicron impactor in taking any samples in underground metal and nonmetal mines, and has included this requirement in the rule. Specifically, 57.5061(b) now provides:

(b) The Secretary will collect samples of diesel particulate matter by using a respirable dust sampler equipped with a submicrometer impactor and analyze the samples for the amount of total carbon using the method described in NIOSH Analytical Method 5040, except that the Secretary may also use any methods of collection and analysis subsequently determined by NIOSH to provide equal or improved accuracy for the measurement of diesel particulate matter in mines subject to this part.

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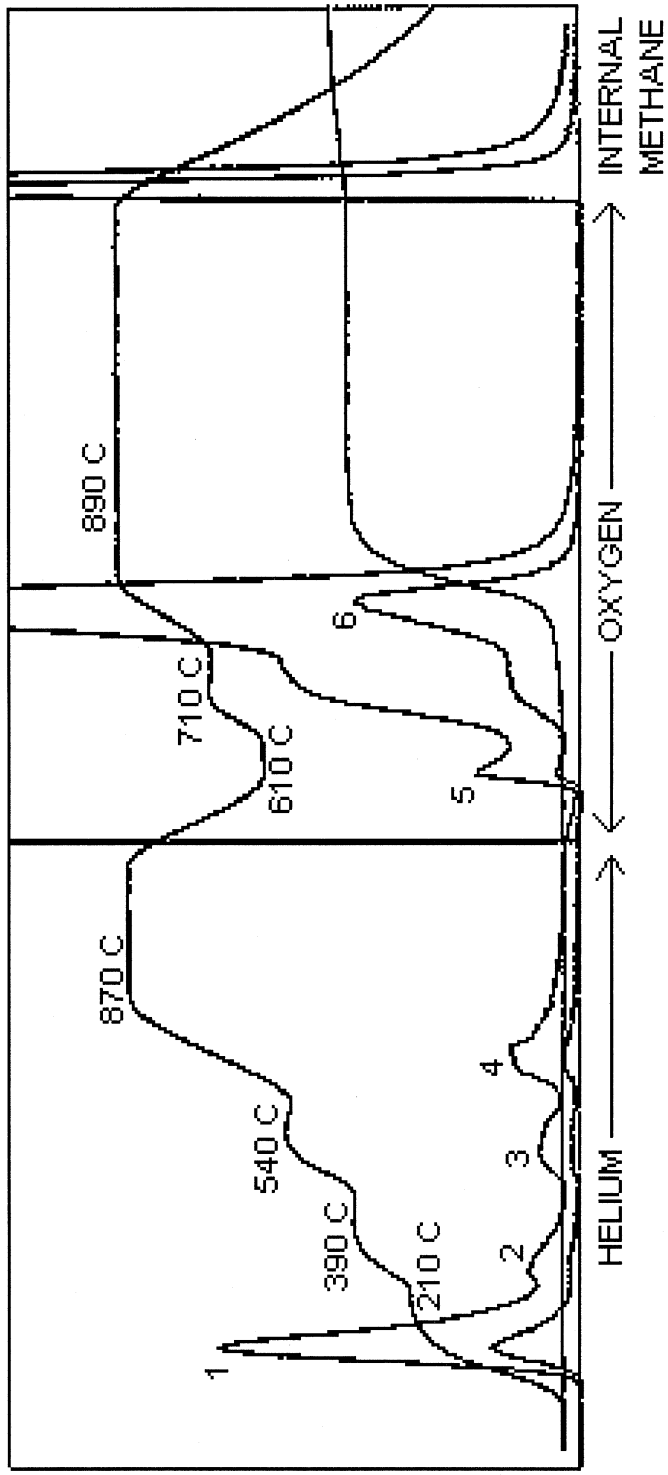

Figure II-4 Thermogram from analysis of a respirable dust sample.

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In keeping with established metal and nonmetal sampling protocol, the samplers will be operated at a flow rate of 1.7 LPM. At a flow rate of 1.7 LPM, the cut point for the impactor is 0.9 micrometers.

Any organic carbon detected at the fourth peak will be subtracted from the organic carbon portion of the sample analysis using the software supplied with the analytical program. The only samples that MSHA anticipates that will be acidified are those collected in trona mines. These samples contain a bicarbonate which evolves in several of the organic peaks but can be removed by acidification. Use of the submicron impactor will also insure a uniform distribution of diesel particulate and mineral dust on the filter.

Some Commenters indicated that a uniform deposit of mineral dust was sometimes not obtained with certain respirable dust sampler configurations. For some commodities such as salt and potash, where carbonate may not be an interference, it is probably not necessary to sample with the submicron impactor. However, in order to be consistent, MSHA will sample all commodities using a respirable dust sampler equipped with a submicrom impactor, and has so noted in the rule.

Proper use of sample blanks. Each set of samples collected to measure the diesel particulate concentration of a mine environment, must be accompanied by a field blank (a filter cassette that is treated and handled in the same manner as filters used to collect the samples) when submitted for analysis. The amount of total carbon determined from the analysis of the blank sample must be applied to (subtracted from) the carbon analysis of each individual sample. The field blank correction is applied to account for non-sampled carbon that attaches to the filter media. The blank correction is applied to the organic fraction as, typically, no elemental carbon is found on the blank filters.

Failure to adjust for the blanks can lead to incorrect results, as was the case with samples collected by some commenters. While field blanks were submitted and analyzed with their samples, the field blank analytical results were not used to correct the individual samples for nonsampled carbon content. Typically the carbon content on the reviewed field blanks ranged from 2 to 3 μg/square centimeter of filter area. For a one-hour sample, not using a blank correction of this magnitude, could result in an overestimate of 250 μg/m^3 of dpm (3×8.55×1000/(1.7 * 60)=250). For an eight-hour sample, not using a blank correction, could result in an overestimate of 30 μg/m^3 of dpm (3×8.55×1000/(1.7* 480)=30).

Variability of Sample Blanks

In response to the July 1, 2000, reopening of the record, one commenter submitted summary data from a study that examined diesel exposures in seven underground facilities where trona, salt, limestone, and potash were mined. The purpose of this study was to determine the precision and accuracy of the NIOSH 5040 method in these environments. According to the commenter, the study data ''provide strong evidence that the NIOSH 5040 Method * * * is not feasible as a measure of DPM exposure.'' The commenter's conclusion was based on five ''difficulties'' that, according to the commenter, were documented when sampling for DPM using organic carbon or total carbon as a surrogate. These difficulties were:

(1) High and variable blank values from filters;

(2) High variability from duplicate punches from the same sampling filter;

(3) Consistently positive interference when open-faced monitors were sampled side-by-side with cyclones;

(4) Poor correlation of organic carbon to total carbon levels; and

(5) Interference from limestone that could not be adequately corrected with acid-washing.

As discussed elsewhere in this preamble, difficulties #3 and #5 will be resolved by the use of a submicrometer impactor sampler. Difficulty #4, the lack of a strong correlation between organic carbon and total carbon, has long been recognized by MSHA. That is one of the reasons MSHA chose total carbon (TC=EC+OC) as the best surrogate to use for assessing DPM levels in underground metal and nonmetal mines. MSHA has never proposed using organic carbon as a surrogate measure of DPM.

The summary data that the commenter submitted do not appear to demonstrate the first two items of ''difficulties'' with respect to TC measurements. Because MSHA has not experienced the difficulties of (1) high and variable blank values and (2) high variability between duplicate punches from the same sampling filter, MSHA also performed its own analysis of the data submitted by the commenter. MSHA's examination of the data included:

- Estimating the mean, within-mine standard deviation, and relative standard deviation (RSD) for blank TC values, based on the ''Summary of Blank Sample Results'' submitted; and
- Estimating the variability (expressed as RSD) associated with the TC analysis of duplicate punches from the same filter, based on individual sample data submitted earlier by the same commenter for five of the mines.

Based on the summary data, the overall average mean TC content per blank filter, weighted by the number of blank samples in each mine, was 16.9 μg TC. This represents the average value that would be subtracted from the TC measurement from an exposed sample before making a noncompliance determination. At a TC concentration of 160 μg/m^3 (the final limit established by this rule), the TC accumulated on a filter after an 8-hour sampling period would be approximately 130 μg. Therefore, these data show that the mean TC value for a blank is less than 13 percent of TC accumulated at the concentration limit, and an even lower percentage of total TC accumulated at concentrations exceeding the limit. MSHA considers this to be acceptable for samples used to make noncompliance determinations. Based on the same summary data presented for TC measurements on blank samples, the weighted average of within-mine standard deviations is 6.4 μg. Compared to TC values greater than or equal to 130 μg, this corresponds to an RSD no greater than 6.4/130 = 4.9 percent. MSHA also regards this degree of variability in blank TC values to be acceptable for purposes of noncompliance determination.

To estimate the measurement variability associated with analytical errors in the TC measurements, MSHA examined the individual TC results from duplicate punches on the same filter. These data were submitted earlier by the same commenter for five mines. As shown, by the commenter's summary table, data obtained from the first mine were invalid, leaving data from four mines (2–5) for MSHA's data analysis. Data were provided on a total of 73 filters obtained from these four mines, yielding 73 pairs of duplicate TC measurements, using the initial and first repeated measurement provided for both elemental and organic carbon. MSHA calculated the mean percent difference within these 73 pairs of TC measurements (relative to the average for each pair) to be 8.2 percent (95-percent confidence interval = 5.6 to 10.9 percent). Based on the same data, MSHA calculated an estimated RSD = 10.0 percent for the analytical error in a single determination of TC.[1] Contrary

[1] This estimate was obtained by first calculating the standard deviation of the differences between the natural logarithms of the TC measurements within each pair. Since each of these differences

to the commenter's conclusion, this result supports MSHA's position that TC measurements do not normally exhibit excessive analytical errors.

This estimate of the RSD = 10.0 percent for TC measurements is also consistent with the replicated area sample results submitted by the commenter for the seven mines. In this part of the study, designed to evaluate measurement precision, 69 sets of simultaneous samples were collected at the seven mines. Each set, or ''basket,'' of samples normally consisted of five simultaneous samples taken at essentially the same location. Since the standard deviation of the TC measurements within each basket was based on a maximum of five samples, the standard deviation calculated within baskets is statistically unstable and does not provide a statistically reliable basis for estimating the RSD within individual baskets. However, as shown in the summary table submitted by the commenter, the mean RSD across all 69 baskets was 10.6 percent. This RSD, which includes the effects of normal analytical variability, variability in the volume of air pumped, and variability in the physical characteristics of individual sampler units, is not unusually high, in the context of standard industrial hygiene practice.

MSHA also examined data submitted by another commenter to estimate the total variability associated with TC sample analysis by different laboratories. Based on 25 pairs of simultaneous TC samples (using a cyclone) analyzed by different laboratories, this analysis showed a total RSD of approximately 20.6 percent. If the most extreme of three statistical outliers in these data is excluded, the result based on 24 pairs is an estimated RSD of 11.7 percent. Like the first commenter's estimate of RSD = 10.6 percent, based on simultaneous samples analyzed at the same laboratory, these RSD's include not only normal analytical variability in a TC determination, but also variability in the volume of air pumped and variability in the physical characteristics of individual sampler units. The higher estimates, however, also cover uncertainty in a TC measurement attributable to differences between laboratories.

Based on these analyses, MSHA has concluded that the data submitted to the record by commenters support the Agency's position that NIOSH Method 5040 is a feasible method for measuring DPM concentrations in underground M/NM mines.

Availability of analysis and samplers. One of the concerns expressed by commenters was the limited number of commercial laboratories available to analyze diesel particulate samples, and the availability of required samplers. While MSHA will be doing all compliance sampling itself, and running the analyses in its AIHA accredited laboratory in Pittsburgh, pursuant to § 57.5071 of the rule, operators in underground metal and nonmetal mines will be required to do environmental monitoring; and although they will not be required to use the same methods as MSHA to determine dpm concentrations, MSHA presumes that many will wish to do so. Moreover, there are certain situations (*e.g.,* verification that a dpm control plan is working) where the rule requires operators to use this method (§ 57.5062(c)).

Currently there are four commercial labs that have the capability to analyze for dpm using the NIOSH 5040 Method. These labs are: Sunset Laboratory, Forest Grove, Oregon and Chapel Hill, North Carolina; Data Chem, Salt Lake City, Utah; and Clayton Group Services, Detroit, MI. All of these labs, as well as including the NIOSH Laboratories in Cincinnati and Pittsburgh and the MSHA laboratory in Pittsburgh participate in a round robin analytical test to verify the accuracy and precision of the analytical method being used by each. As MSHA indicated in the preamble to its proposed rule, it believes that once there is a commercial demand for these tests, additional laboratories will offer such services.

The cost of the analysis from the commercial labs is approximately $30 to $50 for a single punch analysis and a report. This is about the same amount as a respirable silica analysis. The labs charge another $75 to acidify and analyze a second punch from the same filter and to prepare an analytical report. The labs report both organic and elemental carbon. By using the submicron impactor, operators can significantly reduce the number of situations where acidification is required, and thus reduce the cost of sample analysis.

The availability of samplers has been the subject of many comments—not so much because of concern about availability once the rule is in effect, but because of assertions that they are not available now. In particular, it has been alleged by some commenters that they have been unable to conduct their own ''independent evaluation'' of the NIOSH method because the agency has kept from them the samplers needed to properly conduct such testing. Some commenters even accused the agency of deliberately withholding the needed samplers.

As indicated in MSHA's toolbox and the preamble to the proposed rule, the former Bureau of Mines (BOM) submitted information on the development of a prototype dichotomous impactor sampling device that separates and collects the submicron respirable particulate from the respirable dust sampled. Information on this sampling device has been available to the industry since 1992. A picture of the sampler is shown above as Figure II–3. The impactor plate is made out of brass and the nozzles are drilled. The former BOM made available to all interested parties detailed design drawings that permitted construction of the dichotomous impactor sampler by any local machine shop. NIOSH and MSHA had hundreds of these sampling devices made for use in their programs to measure dpm concentrations. Anyone could have had impactor samplers built by a local machine shop at a cost ranging from $50 to $100.

In 1998, MSHA provided NIOSH with research funds for the development of a disposable sampling device that would have the same sampling characteristics as the BOM sampler, and including an impactor with the same sampling characteristics as the metal one. NIOSH awarded SKC the contract for the development of the disposable sampler. MSHA estimates the cost of the disposable sampler will be less than $50. The sampler is designed to interface with the standard 10 millimeter Dorr Oliver cyclone particle classifier and to fit in a standard MSHA respirable dust breast plate assembly. The quartz fiber filter used for the collection of diesel particulate in accordance with NIOSH Method 5040 has been encapsulated in an aluminum foil to make handling during the analytical procedure easier. To reduce manufacturing expense (and therefore, sampler cost), the nozzle plate in the SKC sampler is made of plastic instead of brass. In order to ensure that the nozzles in the impaction plate would hold their tolerances during manufacturing, the plastic nozzle plate for the SKC sampler is fitted with synthetic sapphire nozzles. This nozzle plate and nozzle assembly have the same performance as the BOM-designed sampler.

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contains two TC determinations, and two corresponding analytical errors, this standard deviation was divided by the square root of 2. Using standard propagation of error formulas, the result provides a reasonably good estimate of the RSD over the range of TC values reported. MSHA used the same technique to estimate the RSD for the 25 pairs of TC samples analyzed at different laboratories, as described below.

As of the time MSHA conducted its verification sampling for interferences, SKC had developed several prototypes of the disposable unit. However, testing of the devices by NIOSH indicated that a minor design modification was needed to better secure the impaction plate and nozzle plate to the sampler housing for a production unit. In its verification sampling, MSHA used both BOM designed and SKC prototype samplers. Prior to its verification tests, MSHA replaced the brass nozzle plates in the BOM design impactors with plastic nozzle-plates fitted with sapphire nozzles, as used in the SKC prototype sampler. However, because there was no change in nozzle geometry, this change in the BOM impactors did not affect their performance. During MSHA's verifications testing, no problems were experienced with dislodgement of the impaction plates or nozzle plates. The impactors used by MSHA in its verification sampling were not defective in any way, as suggested by several Commenters.

Under the Mine Act, MSHA has no obligation to make devices available to the mining community to conduct its own test sampling or to verify MSHA's results, nor does the mining industry have any explicit authority under the Mine Act to ''independently evaluate'' MSHA's results. The responsibility for determining the accuracy of the device and method for sampling rests with the agency, not the mining community. Accordingly, although some commenters requested that MSHA remove its interference studies from the record, the agency declines to do so. These studies are discussed in more detail below; additional questions raised about the sampling devices used in the studies, and the procedures for that sampling, are discussed in that context.

Some commenters initially asserted that their inability to conduct their own testing would prevent them from making comments of MSHA's verification studies. Based on the detailed comments subsequently provided, this initial concern appears to have been overstated.

It appears from some of the comments on MSHA's studies that members of the mining community may have understood MSHA to say that use of an impactor sampler would remove all interferences. MSHA can find no such statement. As noted in more detail below, use of the impactor will remove most of the interferences (albeit at the cost of eliminating some dpm as well).

Choice of Total Carbon as Measurement of Diesel Particulate Matter. MSHA asserted that the amount of total carbon (determined by the sampling and analytical methods discussed above) would provided the agency with an accurate representation of the amount of dpm present in an underground metal and nonmetal mine atmosphere at the concentration levels which will have to be maintained under the new standard. Some commenters questioned MSHA's statements concerning the consistency of the ratio between total carbon and diesel particulate, and the amount of that ratio. Other commenters suggested that elemental carbon may be a better indicator of diesel particulate because it is not subject to the interference that could effect a total carbon measurement.

Under the approach incorporated into the final rule, the concentration of organic and elemental carbon (in µg per square centimeter) are separately determined from the sample analysis and added together to determine the amount of total carbon. The interference from carbonate or mineral dust quantified by the fourth organic carbon peak is subtracted from the organic carbon results. The field blank correction is then subtracted from the organic analysis (the blank does not typically contain elemental carbon). Concentrations (time weighted average) of carbon are calculated from the following formula:

$$\frac{C\left(\mu g/cm^2\right) * A\left(cm^2\right) * 1{,}000\ L/m^3}{1.7\ LPM * time\ (min)}$$

Where:

C=The Organic Carbon (OC) or Elemental Carbon (EC) concentration, in µg/m³, measured in the thermal/optical carbon analyzer (corrected for carbonate and field blank).

A=The surface area of the filter media used. The surface areas of the filters are as follows: quartz fiber filter without aluminum cover is 8.55 cm²; quartz fiber filter with aluminum cover is 8.04 cm².

The 80 percent factor MSHA used to establish the total carbon level equivalents of the 500 µg/m³ and 200 µg/m³ dpm concentration limits being set by the rule was based on information obtained from laboratory measurements conducted on diesel engines (Birch and Cary, 1996). Since the publishing of the proposed rule, this value has been confirmed by measurements collected in underground mines in Canada (Watts, 1999)

MSHA agrees that the total carbon measurement is more subject to interferences than the elemental carbon measurement. However, because the ratio of elemental carbon to total carbon in underground mines is dependent on the duty cycle at which the diesel engine is operated (found to vary between 0.2 and 0.7), MSHA believes that total carbon is the best indicator of diesel particulate for underground mines. Additionally, MSHA has observed that some controls, such as filtration systems on cabs can alter the ratio of elemental to total carbon. The ratio can be different inside and outside a cab on a piece of diesel equipment. MSHA notes that NIOSH has asserted that the ratio of elemental carbon to dpm is consistent enough to provide the basis for a standard based on elemental carbon (''* * * the literature and the MSHA laboratory tests support the assertion that DPM, on average, is approximately 60 to 80% elemental carbon, firmly establishing EC as a valid surrogate for DPM''). However, while an average value for elemental carbon percent may be a useful measure for research purposes, data submitted by commenters show that elemental carbon can range from 8 percent to 81 percent of total carbon.

MSHA does not believe elemental carbon is a valid surrogate for dpm in the context of a compliance determination that, like all other metal and nonmetal health standards, can be based on a single sample. By contrast, as noted above, studies have shown that there is a consistent ratio between total carbon and dpm (from 80 to 85%). Moreover, although the ratio of the elemental carbon to organic carbon components obtained using the NIOSH Method 5040 may vary, total carbon determinations obtained with this method are very consistent, and agree with other carbon methods (Birch, 1999). Accordingly, while total carbon sampling does necessitate sampling protocols to avoid interferences, of the sort discussed below, MSHA has concluded that it would not be suitable at this time to use elemental carbon as a surrogate for dpm.

Potential Sample Interferences/ Contributions. As noted in the introduction to this section, many commenters asserted that the analytical method would not be able to distinguish between dpm and various other substances in the atmosphere of underground metal and nonmetal mines—carbonates and carbonaceous minerals, graphitic materials, oil mists and organic vapors, and cigarette smoke. The agency carefully reviewed the information submitted by commenters, both during the hearings and in writing, and found that it was in general insufficient to establish that such interferences would be a problem. Limitations in the data submitted by the

commenters included, for example, failure to utilize blanks, failure to blank correct sample results, open face and respirable samples that were collected in the presence of high levels of carbonate interference, the amount of carbonate interference was not quantified, dpm was not uniformly deposited on filters and sample punches were taken where the deposit was heaviest, failure to adjust sample results due to short sampling times, failure to consider the impact of interferences such as carbonate, oil mist, and cigarette smoke on dpm exposure.

Rather than dismiss these assertions, however, the agency decided to conduct some investigations to verify the validity of the comments. As a result of these tests, the agency has determined that certain interferences can exist, within certain parameters; and was also able to demonstrate how these interferences can be minimized or avoided. The material which follows reviews the information MSHA has on this topic, including representative comments MSHA received on these verification studies. Part IV of this preamble reviews in some detail the adjustments MSHA has made to the proposed rule, and the practices MSHA will follow in compliance sampling, to avoid these interferences.

General discussion of interference studies. As noted above, MSHA conducted the verifications to determine if the alleged interferences were in fact measurable in underground mining environments. At the same time, the studies gave MSHA an opportunity to identify sampling techniques that would minimize or eliminate the interferences, evaluate analytical techniques to minimize or eliminate the interferences from the samples, and develop a sampling and analytical strategy to assure reliable dpm measurements in underground mines.

A total of six studies were conducted. One field study was conducted at Homestake Mine, a gold mine in Lead, South Dakota, three field studies were conducted at gold mines near Carlin, Nevada. These included Newmont, South Area Carlin Mine and Barrick Goldstrike. One study was conducted in the NIOSH Research Laboratory's experimental mine in Pittsburgh, Pennsylvania and one study conducted in a laboratory dust chamber at the NIOSH Pittsburgh Research Laboratory. For example the studies conducted at Carlin and Homestake were to evaluate interference from oil mist and the studies conducted at Homestake, Newmont and Barrick were to assess interference from carbonaceous dust. These locations were carefully selected in light of the assertions about interferences which had been made by commenters.

Despite the care that went into designing where to conduct the verification samples, there were a number of comments asserting the samples were not representative. For example, it was asserted that MSHA did not sample a representative particle size distribution and sampled the wrong material (i.e., ores with the highest carbon content). On the contrary the samples that MSHA collected were representative of the respirable and submicron fractions of the dust in the environment as well as the total dust in the environment. Therefore, MSHA believes that the particle size distribution of the samples collected were representative. Also, MSHA obtained a bulk sample of the various ores tested. While the samples collected at the crushers were low carbon content (0–10.3%), the carbon content (30.3%) of the ore collected at the underground mining area sampled at Carlin was similar to the high carbon content (31.4%) ores obtained at Barrick. The sampling therefore included a cross section of the ores in question.

Some commenters objected to the fact that no personal samples were collected in these studies. Packages of samplers were placed in areas that were close to the breathing zone of the workers. Upwind and downwind samples were used to determine the extent of the interference. The regulation recognizes the validity of area samples. As a result these samples provided valid information on interferences that are likely to be encountered during sampling by MSHA inspectors.

More generally, commenters asserted that MSHA lacked enough studies for statistical analysis. MSHA notes again that the studies were conducted to verify specific industry assertions, and were properly designed to try and verify those assertions. However, the same studies which confirmed that such interferences could be measured in certain conditions were also able to determine that these interferences could not be measured, or were not significant in scope, if some of the conditions were changed. Part IV of this preamble discusses what actions the agency plans to take as a result of its current information on this matter.

Some commenters asserted that MSHA made certain incorrect technical assumptions in its verification sampling: about the sampling method used to conclude that overall dust levels would meet MSHA's standards; about the concentration of EC in submicrometer dust; and about the variability of carbonaceous ores. With respect to the first point, the final sampling strategy adopted by MSHA for dpm allows for either personal or area sampling using a submicrometer sampler preceded by a respirable cyclone. Because of the sampling and analytic procedures, the only potential mineral interferent would be the graphitic contribution (elemental carbon). The carbonate and carbonaceous contribution would be eliminated or reduced by the use of the impactor sampler and using the software integration procedure described in Method 5040.

With respect to the second point, the concentration of EC in the submicrometer dust, for personal and most area samples, the allowable silica exposure would limit the amount of submicrometer mineral dust sampled. This has been demonstrated for samples collected in coal mines where the coal dust contains high levels of elemental carbon, but the interference for EC from submicrometer samples has been less that 4 $\mu g/m^3$.

With respect to the last point which addresses the geology of the ore, MSHA acknowledges that there would be variation in the carbon content of the ore. However, it would be unlikely that the carbon content would exceed that of coal mine dust where the elemental carbon interference has been found to be negligible.

The sampling was performed with the BOM designed or SKC prototype samplers as described in the prior section. All samplers used the more precise sapphire nozzles. Samples were collected using standard procedures developed by MSHA for assessing particulate concentrations in mine environments. Samples were analyzed for total carbon using NIOSH Method 5040. The analyses was performed by MSHA at the Pittsburgh Safety and Health Technology Center's Dust Division laboratory. For some samples a second analysis was performed using an acidification procedure.

Commenters alleged a number of technical problems with how the sampling was performed. Some asserted that defective devices were used for the sampling, or that MSHA did not properly calibrate its equipment. MSHA did not experience any problems with the samplers, and did calibrate its equipment according to standard procedures. Some pointed out that MSHA conducted the verifications with samplers different from those required by the rule. MSHA presumes this comment reflects the fact that the proposed rule did not require an

impactor to be used; this is, however, the case with the final rule.

Some commenters noted that MSHA voided some sample results and that, lacking further explanation, it might be assumed the agency simply eliminated those samples which gave results that did not agree with the conclusions it sought. The only samples that were voided were chamber samples. Some voided samples were higher than, and some void samples were lower than, the sample used. These were duplicate samples collected for short time periods. Samples were voided because they were inconsistent with other samples in the set of six samples collected. These inconsistencies as-well-as variability between other duplicate samples were attributed to short sample times. Voided sample results are shown for Homestake (1 of 12 impactors). No impactor samples were voided at Barrick nor at the Newmont crusher. In the Jackleg drill tests conducted at Carlin Mine, there were 2 of 6 impactor samples voided.

Others asserted that MSHA failed to validate the design of the box which held the sampling equipment. In fact, all of the issues mentioned relative to the sampling box (i.e., pressure build up, leakage of chamber, impaction of particles, pump calibration) had been carefully examined by MSHA prior to the tests and found not to be a problem. Also, this sample chamber has been used extensively in other field tests where duplicate samples or a variety of samplers have been used and has worked extremely well.

One commenter stated that these studies confirm that measurement interference cannot be eliminated by blank correction and longer sample times, and that the proposed single sample enforcement policy would not be representative of typical mine conditions. MSHA disagrees with this conclusion from the verification tests. The MSHA tests demonstrated that blank correction does eliminate a source of interference. The residual organic carbon indicated in several of the samples collected at crushers were attributed to short sample time and normal variation in the range of blank values. The verification tests did not address sample time. However, when converting the mass collected to a concentration, the mass is divided by the sample time. Dividing by a longer time will always reduce an interference caused by a positive bias.

Other commenters alleged that there were problems with the MSHA personnel performing the studies. Some asserted these personnel failed to listen to suggestions made by representatives of mine companies who accompanied MSHA in their facilities during in-mine testing, suggestions which they assert would have corrected asserted problems in the testing procedure. Others simply assert that the MSHA personnel were biased, manipulated the data, and tried to conform the study results to those they wanted to find. It was also asserted that any potential for bias should have been removed through independent peer review of the results, or performance or confirmation of the studies by independent personnel or laboratories.

The tests were designed and conducted by personnel from MSHA's Pittsburgh Safety and Heath Technology's Dust Division. This laboratory at this facility is AIHA accreditated, and its personnel are among the foremost experts in particulate sampling analysis in the mining industry. They are widely published and are accustomed to performing work that must survive legal and scientific scrutiny. Moreover, the personnel designing and performing these studies have more experience than anybody else with dust sampling in general, and with this particular measurement application. While the agency welcomes scrutiny of its work, and repetition by others, it also recognizes that such efforts take time. In this case, the agency elected to conduct tests to address specific concerns, given its obligation to respond to the risks to miners reviewed in Part III of this preamble. It did so using a sound study design and expert personnel, and has made the detailed results of its studies a matter of public record.

In this regard, a number of commenters made reference to a study currently being conducted by NIOSH of possible interferences with the 5040 method. Some of these commenters provided MSHA with a copy of what is apparently the final protocol for the study, asserted that it would provide better information than the verification studies conducted by MSHA, and urged the agency to wait for completion of this study.

MSHA welcomes the NIOSH study, and will carefully consider its results—and the results of any other studies of this matter—in refining the compliance practices outlined in part IV of this preamble. But given the agency's obligation to respond to the risks to miners reviewed in Part III of this preamble, and the recommendations of NIOSH to take action in light of that risk, it would be inappropriate to await the results of another study.

Carbonates and Carbonaceous Minerals. As noted in the discussion of the analytical method (NIOSH Method 5040), carbonates have been known to cause an interference when determining the total carbon content of a diesel particulate sample. Carbonates are generally in two forms—carbonates such as limestone and dolomite and bicarbonate which is associated with trona (soda ash). As further noted, the amount of carbonate and bicarbonate collected on a sample can be significantly reduced or eliminated through the use of a submicrometer impactor. If the total carbon analysis of a sample indicates that a carbonate interference exists after the use of a submicrometer impactor, any remaining interfering effect may be removed or diminished using the acidification process described in NIOSH Method 5040.

Carbonate interference can also be removed during the analytical process by mathematically subtracting the organic carbon quantified by the fourth peak in the thermogram. Because bicarbonate is evolved over several temperature ranges, subtraction of only one peak does not remove all of the interference from bicarbonate. As a result, the sample needs to be acidified to remove all of the bicarbonate interference.

Commenters correctly pointed out that other carbonaceous minerals are not removed by the acidification process and in fact in some cases, the acidification process may cause a positive bias to the elemental carbon measurement. However, MSHA has verified that through the use of the submicrometer impactor, which reduces the mineral dust collected, combined with the subtraction of organic carbon quantified by the fourth organic carbon peak, this source of interference can be eliminated (PS&HTC–DD–505, PS&HTC–DD–509, PS&HTC–DD–510 and PS&HTC–DD–00–523).

MSHA has verified the use of a submicron impactor to remove carbonate interference through field and laboratory measurements. In the field measurements, simultaneous respirable and submicron dust samples were collected near crushing operations where there was no diesel equipment operating. In the laboratory measurements, a aerosol containing carbonate dust was introduced into a dust chamber and simultaneous submicron, respirable and total dust samples were collected. For both the field and laboratory measurements, the samples were analyzed for carbon using NIOSH Method 5040. Results of analysis of these samples showed that for respirable dust samples, acidification of the sample removed the carbonate.

Carbonate was evolved in the fourth peak of the organic portion of the analysis. The carbon evolved by the analysis was approximately 10 percent of the carbonate collected on the gravimetric sample, roughly equating to 12 percent carbon contained in calcium carbonate tested (limestone). Sampling with the submicron impactor removed the carbonate and carbonaceous component from the sample. A commenter noted that in the dust chamber tests, organic carbon was reported, even though the carbonate was removed by sampling, acidification or software integration. This organic carbon was attributed to oil vapors leaking from the compressor that delivered the dust to the chamber. This oil leak was reported to MSHA after the tests were completed.

Sample results further indicated that the total carbon mass determined for the respirable diesel particulate samples was approximately 95 percent of the diesel particulate mass determined gravimetrically and the total carbon mass determined from the impactor diesel particulate samples was approximately 82 percent of the respirable value. Use of the impactor reduced the amounts of carbonate collected on the sample by 90 percent.

The difference between the respirable total carbon determinations and the gravimetric diesel particulate can be attributed to sulfates or other noncarbonaceous minerals in the diesel particulate. The difference between the submicron total carbon and the respirable total carbon determinations is attributed to the removal of diesel particulate particles that are greater than 0.9 micrometers in size. The difference between the carbonate measured by NIOSH Analytical Method 5040 and the gravimetric carbonate is attributed to impurities in the material. The expected ratio of evolved carbon from the carbonate to carbonate (C/CaCo3) would be 0.12 (12/(40 + 12 + 48)).

Graphitic Minerals. Commenters reported that several ores, primarily associated with gold mines, contain graphitic carbon, and that this carbon shows up as elemental carbon in an airborne dust sample. MSHA has collected samples of this ore and has found that in fact this is true (PS&HTC-DD–505, PS&HTC-DD–509, PS&HTC-DD–510). MSHA has verified the use of a submicron impactor to remove graphitic carbon interference through field measurements.

In the field measurements, simultaneous respirable and submicron dust samples were collected near crushing operations where there was no diesel equipment operating. For both the field and laboratory measurements, the samples were analyzed for carbon using NIOSH Method 5040. Results of analysis of these samples showed that for respirable dust samples, several μg/m^3 of elemental carbon could be present in the sample.

However, MSHA has found this interference is very small, and can be reduced still further through the use of the submicron impactor on the sampler. The highest elemental carbon content of the ores was less than 5 percent. These ores also contain at least 20 percent respirable silica, as determined from samples collected near crushers where diesel particulate was not present. Based on a 20 percent respirable silica content in the dust in the environment, the allowable respirable dust exposure would be limited to 0.45 mg/m^3. Based on a 5 percent elemental carbon content in the sample, this sample could contain 23 μg/m^3 of elemental carbon. Typically 10 percent of mineral dust is less than one micron. By using the submicron impactor, the interference from graphitic carbon in the ore would be less than 3 μg/m^3. Samples collected by MSHA, near crushing operations, using submicron impactors, did not contain elemental carbon.

Accordingly, MSHA plans to sample for diesel particulate matter using submicron impactors to reduce the potential interference from carbonates, carbonaceous minerals and graphitic ores. As noted previously, this requirement is being specifically added to the regulation.

Oil Mist and Organic Vapors. Commenters indicated that diesel particulate sample interference can occur from sampling around drilling operations and from organic solvents.

To verify the existence and extent of any such interference, MSHA collected samples at stoper drilling, jack leg drilling and face drilling operations. The stoper drill and jack leg drill were pneumatic. The face drill was electrohydraulic. Interference from drill oil mist was observed for both the stoper drill and jack leg drill operations (PS&HTC–DD–505, PS&HTC–DD–511). Respirable and submicron samples were collected in the stope, the intake air to the stope and the exhaust air from the stope. Interference from drill oil mist was not found in submicron samples collected on the electrohydraulic face drill (PS&HTC–DD–505). The oil mist interference for the stoper drill was confined to the drill location due to the use of a high viscosity lube grease. The amount of interference in the stope on a submicron sample for the stoper drill was 4.5 μg/m^3 per hour of drilling. The interference from the oil mist on the jack leg operation extended throughout the mining stope area, but it did not extent into the main ventilation heading. The amount of interference in the stope on a submicron sample for the jack leg drill was 9 to 11 μg/m^3 per hour of drilling. MSHA believes that similar interferences could occur when miners are working near organic solvents.

Accordingly, this is an interference that can be addressed by not sampling too close to the source of the interference. As discussed in more detail in Part IV of this preamble, when MSHA collects compliance samples on drilling operations that produce an oil mist, or where organic solvents are used, personal samples will not be collected. Instead, an area sample will be collected, upwind of the driller or organic solvent source.

A commenter suggested that the lack of organic carbon reduction from outside to inside the cab at Homestake Mine indicated additional sources of organic carbon that have not been identified. MSHA believes that the reduction in elemental but not organic carbon from outside to inside the cab at Homestake Mine was attributed to size distribution. The organic carbon is small enough to pass through a filter. The organic carbon in the cab could not have been generated from a source inside the cab or attributed to residual cigarette smoke as the air exchange rate for the cab was one air change per minute. The cab operator did not smoke.

Cigarette Smoke. Cigarette smoke is a form of organic carbon. Commentors indicated that cigarette smoke can interfere with a diesel particulate measurement when total carbon is used as the indicator of dpm. Industry Commenters collected samples in a surface ''smoke room'' where the airflow and number of cigarettes were not monitored.

To verify the existence and the extent of any such interference, MSHA took samples in an underground mine where controlled smoking took place. Two series of cigarette tests were conducted. A test site was chosen in the NIOSH, PRL, Experimental Mine. The site consisted of approximately 75 feet of straight entry. The entry was approximately 18.5 feet wide and 6.2 feet high (115 square feet area). In the first test, the airflow rate through the test area was 6,000 cfm and 4 cigarettes were smoked over a 120 minute period. In the second test, the airflow was 3,000 cfm and 28 cigarettes were smoked over a 210 minute period. A control filter was used to adjust for organic carbon present on the filter media. MSHA collected samples on the smokers, twenty-five feet upwind of the smokers,

twenty-five feet downwind of the smokers and fifty feet downwind of the smokers. Results of the underground test did verify that smoking could be an interference on a dpm measurement.

Analysis of the thermogram from the smoking test showed that cigarette smoke showed up only in the organic portion of the analysis. In this test with the cigarette smoke, a fifth organic peak was observed. This peak contributed approximately 0.5 $\mu g/m^2$ to the analysis. This would be equivalent to an 8 hour full shift concentration of 5 $\mu g/m^3$. The thermogram otherwise is not distinguishable from the organic portion of a thermogram for a diesel particulate sample. Analysis of the thermogram indicated that 30 percent of the organic carbon appeared in the first organic peak, 15 percent appeared in the second organic peak, 10 percent appeared in the third organic peak, 25 percent of the cigarette smoke appeared in the fourth organic peak, and 20 percent of the cigarette smoke appeared in the fifth organic peak. While the amount of carbon identified by the fourth organic peak can be quantified and mathematically subtracted from the amount of total carbon measured, the remaining three peaks, representing 83 percent of the total carbon associated with smoking, would be an interferrant to the diesel particulate matter measurement.

However, the effect of cigarette smoke was even more localized to the smoker than the oil mist was to the stoper or jack leg drill operator. Twenty five feet upwind of the smoker, no carbon attributed to cigarette smoke was detected. For the smoker, each cigarette smoked would add 5 to 10 $\mu g/m^3$ to the exposure, depending on the airflow. Smoking 10 cigarettes would add 50 to 100 $\mu g/m^3$ to a worker's exposure. At both twenty five feet and fifty feet downwind of the smoker, after mixing with the ventilating air, the contribution of carbon attributed to smoking was reduced to 0.3 $\mu g/m^3$ for each cigarette smoked. Sampling twenty-five to fifty feet down wind of a worker smoking 10 cigarettes per day would add no more than 3 $\mu g/m^3$ to the worker's exposure (PS&HTC–DD–518). The air velocities in this test (30 to 60 feet per minute) were relatively low compared to typical mine air velocities. The interference would be even less at the higher air velocities normally found in mines.

Accordingly, as discussed in more detail in Part IV of this preamble, when MSHA collects compliance samples, miners will be requested not to smoke. If a miner does want to smoke while being sampled, and is not prohibited from doing so by the mine operator, the inspector will collect an area sample a minimum of twenty-five feet upwind or downwind of the smoker. Smokers working inside cabs will not be sampled.

Summary of Conclusions from Verification Studies. In summary, MSHA was able to draw the following conclusions from these studies:

- As specified in NIOSH Method 5040, it is essential to use a blank to correct organic carbon measurements.
- Contamination (interference) from carbonate and carbonaceous minerals is evolved in the fourth organic peak of the thermogram.
- Interference from graphitic minerals may appear in the elemental carbon portion of the analysis.
- Interference from cigarette smoke and oil mist from pneumatic drills appears in several peaks of the organic analysis.
- Use of the submicron impactor removes the mineral interference from carbonate, carbonaceous minerals and graphitic minerals.
- Acidification is required to remove the interference from bicarbonate which maybe evolved in several of the organic peaks.
- Subtraction of the fourth organic peak by software integration can be used to correct for interference from carbonaceous minerals.
- Interference from cigarette smoke and oil mist from pneumatic drills is localized. It can be avoided by sampling upwind or downwind of the interfering source.
- Total carbon from cigarettes smoke and oil mist are small compared to emissions from a diesel engine.
- Sampling can be conducted down wind of the interfering source after the contaminated air current has been diluted with another air current.

The magnitude of interferences measured during the verifications were small compared to the levels of total carbon measured in underground mines (as reported in Part III of this preamble). The discussion of section 5061 in Part IV of this preamble provides further information on how MSHA will take this information about interferences into account in compliance sampling; in addition, MSHA will provide specific guidance to inspectors as to how to avoid interferences when taking compliance samples.

(4) Limiting the Public's Exposure to Diesel and Other Fine Particulates—Ambient Air Quality Standards.

Pursuant to the Clean Air Act, the Federal Environmental Protection Agency (EPA) is responsible for setting air pollution standards to protect the public from toxic air contaminants. These include standards to limit exposure to particulate matter. The pressures to comply with these limits have an impact upon the mining industry, which limits various types of particulate matter into the environment during mining operations, and a special impact on the coal mining industry whose product is used extensively in particulate emission generating power facilities. But those standards hold interest for the mining community in other ways as well, for underlying some of them is a large body of evidence on the harmful effects of airborne particulate matter on human health. Increasingly, that evidence has pointed toward the risks of the smallest particulates—including the particles generated by diesel engines.

This section provides an overview of EPA's rulemaking efforts to limit the ambient air concentration of particulate matter, including its recent particular focus on diesel and other fine particulates. Additional and up-to-date information about the most current rulemaking in this regard is available on EPA's Web site, http://www.epa.gov/ttn/oarpg/naaqsfin/.

EPA is also engaged in other work of interest to the mining community. Together with some state environmental agencies, EPA has actually established limits on the amount of particulate matter that can be emitted by diesel engines. This topic is discussed in the next section of this Part (section 5). Environmental regulations also establish the maximum sulfur content permitted in diesel fuel, and such sulfur content can be an important factor in dpm generation. This topic is discussed in section 6 of this Part. In addition, EPA and some state environmental agencies have also been exploring whether diesel particulate matter is a carcinogen or a toxic material at the concentrations in which it appears in the ambient atmosphere. Discussion of these studies can be found in Part III of this preamble.

Background. Air quality standards involve a two-step process: standard setting by EPA, and implementation by each State.

Under the law, EPA is specifically responsible for reviewing the scientific literature concerning air pollutants, and establishing and revising National Ambient Air Quality Standards (NAAQS) to minimize the risks to health and the environment associated with such pollutants. This review is to be conducted every five years. Feasibility of compliance by pollution sources is not supposed to be a factor in establishing NAAQS. Rather, EPA is required to set the level that provides

''an adequate margin of safety'' in protecting the health of the public.

Implementation of each national standard is the responsibility of the states. Each must develop a state implementation plan that ensures air quality in the state consistent with the ambient air quality standard. Thus, each state has a great deal of flexibility in targeting particular modes of emission (*e.g.,* mobile or stationary, specific industry or all, public sources of emissions vs. private-sector sources), and in what requirements to impose on polluters. However, EPA must approve the state plans pursuant to criteria it establishes, and then take pollution measurements to determine whether all counties within the state are meeting each ambient air quality standard. An area not meeting an NAAQS is known as a ''nonattainment area''.

TSP. Particulate matter originates from all types of stationary, mobile and natural sources, and can also be created from the transformation of a variety of gaseous emissions from such sources. In the context of a global atmosphere, all these particles are mixed together, and both people and the environment are exposed to a ''particulate soup'' the chemical and physical properties of which vary greatly with time, region, meteorology, and source category.

The first ambient air quality standards dealing with particulate matter did not distinguish among these particles. Rather, the EPA established a single NAAQS for ''total suspended particulates'', known as ''TSP.'' Under this approach, the states could come into compliance with the ambient air requirement by controlling any type or size of TSP. As long as the total TSP was under the NAAQS—which was established based on the science available in the 1970s—the state met the requirement.

PM_{10}. When the EPA completed a new review of the scientific evidence in the mid-eighties, its conclusions led it to revise the particulate NAAQS to focus more narrowly on those particulates less than 10 microns in diameter, or PM_{10}. The standard issued in 1987 contained two components: an annual average limit of 50 μg/m^3, and a 24-hour limit of 150 μg/m^3. This new standard required the states to reevaluate their situations and, if they had areas that exceeded the new PM_{10} limit, to refocus their compliance plans on reducing those particulates smaller than 10 microns in size. Sources of PM_{10} include power plants, iron and steel production, chemical and wood products manufacturing, wind-blown and roadway fugitive dust, secondary aerosols and many natural sources.

Some state implementation plans required surface mines to take actions to help the state meet the PM_{10} standard. In particular, some surface mines in Western states were required to control the coarser particles—*e.g.,* by spraying water on roadways to limit dust. The mining industry has objected to such controls, arguing that the coarser particles do not adversely impact health, and has sought to have them excluded from the EPA ambient air standards.

$PM_{2.5}$. The next scientific review was completed in 1996, following suit by the American Lung Association and others. A proposed rule was published in November of 1996, and, after public hearings and review by the Office Management and Budget, a final rule was promulgated on July 18, 1997. (62 FR 38651).

The new rule further modifies the standard for particulate matter. Under the new rule, the existing national ambient air quality standard for PM_{10} remains basically the same—an annual average limit of 50 μg/m^3 (with some adjustment as to how this is measured for compliance purposes), and a 24-hour ceiling of 150 μg/m^3. In addition, however, a new NAAQS has now been established for ''fine particulate matter'' that is less than 2.5 microns in size. The $PM_{2.5}$ annual limit is set at 15 μg/m^3, with a 24-hour ceiling of 65 μg/m^3.

The basis for the $PM_{2.5}$ NAAQS is a large body of scientific data suggesting that particles in this size range are the ones responsible for the most serious health effects associated with particulate matter. The evidence was thoroughly reviewed by a number of scientific panels through an extended process. The proposed rule resulted in considerable press attention, and hearings by Congress, in which this scientific evidence was further discussed. Moreover, challenges to EPA's determination that this size category warranted rulemaking were rejected by a three judge panel of the DC Circuit Court. (American Trucking Association vs. EPA, 275 F.3d 1027).

Second, the majority of the panel agreed with challenges to the EPA's determination to keep the existing requirements on PM10 as a surrogate for the coarser particulates in this category (those particulates between 2.5 and 10 microns in diameter); instead, the panel ordered EPA to develop a new standard for this size category. (Op.Cit., *23.)

Implications for the Mining Community. As noted earlier in this part, diesel particulate matter is mostly less than 1.0 micron in size. It is, therefore, a fine particulate; indeed, in some regions of the country, diesel particulate generated by highway and off-road vehicles constitutes a significant portion of the ambient fine particulate (June 16, 1997, PM–2.5 Composition and Sources, Office of Air Quality Planning and Standards, EPA). Moreover, as noted in Part III of this preamble, some of the scientific studies of health risk from fine particulates used to support the EPA rulemaking were conducted in areas where the major fine particulate was from diesel emissions. Accordingly, MSHA has concluded that it must consider the body of evidence of human health risk from environmental exposure to fine particulates in assessing the risk of harm to miners of occupational exposure to diesel particulate. Comments on the appropriateness of the conclusion by MSHA, and whether MSHA should be working on a fine particulate standard rater than just one focused on diesel particulate are reviewed in Part III.

(5) The Effects of Existing Standards—MSHA Standards on Diesel Exhaust Gases (CO, CO_2, NO, NO_2, and SO_2), and EPA Diesel Engine Emission Standards—on the Concentration of dpm in Underground Metal and Nonmetal Mines

With the exception of diesel engines used in certain classifications of gassy mines, MSHA does not require that the emissions from diesel engines used in underground metal and nonmetal mines, as measured at the tailpipe, meet certain minimum standards of cleanliness. (Some states may require engines used in underground metal and nonmetal mines to be MSHA Approved.) This is in contrast to underground coal mines, where only engines which meet certain standards with respect to gaseous emissions are ''approved'' for use in underground coal mines. Indeed, as discussed in section 7 of this part, the whole underground coal mine fleet must now consist of approved engines, and the engines must be maintained in approved condition. While such restrictions do not directly control dpm emissions of underground coal equipment, they do have some indirect impact on them.

MSHA does have some requirements for underground metal and nonmetal mines that limit the exposure of miners to certain gases emitted by diesel engines. Accordingly, those requirements are discussed here.

Engine emissions of dpm in underground metal and nonmetal mines are gradually being impacted by Federal environmental regulations, supplemented in some cases by State restrictions. Over time, these regulations have required, and are continuing to

require, that new diesel engines meet tighter and tighter standards on dpm emissions. As these cleaner engines replace or supplement older engines in underground metal and nonmetal mines, they can significantly reduce the amount of dpm emitted by the underground fleet. Much of this section reviews developments in this area. Although this subject was discussed in the preamble of the proposed dpm rule (63 FR 58130 *et seq.*), the review here updates the relevant information.

MSHA Limitations on Diesel Gases. MSHA limits on the exposure of miners to certain gases in underground mines are listed in Table II–2, for both coal mines and metal/nonmetal mines, together with information about the recommendations in this regard of other organizations. As indicated in the table, MSHA requires mine operators to comply with gas specific threshold limit values (TLV®s) recommended by the American Conference of Governmental Industrial Hygienists (ACGIH) in 1972 (for coal mines) and in 1973 (for metal and nonmetal mines).

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TABLE II-2 GASEOUS EXPOSURE LIMITS (PPM)

Pollutant	Range of Limits Recommended		MSHA Limits	
			Coal[A]	M/NM[B]
HCHO (formaldehyde)	0.016[C]	0.3[D]	2	2
CO	25[D]	50	50	50
CO_2	5,000[C]	5,000	5,000	5,000
NO	25[C,D,E]	25	25	25
NO_2	1[F]	3[D]	5	5
SO_2	2[C,D]	5[E]	2	5

Table Notes:

A) ACGIH, 1972

B) ACGIH, 1973

C) NIOSH recommended exposure limit (REL), based on a 10-hour, time-weighted average

D) ACGIH, 1996

E) OSHA permissible exposure limit (PEL)

F) NIOSH recommends only a 1-ppm, 15-minutes, short-term exposure limit (STEL)

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To change an exposure limit at this point in time requires a regulatory action; the rule does not provide for their automatic updating. In 1989, MSHA proposed changing some of these gas limits in the context of a proposed rule on air quality standards. (54 FR 35760). Following opportunity for comment and hearings, a portion of that proposed rule, concerning control of drill dust and abrasive blasting, has been promulgated, but the other components are still under review.

One commenter expressed concern that MSHA would attempt to regulate dpm together with diesel exhaust gases based on their additive or combined effects. As discussed in greater detail in Part IV of this preamble, MSHA does not, at this time, have sufficient information upon which to enforcement limits for dpm and diesel exhaust gases on the basis of their additive or combined effects, if any.

Authority for Environmental Engine Emission Standards. The Clean Air Act authorizes the Federal Environmental Protection Agency (EPA) to establish nationwide standards for mobile vehicles, including those powered by diesel engines (often referred to in environmental regulations as ''compression ignition'' or ''CI'' engines). These standards are designed to reduce the amount of certain harmful atmospheric pollutants emanating from mobile sources: the mass of particulate matter, nitrogen oxides (which as previously noted, can result in the generation of particulates in the atmosphere), hydrocarbons and carbon monoxide.

California has its own engine emission standards. New engines destined for use in California must meet standards under the law of that State. The standards are issued and administered by the California Air Resources Board (CARB). In many cases, the California standards are the same as the national standards; as noted herein, the EPA and CARB have worked on certain agreements with the industry toward that end. In other situations, the California standards may be more stringent.

Regulatory responsibility for implementation of the Clean Air Act is vested in the Office of Transportation and Air Quality (formerly the Office of Mobile Sources), part of the Office of Air and Radiation of the EPA. Some of the discussion which follows was derived from materials which can be accessed from the agency's home page on the World Wide Web at (http://www.epa.gov/omswww/omshome.htm). Information about the California standards may be found at the CARB home page at (http://www.arb.ca.gov/homepage.htm).

Diesel engines are generally divided into three broad categories for purposes of engine emissions standards, in accordance with the primary use for which the type of engine is designed: (1) light duty vehicles and light duty trucks (i.e., those engines designed primarily to power passenger transport or transportation of property); (2) heavy duty highway engines (i.e., those designed primarily to power over-the-road truck hauling); and (3) nonroad vehicles (i.e., those engines designed primarily to power small equipment, construction equipment, locomotives and other non-highway uses).

The exact emission standards which a new diesel engine must meet varies with engine category and the date of manufacture. Through a series of regulatory actions, EPA has developed a detailed implementation schedule for each of the three engine categories noted. The schedule generally forces technology while taking into account certain technological realities.

Detailed information about each of the three engine categories is provided below; a summary table of particulate matter emission limits is included at the end of the discussion.

EPA Emission Standards for Light-Duty Vehicles and Light Duty Trucks.[2]

Current light-duty vehicles generally comply with the Tier 1 and National LEV emission standards. Particulate matter emission limits are found in 40 CFR Part 86. In 1999, EPA issued new Tier 2 standards that will be applicable to light-duty cars and trucks beginning in 2004. With respect to pm, the new rules phase in tighter emissions limits to parts of production runs for various subcategories of these engines over several years; by 2008, all light duty trucks must limit pm emissions to a maximum of 0.02 g/mi. (40 CFR 86.1811–04(c)). Engine manufacturers may, of course, produce complying engines before the various dates required.

EPA Emissions Standards for Heavy-Duty Highway Engines. In 1988, a standard limiting particulate matter emitted from the heavy duty highway diesel engines went into effect, limiting dpm emissions to 0.6 g/bhp-hr. The Clean Air Act Amendments of 1990 and associated regulations provided for phasing in even tighter controls on NO_X and particulate matter through 1998. Thus, engines had to meet ever tighter standards for NO^X in model years 1990, 1991 and 1998; and tighter standards for PM in 1991 (0.25 g/bhp-hr) and 1994 (0.10 g/bhp-hr). The latter remains the standard for PM from these engines for current production runs (40 CFR 86.094–11(a)(1)(iv)(B)). Since any heavy duty highway engine manufactured since 1994 must meet this standard, there is a supply of engines available today which meet this standard. These engines are used in mining in the commercial type pickup trucks.

New standards for this category of engines are gradually being put into place. On October 21, 1997, EPA issued a new rule for certain gaseous emissions from heavy duty highway engines that will take effect for engine model years starting in 2004 (62 FR 54693). The rule establishes a combined requirement for NO_X and Non-methane Hydrocarbon (NMHC). The combined standard is set at 2.5 g/bhp-hr, which includes a cap of 0.5 g/bhp-hr for NMHC. EPA promulgated a rulemaking on December 22, 2000 (65 FR 80776) to adopt the next phase of new standards for these engines. EPA is taking an integrated approach to: (a) Reduce the content of sulfur in diesel fuel; and thereafter, (b) require heavy-duty highway engines to meet tighter emission standards, including standards for PM. The purpose of the diesel fuel component of the rulemaking is to make it technologically feasible for engine manufacturers and emissions control device makers to produce engines in which dpm emissions are limited to desired levels in this and other engine categories. The EPA's rule will reduce pm emissions from new heavy-duty engines to 0.01 g/bhp-hr, a reduction from the current 0.1 g/bhp-hr. MSHA assumes it will be some time before there is a significant supply of engines that can meet this standard, and the fuel supply to make that possible.

EPA Emissions Standards for Nonroad Engines. Nonroad engines are those designed primarily to power small portable equipment such as compressors and generators, large construction equipment such as haul trucks, loaders and graders, locomotives and other miscellaneous equipment with non-highway uses. Engines of this type are the ones used most frequently in the underground coal mines to power equipment.

Nonroad diesel engines were not subjected to emission controls as early as other diesel engines. The 1990 Clean Air Act Amendments specifically directed EPA to study the contribution of nonroad engines to air pollution, and

[2] The discussion focuses on the particulate matter requirements for light duty trucks, although the current pm requirement for light duty vehicles is the same. The EPA regulations for these categories apply to the unit, rather than just to the engine itself; for heavy-duty highway engines and nonroad engines, the regulations attach to the engines.

regulate them if warranted (Section 213 of the Clean Air Act). In 1991, EPA released a study that documented higher than expected emission levels across a broad spectrum of nonroad engines and equipment (EPA Fact Sheet, EPA420–F–96–009, 1996). In response, EPA initiated several regulatory programs. One of these set Tier 1 emission standards for larger land-based nonroad engines (other than for rail use). Limits were established for engine emissions of hydrocarbons, carbon monoxide, NO_X, and dpm. The limits were phased in with model years from 1996 to 2000. With respect to particulate matter, the rules required that starting in model year 1996, nonroad engines from 175 to 750 hp meet a limit on pm emissions of 0.4 g/bhp-hr, and that starting in model year 2000, nonroad engines over 750 hp meet the same limit.

Particulate matter standards for locomotive engines were set subsequently (63 FR 18978, April, 1998). The standards are different for line-haul duty-cycle engine and switch duty-cycle engines. For model years from 2000–2004, the standards limit pm emissions to 0.45 g/bhp-hr and 0.54 g/bhp-hr respectively for those engines; after model year 2005, the limits drop to 0.20 g/bhp-hr and 0.24 g/bhp-hr respectively.

In October 1998, EPA established additional standards for nonroad engines (63 FR 56968). Among these are gaseous and particulate matter limits for the first time (Tier 1 limits) for nonroad engines under 50 hp. Tier 2 emissions standards for engines between 50 and 175 hp include pm standards for the first time. Moreover, they establish Tier 2 particulate matter limits for all other land-based nonroad engines (other than locomotives which already had Tier 2 standards). Some of the non-particulate emissions limits set by the 1998 rule are subject to a technology review in 2001 to ensure that the levels required to be met are feasible; EPA has indicated that in the context of that review, it intends to consider further limits for particulate matter, including transient emission measurement procedures. Because of the phase-in of these Tier 2 pm standards, and the fact that some manufacturers will produce engines meeting the standard before the requirements go into effect, there are or soon will be some Tier 2 pm engines in some sizes available, but it is likely to be a few years before a full size range of Tier 2 pm nonroad engines is available.

Table II–3, EPA NonRoad Engine PM Requirements, provides a full list of the EPA required particulate matter limitations on nonroad diesel engines. For example, a nonroad engine of 175 hp produced in 2001 must meet a standard of 0.4 g/hp-hr; a similar engine produced in 2003 or thereafter must meet a standard of 0.15 g/hp-hr.

TABLE II–3.—EPA NONROAD ENGINE PM REQUIREMENTS

kW range	Tier	Year first applicable	PM limit (g/kW-hr)
kW<8	1	2000	1.00
	2	2005	0.80
8≤kW<19	1	2000	0.80
19≤kW<37	1	1999	0.80
	2	2004	0.60
37≤kW<75	1	1998	.....
	2	2004	0.40
75≤kW<130	1	1997	.....
	2	2003	0.30
130≤kW<225	1	1996	0.54
	2	2003	0.20
225≤kW<450	1	1996	0.54
	2	2001	0.20
450≤kW<560	1	1996	0.54
	2	2002	0.20
kW>560	1	2000	0.54
	2	2006	0.20

The Impact of EPA Engine Emission Standards on the Underground Metal and Nonmetal Mining Fleet. In the mining industry, engines and equipment are often purchased in used condition. Thus, many of the diesel engines in an underground mine's fleet may only meet older environmental emission standards, or no environmental standards at all.

By requiring that underground coal mine engines be approved, MSHA regulations have led to a less polluting fleet in that sector than would otherwise be the case. Many highly polluting engines have been barred or phased out as a result. As noted in Part IV of this preamble, such a requirement for the underground metal and nonmetal sector is being added by this rulemaking; however, it will be some time before its effects are felt. Moreover, although the environmental tailpipe requirements will bring about gradual reduction in the overall contribution of diesel pollution to the atmosphere, the beneficial effects on mining atmospheres may require a long timeframe absent actions that accelerate the turnover of mining fleets to engines that emit less dpm.

The Question of Nanoparticles. Comments received from several commenters on the proposed rule for diesel particulate matter exposure of underground coal miners raised questions relative to ''nanoparticles'; i.e., particles found in the exhaust of diesel engines that are characterized by diameters less than 50 nanometers (nm). As the topic may be of interest to this sector as well, MSHA's discussion on the topic is being repeated in this preamble for informational purposes.

One commenter was concerned about recent indications that nanoparticles may pose more of a health risk than the larger particles that are emitted from a diesel engine. This commenter submitted information demonstrating that nanoparticles emitted from the engine could be effectively removed from the exhaust using aftertreatment devices such as ceramic traps. Another commenter was concerned that MSHA's proposed rule for underground coal mines is based on removing 95% of the particulate by mass. His concern was focused on the fact that this reduction in mass was attributed to those particles

greater than 0.1μm but less than 1μm and did not address the recent scientific hypothesis that it may be the very small nanopaticles that are responsible for adverse health effects. Based on the recent specific information on the potential health effects resulting from exposure to nanoparticles, this commenter did not believe that the risk to cancer would be reduced if exposure levels to nanoparticles increased. He indicated that studies suggest that the increase in nanoparticles will exceed 6 times their current levels.

Current environmental emission standards established by EPA and CARB, and the particulate index calculated by MSHA, focus on the total mass of diesel particulate matter emitted by an engine—for example, the number of grams per some unit of measure (i.e., grams/brake-horsepower). Thus, the technology being developed by the engine industry to meet the standards accordingly focuses on reducing the mass of dpm being emitted from the engine.

There is some evidence, however, that some aspects of this new technology, particularly fuel injection, is resulting in an increase in the number of nanoparticles being emitted from the engine.

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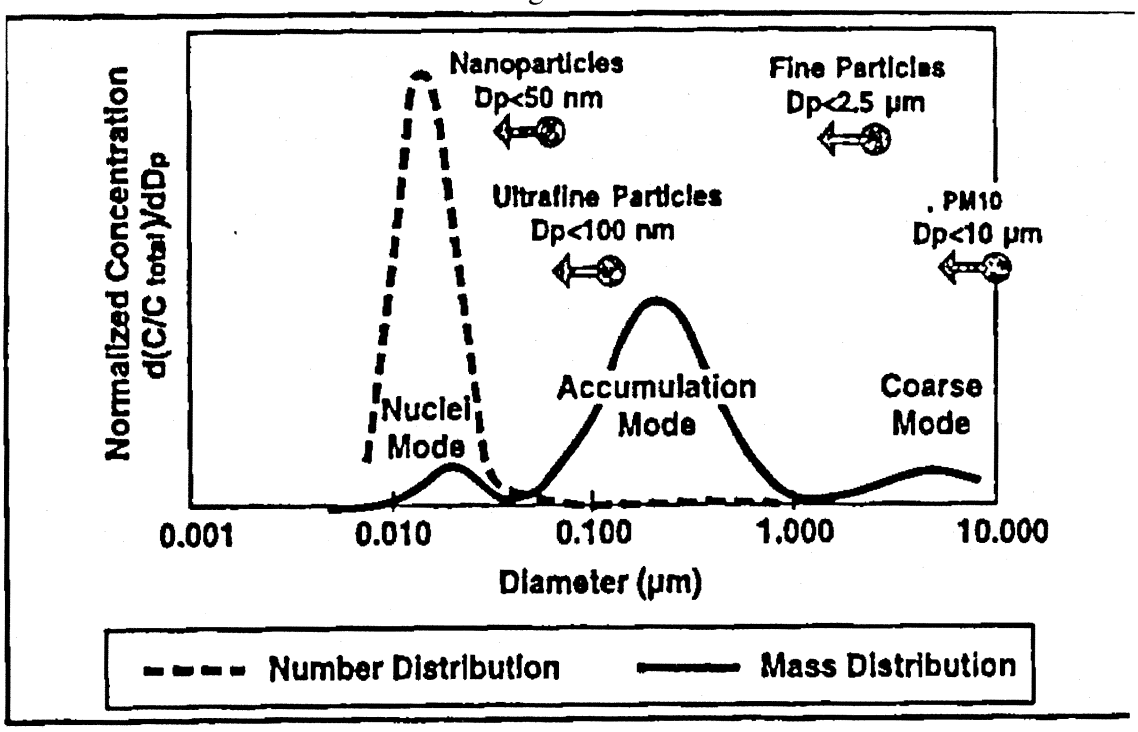
Figure II-3, repeated here from section 2 of this Part, illustrates this situation (Majewski, W. Addy, Diesel Progress, June, 1998).

Figure II-3



Diesel particulate size distribution.

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The formation of particulates starts with particle nucleation followed by subsequent agglomeration of the nuclei particles into an accumulation mode. Thus, as illustrated in Figure II–3, the majority of the mass of dpm is found in the accumulation mode, where the particles are generally between 0.1 and 1 micron in diameter. However, when considering the number of particles emitted from the engine, more than half and sometimes almost all of the particles (by number) are in the nuclei mode.

Various studies have demonstrated that the size of the particles emitted from the new low emission diesel engines, has shifted toward the generation of nuclei mode particles. One study compared a comparable 1991 engine to its 1988 counterpart. The total PM mass in the newer engine was reduced by about 80%; but the new engine generated thousands of times more particles than the older engine (3000 times as much at 75 percent load and about 14,000 times as much at 25 percent load). One hypothesis offered for this phenomenon is that the cleaner engines produce less soot particles on which particulates can condense and accumulate, and hence they remain in nuclei mode. The accumulation particles act as a ''sponge'' for the condensation and/or adsorption of volatile materials. In the absence of that sponge, gas species which are to become liquid or solid will nucleate to form large numbers of small particles (diesel.net technology guide). Mayer, while pointing out that nanoparticle production was a problem with older engines as well, concurs that the technology being used to clean up pollution in newer engines is not having any positive impact on nanoparticle production. While there is scientific evidence that the newer engines, designed to reduce the mass of pollutants emitted from the diesel engine, emit more particles in the nuclei mode, quantifying the magnitude of these particles has been difficult because as dpm is released into the atmosphere the diesel particulate undergoes very complex changes. In addition, current testing procedures can produce spurious increases in the number of nanoparticles that would not necessarily occur under more realistic atmospheric conditions.

Experimental work conducted at WVU (Bukarski) indicate that nanoparticles are not generated during the combustion process, but rather during various physical and chemical processes which the exhaust undergoes in after treatment systems.

While current medical research findings indicate that small particulates, particularly those below 2μm in size, may be more harmful to humans than the larger ones, much more medical research and diesel emission studies are needed to fully characterize diesel nanoparticles emissions and their impact on human health. If nanoparticles are found to have an adverse health impact by virtue of size and number, it could require significant adjustments in environmental engine emission regulation and technology. It could also have implications for the type of controls utilized, with some asserting that aftertreatment filters are the only effective way to limit the emission of nanoparticles and others asserting that aftertreatment filters may under certain circumstances limit the number of nanoparticles.

Research on nanoparticles and their health effects is currently a topic of investigation. (Bagley et al., 1996, EPA Grant). Based on the comments received and a review of the literature currently available on the nanoparticle issue, MSHA believes that, at this time, promulgation of the final rules for underground coal and metal and nonmetal mines is necessary to protect miners. The nanoparticle issues discussed above will not be resolved for some time because of the extensive research required to address the questions raised.

(6) Methods for controlling dpm concentrations in underground metal and nonmetal mines

As discussed in the last section, the introduction of new engines underground will certainly play a significant role in reducing the concentration of dpm in underground metal/nonmetal mines. There are, however, many other approaches to reducing dpm concentrations and occupational exposures to dpm in underground metal/nonmetal mines. Among these are: aftertreatment devices to eliminate particulates emitted by an engine; altering fuel composition to minimize engine particulate emission; maintenance practices and diagnostic systems to ensure that fuel, engine and aftertreatment technologies work as intended to minimize emissions; enhancing ventilation to reduce particulate concentrations in a work area; enclosing workers in cabs or other filtered areas to protect them from exposure; and work and fleet practices that reduce miner exposures to emissions.

As noted in section 9 of this Part, information about these approaches was solicited from the mining community in a series of workshops in 1995, and highlights were published by MSHA as an appendix to the proposed rule on dpm ''Practical Ways to Control Exposure to Diesel Exhaust in Mining—a Toolbox.'' During the hearings and in written comments on this rulemaking, mention was made of all these control methods.

This section provides updated information on two methods for controlling dpm emissions: aftertreatment devices and diesel fuel content. There was considerable comment on aftertreatment devices because MSHA's proposed rule would require high-efficiency particulate filters be installed on a certain percentage of the fleet in order to meet both the interim and final dpm concentration; and the current and potential efficiency of such devices remains an important issue in determining the technological and economic feasibility of the final rule. Moreover, some commenters strongly favored the use of oxidation catalytic converters, a type of aftertreatment device used to reduce gaseous emission but which can also impact dpm levels. Accordingly, information about such devices is reviewed here. With respect to diesel fuel composition, a recent rulemaking initiative by EPA, and actions taken by other countries in this regard, are discussed here because of the implications of such developments for the mining community.

Emissions aftertreatment devices. One of the most discussed approaches to controlling dpm emissions involves the use of devices placed on the end of the tailpipe to physically trap diesel particulate emissions and thus limit their discharge into the mine atmosphere. These aftertreatment devices are often referred to as ''particle traps'' or ''soot traps'', but the term filter is often used. The two primary categories of particulate traps are those composed of ceramic materials (and thus capable of handling uncooled exhaust), and those composed of paper materials (which require the exhaust to first be cooled). Typically, the latter are designed for conventional permissible equipment mainly used in coal mining which have water scrubbers installed which cool the exhaust. However, another alternative that is now utilized in coal is the ''dry system technology'' which cools the diesel exhaust with a heat exchanger and then uses a paper filter. The dry system was first developed for oil shale mining applications where permissibility was required. However, when development of the oil shale industry faltered, manufacturers looked to coal mining for

application of the dry system technology. However, dry systems could be used as an alternative to the wet scrubbers for the relatively small number of permissible machines used in the metal/nonmetal industry. In addition, ''oxidation catalytic converters,'' devices used to limit the emission of diesel gases, and ''water scrubbers'', devices used to cool the exhaust gases, are discussed here as well, because they also can have a significant effect on limiting particle emission.

Water Scrubbers. Water scrubbers are devices added to the exhaust system of certain diesel equipment. Water scrubbers are essentially metal boxes containing water through which the diesel exhaust gas is passed. The exhaust gas is cooled, generally to below 170 degrees F. A small fraction of the unburned hydrocarbons are condensed and remain in the water along with a portion of the dpm. Tests conducted by the former Bureau of Mines and others indicate that no more than 20 to 30 percent of the dpm is removed. This information was presented in the Toolbox publication. The water scrubber does not remove any of the carbon monoxide, the oxides of nitrogen, or any other gaseous emission that remains a gas at room temperature so their effectiveness as aftertreatment devices is questionable.

The water scrubber does serve as an effective spark and flame arrester and as a means to cool the exhaust gas when permissibility is required. Consequently, it is used in the majority of the permissible diesel equipment in mining as part of the safety components needed to gain MSHA approval.

The water scrubber has several operating characteristics which keep it from being a candidate for use as an aftertreatment device on nonpermissible equipment. The space required on the vehicle to store sufficient water for an 8 hour shift is not available on some equipment. Furthermore, the exhaust contains a great deal of water vapor which condenses under some mining conditions creating a fog which can adversely effect visibility. Also, operation of the equipment on slopes can cause the water level in the scrubber to change resulting in water being blown out the exhaust pipe. Control devices are sometimes placed within the scrubber to maintain the appropriate water level. Because these devices are in contact with the water through which the exhaust gas has passed, they need frequent maintenance to insure that they are operating properly and have not been corroded by the acidic water created by the exhaust gas. The water scrubber must be flushed frequently to remove the acidic water and the dpm and other exhaust residue which forms a sludge that adversely effects the operation of the unit. These problems, coupled with the relatively low dpm removal efficiency, have prevented widespread use of water scrubbers as a dpm control device on nonpermissible equipment.

Oxidation Catalytic Converters. Oxidation catalytic converters (OCCs) were among the first devices added to diesel engines in mines to reduce the concentration of harmful gaseous emissions discharged into the mine environment. OCCs began to be used in underground mines in the 1960's to control carbon monoxide, hydrocarbons and odor. That use has been widespread. It has been estimated that more than 10,000 OCCs have been put into the mining industry over the years.

Several of the harmful emissions in diesel exhaust are produced as a result of incomplete combustion of the diesel fuel in the combustion chamber of the engine. These include carbon monoxide and unburned hydrocarbons including harmful aldehydes. Catalytic converters, when operating properly, remove significant percentages of the carbon monoxide and unburned hydrocarbons. Higher operating temperatures, achieved by hotter exhaust gas, improve the conversion efficiency.

Oxidation catalytic converters operate by, in effect, continuing the combustion process outside the combustion chamber. This is accomplished by utilizing the oxygen in the exhaust gas to oxidize the contaminants. A very small amount of material with catalytic properties, usually platinum or some combination of the noble metals, is deposited on the surfaces of the catalytic converter over which the exhaust gas passes. This catalyst allows the chemical oxidation reaction to occur at a lower temperature than would normally be required.

For the catalytic converter to work effectively, the exhaust gas temperature must be above 370 degrees Fahrenheit for carbon monoxide and 500 degrees Fahrenheit for hydrocarbons. Most converters are installed as close to the exhaust manifold as possible to minimize the heat loss from the exhaust gas through the walls of the exhaust pipe. Insulating the segment of the exhaust pipe between the exhaust manifold and the catalytic converter extends the portion of the vehicle duty cycle in which the converter works effectively.

The earliest catalytic converters for mining use consisted of alumina pellets coated with the catalytic material and enclosed in a container. The exhaust gas flowed through the pellet bed and the exhaust gas came into contact with the catalyst. Designs have evolved, and the most common design is a metallic substrate, formed to resemble a honeycomb, housed in a metal shell. The catalyst is deposited on the surfaces of the honeycomb. The exhaust gas flows through the honeycomb and comes into contact with the catalyst.

Soon after catalytic converters were introduced, it became apparent that there was a problem brought about by the sulfur found in diesel fuels in use at that time. Most diesel fuels in the United States contained anywhere from 0.25 to 0.50 percent sulfur or more on a mass basis. In the combustion chamber, this sulfur was converted to SO_2, SO_3, or SO_4 in various concentrations, depending on the engine operating conditions. In general, most of the sulfur was converted to gaseous SO_2. When exhaust containing the gaseous sulfur dioxide passed through the catalytic converter, a large proportion of the SO_2 was converted to solid sulphates which are in fact, diesel particulate. Sulfates can ''poison'' the catalyst, severely reducing its life.

Recently, as described elsewhere in this preamble, the EPA required that diesel fuel used for over the road trucks contain no more than 500 ppm sulfur. This action made low sulfur fuel available throughout the United States. MSHA, in its recently promulgated regulations for the use of diesel powered equipment in underground coal mines requires that this low sulfur fuel be used. MSHA is now extending this requirement for low sulfur fuel (<500ppm) to underground metal/nonmetal mines in this final rule. When the low sulfur fuel is burned in an engine and passed through a converter with a moderately active catalyst, only small amounts of SO_2 and additional sulfate based particulate are created. However, when a very active catalyst is used, to lower the operating temperature of the converter or to enhance the CO removal efficiency, even the low sulfur fuel has sufficient sulfur present to create an SO_2 and sulfate based particulate problem. Consequently, as discussed later in this section, the EPA has notified the public of its intentions to promulgate regulations that would limit the sulfur content of future diesel fuel to 15 ppm for on-highway use in 2006.

The particulate reduction capabilities of some OCCs are significant in gravimetric terms. In 1995, the EPA implemented standards requiring older buses in urban areas to reduce the dpm emissions from rebuilt bus engines. (40

CFR 85.1403). Aftertreatment manufacturers developed catalytic converter systems capable of reducing dpm by 25%. Such systems are available for larger diesel engines common in the underground metal and nonmetal sector. However, as has been pointed out by Mayer, the portion of particulate mass that seems to be impacted by OCCs is the soluble component, and this is a smaller percentage of particulate mass in utility vehicle engines than in automotive engines. Moreover, some measurements indicate that more than 40% of NO is converted to more toxic NO_2, and that particulate mass actually increases using an OCC at full load due to the formation of sulfates. In summation, Mayer concluded that the OCCs do not reduce the combustion particulates, produce sulfate particulates, have unfavorable gaseous phase reactions increasing toxicity, and that the positive effects are irrelevant for construction site diesel engines. Indeed, he indicates the negative effects outweigh the benefits. (Mayer, 1998. The Phase 1 interim data report of the Diesel Emission Control-Sulfur Effects (DECSE) Program (a joint government-industry program to explore lower sulfur content that is discussed in more detail later in this section) similarly indicates that using OCCs under certain operating conditions can increase dpm emissions due to an increase in the sulfate fraction (DECSE Program Summary, Dec. 1999). Another commenter also notes that oxidation catalytic activity can increase sulfates and submicron particles under certain operating conditions.

Other commenters during the rulemaking strongly supported the use of OCCs as an interim measure to reduce particulate and other diesel emission to address transitory employee effects that were mentioned in the proposed preamble. MSHA views the use of OCCs as one tool that mine operators can use to reduce the dpm emissions from certain vehicles alone or in combination of other aftertreatment controls to meet the interim and final dpm standards. The overall reduction in dpm emissions achieved with the exclusive use of an OCC is low compared to the reductions required to meet the standards. MSHA is aware of the negative effects produced by OCCs. However, with the use of low sulfur fuel and a catalyst that is formulated for low sulfate production, this problem can be resolved. Mine operators must work with aftertreatment manufacturers to come up with the best plan for their fleet for dpm control.

Hot gas filters. Throughout this preamble, MSHA is referring to the particulate traps (filters) that can be used in the undiluted hot exhaust stream from the diesel engine as hot gas filters. Hot gas filters refer to the current commercially available particulate filters, such as ceramic cell, woven fiber filters, sintered metal filters, etc.

Following publication of EPA rules in 1985 limiting diesel particulate emissions from heavy duty diesel engines, aftertreatment devices capable of significant reductions in particulate levels began to be developed for commercial applications.

The wall flow type ceramic honeycomb diesel particulate filter system was initially the most promising approach. These consisted of a ceramic substrate encased in a shock and vibration absorbing material and covered with a protective metal shell. The ceramic substrate is arranged in the shape of a honeycomb with the openings parallel to the centerline. The ends of the openings of the honeycomb cells are plugged alternately. When the exhaust gas flows through the particulate trap, it is forced by the plugged end to flow through the ceramic wall to the adjacent passage and then out into the mine atmosphere. The ceramic material is engineered with pores in the ceramic material sufficiently large to allow the gas to pass through without adding excessive back pressure on the engine, but small enough to trap the particulate on the wall of the ceramic material. Consequently, these units are called wall flow traps.

Work with ceramic filters in the last few years has led to the development of the ceramic fiber wound filter cartridge (SAE, SP–1073, 1995). The ceramic fiber has been reported by the manufacturer to have dpm reduction efficiencies up to 80 percent. This system has been used on vehicles to comply with German requirements that all diesel engines used in confined areas be filtered. Other manufacturers have made the wall flow type ceramic honeycomb dpm filter system commercially available to meet the German standard.

The development of these devices has proceeded in response to international and national efforts to regulate dpm emissions. However, due to the extensive work performed by the engine manufacturers on new technological designs of the diesel engine's combustion system, and the use of low sulfur fuel, particulate traps turned out to be unnecessary to comply with the EPA standards of the time for vehicle engines.

These devices proved to be very effective at removing particulate achieving particulate removal efficiencies of greater than 90 percent.

It was quickly recognized that this technology, while not immediately required for most vehicles, might be particularly useful in mining applications. The former Bureau of Mines investigated the use of catalyzed diesel particulate filters in underground mines in the United States (BOM, RI–9478, 1993). The investigation demonstrated that filters could work, but that there were problems associated with their use on individual unit installations, and the Bureau made recommendations for installation of ceramic filters on mining vehicles.

Canadian mines also began to experiment with ceramic traps in the 1980's with similar results (BOM, IC 9324, 1992). Work in Canada today continues under the auspices of the Diesel Emission Evaluation Program (DEEP), established by the Canadian Centre for Mineral and Energy Technology in 1996 (DEEP Plenary Proceedings, November 1996). The goals of DEEP are to: (1) Evaluate aerosol sampling and analytical methods for dpm; and (2) evaluate the in-mine performance and costs of various diesel exhaust control strategies.

Perhaps because experience is still limited, the general perception within the mining industry of the state of this technology in recent years is that it remains limited in certain respects; as expressed by one commenter at one of the MSHA workshops in 1995, ''while ceramic filters give good results early in their life cycle, they have a relatively short life, are very expensive and unreliable.''

One commenter reported unsuccessful experiments with ceramic filters in 1991 due to their inability to regenerate at low temperatures, lack of reliability, high cost of purchase and installation, and short life.

In response to the proposed rule, MSHA received a variety of information and claims about the current efficiency of such technologies. Commenters stated that in terms of technical feasibility to meet the standards, the appropriate aftertreament controls are not readily available on the market for the types and sizes of equipment used in underground mines. Another commenter stated that MSHA has not identified a technology capable of meeting the proposed standards at their mine and they were not aware of any technology currently available or on the horizon that would be capable of attaining the standards. Yet another commenter stated that both ceramic and paper filters are not technically feasible at their mine because of the high operating temperatures needed to regenerate filters or the difficulties

presented by periodic removal of the filters for regeneration. Periodic removal of fragile ceramic filters subjects them to chipping and cracking and requires a large inventory of surplus filters. Commenter also stated that paper filters require exhaust gas cooling so that the paper filter does not burn. Commenter stated that they have been working with a manufacturer on installing one of these on a piece of equipment, but it is experimental and this installation was the first time a paper filter would be used on equipment of this size and type.

In response to the paper filter comment, dry system technology as described above was first tested on a large haul truck used in oil shale mining and then later applied to coal mining equipment. Paper filter systems have also been successfully installed on coal mining equipment that is identical to LHD machines used in metal/nonmetal mines. Therefore this technology has been applied to engine of the type and size used in metal/nonmetal mines. Commenters have stated that filters are not feasible at this time from the above comments. However, MSHA believes that the technology needed to reduce dpm emissions to both the interim and final standards is feasible. Much work has occurred in the development of aftertreatment controls, especially OCCs and hot gas filters. Aftertreatment control manufacturers have been improving both OCCs and ceramic type filters to provide better performance and reliability. New materials are currently available commercially and new filter systems are being developed especially in light of the recent requirements in Europe and the new proposals from the EPA. Consequently, MSHA does not agree with the commenter concerning chipping of the traps when removed. As stated, manufacturers have designed systems to either be removed easily or even regenerated on the vehicle by simply plugging the unit in without removing the filter.

Two groups in particular have been doing some research comparing the efficiency of recent ceramic models: West Virginia University, as part of that State's efforts to develop rules on the use of diesel-powered equipment underground; and VERT (Verminderung der Emissionen von Realmaschinen in Tunnelbau), a consortium of several European agencies conducting such research in connection with major planned tunneling projects in Austria, Switzerland and Germany to protect occupational health and subsequent legislation in each of the three countries restricting diesel emissions in tunneling.

The State of West Virginia legislature enacted the West Virginia Diesel Act, thereby creating the West Virginia Diesel Commission and setting forth an administrative vehicle to allow and regulate the use of diesel equipment in underground coal mines in West Virginia. West Virginia University was appropriated funds to test diesel exhaust controls, as well as an array of diesel particulate filters. The University was asked to provide technical support and data necessary for the Commission to make decisions on standards for emission controls. Even though the studies were intended for the Commission's work for underground coal, the control technologies tested are relevant to metal/nonmetal mines.

The University reported data on four different engines and an assortment of configurations of available control devices, both hot gas filters and the DST® system, a system which first cools the exhaust and then runs it through a paper filter. The range of collection efficiencies reported for the ceramic filters and oxidation catalysts combined fell between 65% and 78%. The highest collection efficiency obtained using the ISO 8 mode test cycle (test cycle described in rule) was 81% on the DST® system (intended for coal use). The University did report problems with this system that would account for the lower than expected efficiency for a paper filter type system.

VERT's studies of particulate traps are detailed in two articles published in 1999 which have been widely disseminated to the diesel community here through www.DieselNet.com. The March article focuses on the efficiency of the traps; the April article compares the efficiency of other approaches (OCCs, fuel reformulation, engine modifications to reduce ultra-fine particulates) with that of the traps. Here we focus only on the information about particulate traps.

The authors of the March article report that 29 particulate trap systems were tested using various ceramic, metal and fiber filter media and several regeneration systems. The authors of the March article summarize their conclusions as follows:

> The results of the 4-year investigations of construction site engines on test rigs and in the field are clear: particulate trap technology is the only acceptable choice among all available measures. Traps proved to be an extremely efficient method to curtail the finest particles. Several systems demonstrated a filtration rate of more than 99% for ultra-fine particulates. Specific development may further improve the filtration rate.
>
> A two-year field test, with subsequent trap inspection, confirmed the results pertaining to filtration characteristics of ultra-fine particles. No curtailment of the ultra-fine particles is obtained with any of the following: reformulated fuel, new lubricants, oxidation catalytic converters, and optimization of the engine combustion.
>
> Particulate traps represent the best available technology (BAT). Traps must therefore be employed to curtail the particulate emissions that the law demands are minimized. This technology was implemented in occupational health programs in Germany, Switzerland and Austria.

On the bench tests, it appears that the traps reduce the overall particulate matter by between 70 and 80%, with better results for solid ultrafine particulates; under hot gas conditions, it appears the non-solid components of particulate matter cannot be dependably retained by these traps. Consistent with this finding, it was found that polycyclic aromatic hydrocarbons (PAHs) decreased proportionately to the gravimetric decrease of carbon mass. The tests also explored the impact of additives on trap efficiency, and the impact of back pressure.

The field tests confirmed that the traps were easy to mount and retained their reliability over time, although regeneration was required when low exhaust temperatures failed to do this automatically. Electronic monitoring of back pressure was recommended. In general, the tests confirmed that a whole series of trap systems have a high filtration rate and stable long time properties and are capable of performing under difficult construction site conditions. Again, the field tests indicated a very high reduction (97–99%) of particulates by count, but a lower rate of reduction in terms of mass.

Subsequently, VERT has evaluated additional commercially available filter systems. The filtration efficiency, expressed on a gravimetric basis is shown in the column headed ''PMAG—without additive''. The filtration efficiencies determined by VERT for these 6 filter systems range from 80.7% to 94.5%. The average efficiency of these filters is 87%. MSHA will be updating the list of VERT's evaluated systems as they become available.

VERT has also published information on the extent of dpm filter usage in Europe as evidence that the filter technology has attained wide spread acceptance. This information is included in the record of the coal dpm rulemaking where it has particular significance; it is noted here for informational purposes. The information isn't critical in this case because operators have a choice of controls. MSHA didn't explicitly add the latest VERT data to the Metal/

Nonmetal record during the latest reopening of the record. MSHA believes this information is relevant to metal/nonmetal mining because the tunneling equipment on which these filters are installed is similar to metal/nonmetal equipment. VERT stated that over 4,500 filter systems have been deployed in England, Scandinavia, and Germany. Deutz Corporation has deployed 400 systems (Deutz's design) with full flow burners for regeneration of filters installed on engines between 50–600kw. The company Oberland-Mangold has approximately 1,000 systems in the field which have accumulated an average of 8,400 operating hours in forklift trucks, 10,600 operating hours in construction site engines, and 19,200 operating hours in stationary equipment. The company Unikat has introduced in Switzerland over 250 traps since 1989 and 3,000 worldwide with some operating more than 20,000 hours. German industry annually installs approximately 1,500 traps in forklifts.

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Table II-4

Efficiency of Diesel Particulate Traps VERT-Certification Test

Average 4 operation points, ISO 8187

Trap	Date	PMAG		PZAG		ECAG	
		without Additive	with Additive	without Additive	with Additive	without Additive	with Additive
3M	VERT-Certification Test Part 1 (new)	80.7	-	98.6	99.6	-	-
Oberland		90.5	-	98.4	99.4	-	-
JMC		94.5	-	99.3	-	-	-
IBIDEN		87.2	-	99.9	-	-	-
Corning		84.9	-	99.5	99.8	-	-
HJS/CRT		83.8	-	99.4	-	98.2	-
SHW(LIB1)	After VERT Field Test Part 3 (after 2000 hrs)	3.2	22.2	96.3	97.1	-	93.1
SHW(CAT1)		77.5	87.6	97.8	98.8	97.2	96.5
BUCK(LIB2)		76.5	81.0	95.4	97.8	94.0	95.5
BUCK(CAT3)		64.2	76.2	91.0	96.8	(87.0) [2]	95.3
ECS(LIB3)		12.4	43.0	99.9	99.9	99.3	99.0
DEUTZ(LIB4) [1]		(70.5)	(76.1)	(86.6)	(91.6)	(84.2)	
UNIKAT(CAT4)		54.7	76.2	99.0	99.6	98.1	98.4
AVERAGE		66.4		98.3		97.2	

[1] Small melting damage
[2] Uncertain data
[3] Coulometry is optional for VERT certification test

PMAG: Efficiency according to Total Particulate Mass PM
PZAG: Efficiency according to Integrated Particulate Count (20 - 300 nm) PZ
ECAG: Efficiency according to Elementary Carbon EC (2 state Coulometry)

$$PMAG = \frac{PM_{before\ trap} - PM_{after\ trapF}}{PM_{before\ trapF}} = \frac{PM_{Ref} - PM_{after\ trap}}{PM_{Ref}} \quad (X\ 100\%)$$

$$PZAG = \frac{PZ_{before\ trap} - PZ_{after\ trap}}{PZ_{before\ trap}} = \frac{PZ_{Ref} - PZ_{after\ trap}}{PZ_{Ref}} \quad (X\ 100\%)$$

$$Penetration = 1 - Efficiency = = \frac{PZ_{after\ PF}}{PZ_{Ref}} \quad (X\ 100\%)$$

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Some commenters asserted that the VERT work was for relatively small engines and not for large engines, *i.e.,* 600–700 hp, and hence could not be relied upon to demonstrate the availability of filters of such high efficiencies for the larger equipment used in some underground mines. MSHA believes this comment is misplaced. The efficiency of a filter is attributable to the design of the filter and not the size of the engine. VERT is documenting filter efficiencies of commercially available filters. It is customary in the industry, however, for the filter manufacturer to size the filter to fit the size of the engine. The mine operator must work with the filter manufacturer to verify that the filter needed will work for the intended machine. MSHA believes that this is no different for other types of options installed on machines for underground mining use.

More information about the results of the VERT tests on specific filters, and how MSHA intends to use this information to aid the mining industry to comply with the requirements of the standards are discussed in Part IV of this preamble.

The accumulated dpm must be removed from all particulate traps periodically. This is usually done by burning off the accumulated particulate in a controlled manner, called regeneration. If the diesel equipment on which the trap is installed has a duty cycle which creates an exhaust gas temperature greater than about 650 degrees Fahrenheit for more than 25 percent of the operating time, the unit will be self cleaning. That is, the hot exhaust gas will burn off the particulate as it accumulates. Unfortunately, only hard working equipment, such as load-haul-dump and haulage equipment usually satisfies the exhaust gas temperature and duration requirements.

Techniques are available to lower the temperature required to initiate the regeneration. One technique under development is to use a fuel additive. A comparatively small amount of a chemical is added to the diesel fuel and burns along with the fuel in the combustion chamber. The additive is reported to lower the required regeneration temperature significantly. The additive combustion products are retained as a residue in the particulate trap. The trap must be removed from the equipment periodically to flush the residue. Another technique used to lower the regeneration temperature is to apply a catalyst to the surfaces of the trap material. The action of the catalyst has a similar effect as the fuel additive. The catalyst also lowers the concentration of some gaseous emissions in the same manner as the oxidation catalytic converter described earlier.

A very active catalyst applied to the particulate trap surfaces and a very active catalyst in a catalytic converter installed upstream of the trap can create a situation in which the trap performs less efficiently than expected. Burning low sulfur diesel fuel, containing less than 500 ppm sulfur, will result in the creation of significant quantities of sulfates in the exhaust gas. These sulfates will still be in the gaseous state when they reach the ceramic trap and will pass through the trap. These sulfates will condense later forming diesel particulate. Special care must be taken in the selection of the catalyst formulation to ensure that sulfate formation is avoided. This problem is not present on systems which are designed with a catalytic converter upstream of a water scrubber. The gaseous phase sulfates will condense when contacting the water in the scrubber and will not be discharged into the mine atmosphere. Thus far, no permissible diesel packages have been approved which incorporate a catalytic converter upstream of the water scrubber.

One research project conducted by the former Bureau of Mines which attempted this arrangement was unsuccessful. The means selected to maintain a surface temperature less than the 300 degrees Fahrenheit required for permissibility purposes caused the exhaust gas to be cooled to the point that the catalytic converter did not reach the necessary operating temperature. It would appear that a means to isolate the catalytic converter from the exhaust gas water jacket is necessary for the arrangement to function as intended.

If the machine on which the particulate trap is installed does not work hard enough to regenerate the trap with the hot exhaust gas and the option to use a fuel additive or catalyzed trap is not appropriate, the trap can still be regenerated while installed on the machine. Systems are available whereby air is heated by an externally applied heat source and caused to flow through the particle trap with the engine stopped. The heat can be supplied by an electrical resistance element installed in front of the trap. The heat can also be supplied by a burner installed into the exhaust pipe in front of the trap fueled by an auxiliary fuel line. The fuel is ignited creating large quantities of hot gas. With both systems, an air line is also connected to the exhaust pipe to create a flow of hot gases through the particulate trap. Both systems utilize operator panels to control the regeneration process.

Some equipment owners may choose to remove the particle trap from the machine to perform the regeneration. Particle traps are available with quick release devices that allow maintenance personnel to readily remove the unit from the machine. The trap is then placed on a specially designed device that creates a controlled flow of heated air that is passed through the filter burning off the accumulated particulate.

The selection of the most appropriate means to regenerate the trap is dependent on the equipment type, the equipment duty cycle, and the equipment utilization practices at the mine.

A program under the Canadian DEEP project is field testing dpm filter systems in a New Brunswick Mine. The project is testing four filter systems on trucks and scoops. The initial feedback from Canada is very favorable concerning the performance of filters. Operators are very positive and are requesting the vehicles equipped with the filters because of the noticeable improvement in air quality and an absence of smoke even under transient load conditions. One system being tested utilizes an electrical heating element installed in the filter system to provide the heated air for regeneration of the filter. This heating element requires that the filter be connected to an external electrical source at the end of the shift. Initial results have been successful.

Paper filters. In 1990, the former Bureau of Mines conducted a project to develop a means to reduce the amount of dpm emitted from permissible diesel powered equipment using technologies that were available commercially and that could be applied to existing equipment. The project was conducted with the cooperation of an equipment manufacturer, a mine operator, and MSHA. In light of the fact that all permissible diesel powered equipment in coal and metal/nonmetal, at that time, utilized water scrubbers to meet the MSHA approval requirements, the physical characteristics of the exhaust from that type of equipment were the basis for the selection of candidate technologies. The technology selected for development was the pleated media filter or paper filter as it came to be called. The filter selected was an intake air cleaner normally used for over the road trucks. That filter was acceptable for use with permissible diesel equipment because the temperature of the exhaust gas from the water scrubber was less than 170 degrees F which was

well below the ignition point of the filter material.

Recognizing that under some operating modes water would be discharged along with the exhaust, a water trap was installed in the exhaust stream before it passed through the filter. After MSHA conducted a thorough permissibility evaluation of the modified system, this filter was installed on a permissible diesel coal haulage vehicle and a series of in mine trials conducted. It was determined, by in mine ambient gravimetric sampling, that the particulate filter reduced dpm emissions by 95 percent compared to that same machine without the filter. The testing determined that the filters would last between one and two shifts, depending on how hard the equipment worked. (BOM, IC 9324).

Following the successful completion of the former Bureau of Mines mine trial, several equipment manufacturers applied for and received MSHA approval to offer the paper filter kits as options on a number of permissible diesel machines. These filter kits were installed on other machines at the mine where the original tests were conducted, and later, on machines at other mines. MSHA is not aware of any paper filters installed on permissible equipment in m/nm to date.

Despite the initial reports on the high efficiency of paper filters, during the coal public hearings and in the coal comments on this rulemaking a number of commenters at the coal public hearings questioned whether in practice paper filters could achieve efficiencies on the order of 95% when used on existing permissible equipment. In order to determine whether it could verify those concerns, MSHA contracted with the Southwest Research Institute to verify the ability of such a filter to reduce the dpm generated by a typical engine used in permissible equipment. The results of this verification effort confirmed that paper filters has a dpm removal efficiency greater than 95%. The information about MSHA's verification effort with respect to paper filters is discussed in detail in connection with the companion rule for the coal sector, where it has particular significance.

Dry systems technology. As mentioned earlier, the most recently developed means of achieving permissibility with diesel powered equipment in the United States is the dry exhaust conditioning system or dry system. This system combines several of the concepts described above as well as new, innovative approaches. The system also solves some of the problems encountered with older technologies.

The dry system in its most basic form consists of a heat exchanger to cool the exhaust gas, a mechanical flame arrestor to prevent the discharge of any flame from within the engine into the mine atmosphere, and a spark arrestor to prevent sparks for being discharged. The surfaces of all of these components and the piping connecting them are maintained below the 300 degrees F required by MSHA approval requirements. A filter, of the type normally used as an intake air filter element, is installed in the exhaust system as the spark arrestor. In terms of this dpm regulation, the most significant feature of the system is the use of this air filter element as a particulate filter. The filter media has an allowable operating temperature rating greater than the 300 degree F exhaust gas temperature allowed by MSHA approval regulations. These filters are reported to last up to sixteen hours, depending on how hard the machine operates.

The dry system can operate on any grade without the problems encountered by water scrubbers. Furthermore, there is no problem with fog created by operation of the water scrubber. Dry systems have been installed and are operating successfully in coal mines on diesel haulage equipment, longwall component carriers, longwall component extraction equipment, and in nonpermissible form, on locomotives.

Although the systems were originally designed for permissible equipment applications, they can also be used directly on nonpermissible equipment (whose emissions are not already cooled), or to replace water scrubbers used to cool most permissible equipment with a system that includes additional aftertreatment.

Reformulated fuels. It has long been known that sulfur content can have a significant effect on dpm emissions. In its diesel equipment rule for underground coal mines, MSHA requires that any fuel used in underground coal mines have less than 0.05% (500 ppm) sulfur. EPA regulations requiring that such low-sulfur fuel (less than 500 ppm) be used in highway engines, in order to limit air pollution, have in practice ensured that this type of diesel fuel is available to mine operators, and they currently use this type of fuel for all engines.

EPA has proposed a rule which would require further reductions in the sulfur content of highway diesel fuel. Such an action was taken for gasoline fuel on December 21, 1999.

On May 13, 1999 (64 FR 26142) EPA published an Advance Notice of Proposed Rulemaking (ANPRM) relative to changes for diesel fuel. In explaining why it was initiating this action, EPA noted that diesel engines ''contribute greatly'' to a number of serious air pollution problems, and that diesel emissions account for a large portion of the country's particulate matter and nitrogen oxides a key precursor to ozone. EPA noted that while these emissions come mostly from heavy-duty truck and nonroad engines, they expected the contribution to dpm emissions of light-duty equipment to grow due to manufacturers' plans to greatly increase the sale of light duty trucks. These vehicles are now subject to Tier 2 emission standards whether powered by gasoline or diesel fuel, and such standards may be difficult to meet without advanced catalyst technologies that in turn would seem to require sulfur reductions in the fuel.

Moreover, planned Tier 3 standards for nonroad vehicles would require similar action (64 FR 26143). The EPA noted that the European Union has adopted new specifications for diesel fuel that would limit it to 50 ppm by 2005, (an interim limit of 350 ppm by this year), that the entire diesel fuel supply in the United Kingdom should soon be at 50 ppm, and that Japan and other nations were working toward the same goal (64 FR 26148). In the ANPRM, the EPA specifically noted that while continuously regenerating ceramic filters have shown considerable promise for limiting dpm emissions even at fairly low exhaust temperatures, the systems are fairly intolerant of fuel sulfur. Accordingly, the agency hopes to gather information on whether or not low sulfur fuel is needed for effective PM control (64 FR 26150). EPA's proposed rule was published in June 2000, (65 FR 35430) and proposed a sulfur limit of 15 ppm for on-highway use in 2006–2009.

A joint government-industry partnership is also investigating the relationship between varying levels of sulfur content and emissions reduction performance on various control technologies, including particulate filters and oxidation catalytic convertors. This program is supported by the Department of Energy's Office of Heavy Vehicles Technologies, two national laboratories, the Engine Manufacturers Association, and the Manufacturers of Emission Controls Association. It is known as the Diesel Emission Control-Sulfur Effects (DECSE) Program; more information is available from its web site, http://www.ott.doe.gov/decse.

MSHA expects that once such cleaner fuel is required for transportation use, it will in practice become the fuel used in mining as well—directly reducing

engine particulate emissions, increasing the efficiency of aftertreatment devices, and eventually through the introduction of new generation of cleaner equipment. Mayer states that reducing sulfur content, decreasing aromatic components and increasing the Cetane index of diesel fuel can generally result in a 5% to 15% reduction in total particulate emissions.

Meyer reports the test by VERT of a special synthetic fuel containing neither sulfur nor bound nitrogen nor aromatics, with a very high Cetane index. The fuel performed very well, but produced only abut 10% fewer particulates than low sulfur diesel fuel, nor did it have the slightest improvement in diminishing nonparticulate emissions.

NIOSH provided information on the work that has been done with Biodiesel fuel. Biodiesel fuel is a registered fuel and fuel additive with the EPA and meets clean diesel standards established by the California Air Resources Board. NIOSH stated that the undisputed consensus among the research conducted is that the use of biodiesel will significantly reduce dpm and other harmful emissions in underground mines. MSHA agrees that biodiesel fuel is an option that mine operators can use from the toolbox to meet the dpm standards.

Cabs. A cab is an enclosure around the operator installed on a piece of mobile equipment. It can provide the same type of protection as a booth at a crusher station. While cabs are not available for all mining equipment, they are available for much of the larger equipment that also has application in the construction industry.

Even though cabs are not the type of control device that is bolted onto the exhaust of the diesel engine to reduce emissions, cabs can protect miners from environmental exposures to dpm. Both cabs and control booths are discussed in the context of reducing miners exposures to dpm.

To be effective, a cab should be tightly sealed with windows and doors must be closed. Rubber seals around doors and windows should be in good conditions. Door and window latches should operate properly. In addition to being well sealed, the cab should have an air filtration and space pressurizing system. Air intake should be located away from engine exhaust. The airflow should provide one air change per minute for the cab and should pressurize the cab to 0.20 inches of water. While these are not absolute requirements, they do provide a guideline of how a cab should be designed. If a cab does not have an air filtration and pressurizing system, the diesel particulate concentration inside the cab will be similar to the diesel particulate concentration outside the cab.

MSHA has evaluated the efficiency of cab filters for diesel particulate reduction (Commercial Stone Study, PS&HTC–DD–98–346, Commercial Stone Study, PS&HTC–DD–99–402 and Homestake Mine Study, PS&HTC–DD–00–505.) Several different types of filter media have been tested in underground mines. Depending on the filter media, cabs can reduce diesel particulate exposures by 45 to 90 percent.

(7) MSHA's Diesel Safety Rule for Underground Coal Mines and its Effect on dpm

MSHA's proposed rule to limit the concentration of dpm in underground metal and nonmetal mines included a number of elements which have already proven successful in helping to reduce dpm concentrations in the coal sector. Accordingly, this section provides some background on the substance of the rules that have been in effect in underground coal mines (for more information on the history of rulemaking in the coal sector, please refer to section 9 of this Part). It should be noted, however, that not all of the requirements discussed here are going to be required for underground metal and nonmetal mines; see Part IV of this preamble for details on what is included in the final rule.

Diesel Equipment Rule in Underground Coal Mines. On October 25, 1996, MSHA promulgated standards for the ''Approval, Exhaust Gas Monitoring, and Safety Requirements for the Use of Diesel-Powered Equipment in Underground Coal Mines,'' sometimes referred to as the ''diesel equipment rule'' (61 FR 55412; the history of this rulemaking is briefly discussed in section 9 of this Part). The diesel equipment rule focuses on the safe use of diesels in underground coal mines. Integrated requirements are established for the safe storage, handling, and transport of diesel fuel underground, training of mine personnel, minimum ventilating air quantities for diesel powered equipment, monitoring of gaseous diesel exhaust emissions, maintenance requirements, incorporation of fire suppression systems, and design features for nonpermissible machines.

MSHA Approval Requirements for Engines Used in Underground Coal Mines. MSHA requires that all diesel engines used in underground coal mines be ''approved'' by MSHA for such use, and be maintained by operators in approved condition. Among other things, approval of an engine by MSHA ensures that engines exceeding certain pollutant standards are not used in underground coal mines. MSHA sets the standards for such approval, establishes the testing criteria for the approval process, and administers the tests. The costs to obtain approval of an engine are usually borne by the engine manufacturer or equipment manufacturer. MSHA's 1996 diesel equipment rule made some significant changes to the consequences of approval. The new rule required the whole underground coal fleet to convert to approved engines no later than November 1999.

The new rule also required that during the approval process the agency determine the particulate index (PI) for the engine. The particulate index (or PI), calculated under the provisions of 30 CFR 7.89, indicates the air quantity necessary to dilute the diesel particulate in the engine exhaust to 1 milligram of diesel particulate matter per cubic meter of air.

The PI does not appear on the engine's approval plate. (61 FR 55421). Furthermore, the particulate index of an engine is not, under the diesel equipment rule, used to determine whether or not the engine can be used in an underground coal mine.

At the time the equipment rule was issued, MSHA explicitly deferred the question of whether to require engines used in mining environments to meet a particular PI. (61 FR 55420–21, 55437). While there was some discussion of using it in this fashion during the diesel equipment rulemaking, the approach taken in the final rule was to adopt, instead, the multi-level approach recommended by the Diesel Advisory Committee. This multi-level approach included the requirement to use clean fuel, low emission engines, equipment design, maintenance, and ventilation, all of which appear in the final rule. The requirement for determining the particulate index was included in the diesel equipment rule in order to provide information to the mining community in purchasing equipment—so that mine operators can compare the particulate levels generated by different engines. Mine operators and equipment manufacturers can use the information along with consideration of the type of machine the engines would power and the area of the mine in which it would be used to make decisions concerning the engine's contribution of diesel particulate to the mine's total respirable dust. Equipment manufactures can use the particulate index to design and install exhaust after-treatments. (61 FR 55421). So that the PI for any engine is

known to the mining community, MSHA reports the index in the approval letter, posted the PI and ventilating air requirement for all approved engines on its website, and publishes the index with its lists of approved engines.

Gas Monitoring. As discussed in section 5, there are limitations on the exposure of miners to various gases emitted from diesel engines in both underground coal mines and underground metal and nonmetal mines.

The 1996 diesel equipment rule for underground coal mines supplemented these protections in that sector by providing for the monitoring and control of gaseous diesel exhaust emissions. (30 CFR part 70; 61 FR 55413). The rule requires that underground coal mine operators take samples of carbon monoxide and nitrogen dioxide as part of existing onshift workplace examinations. Samples exceeding an action level of 50 percent of the threshold limits set forth in 30 CFR 75.322 trigger corrective action by the mine operator.

Engine Maintenance. The diesel equipment rule also requires that diesel-powered equipment be maintained in safe and approved condition. As explained in the preamble, maintenance requirements were included because of MSHA's recognition that inadequate equipment maintenance can, among other things, result in increased levels of harmful gaseous and particulate components from diesel exhaust.

Among other things, the rule requires the weekly examination of diesel-powered equipment in underground coal mines. To determine if more extensive maintenance is required, the rule further requires that a weekly check of the gaseous CO emission levels on permissible and heavy duty outby machines be made. The CO check requires that the engine be operated at a repeatable loaded condition and the CO measured. The carbon monoxide concentration in the exhaust provides a good indication of engine condition. If the CO measurement increases to a higher concentration than what was normally measured during the past weekly checks, then a maintenance person would know that a problem has developed that requires further investigation. In addition, underground coal mine operators are required to establish programs to ensure that those performing maintenance on diesel equipment are qualified.

Fuel. The diesel equipment rule also requires that underground coal mine operators use diesel fuel with a sulfur content of 0.05% (500 ppm) or less. Some types of exhaust aftertreatment technology designed to lower hazardous diesel emissions work more effectively when the sulfur content of the fuel is low. More effective aftertreatment devices will result in reduced hydrocarbons, carbon monoxide, and particulate levels. Low sulfur fuel also greatly reduces the sulfate production from the catalytic converters currently in use in underground coal mines, thereby decreasing exhaust particulate. To further reduce miners' exposure to diesel exhaust, the final rule prohibits operators from unnecessarily idling diesel-powered equipment.

Ventilation. The diesel equipment rule requires that as part of the approval process, ventilating air quantities necessary to maintain the gaseous emissions of diesel engines within existing required ambient limits be set. The ventilating air quantities are required to appear on the engine's approval plate. The rule also requires that mine operators maintain the approval plate quantity minimum airflow in areas of underground coal mines where diesel-powered equipment is operated. The engine's approval plate air quantity is also used to determine the minimum air quantity in areas where multiple units of diesel powered equipment are being operated. The minimum ventilating air quantity where multiple units of diesel powered equipment are operated on working sections and in areas where mechanized mining equipment is being installed or removed, must be the sum of 100 percent of the approval plate quantities of all of the equipment. As set forth in the preamble of the diesel equipment rule, MSHA believes that effective mine ventilation is a key component in the control of miners' exposure to gasses and particulate emissions generated by diesel equipment.

Impact of the diesel equipment rule on dpm levels in underground coal mines. The diesel equipment rule has many features which, by reducing the emission and concentration of harmful diesel emissions in underground coal mines, will indirectly reduce particulate emissions.

In developing the diesel equipment rule, however, MSHA did not explicitly consider the risks to miners of a working lifetime of dpm exposure at very high levels, nor the actions that could be taken to specifically reduce dpm exposure levels in underground coal mines. It was understood that the agency would be taking a separate look at the health risks of dpm exposure. For example, the agency explicitly deferred discussion of whether to make operators use only equipment that complied with a specific Particulate Index.

(8) Information on How Certain States are Restricting Occupational Exposure to DPM.

As noted earlier in this part, the Federal government has long been involved in efforts to restrict diesel particulate emissions into the environment—both through ambient air quality standards, and through restrictions on diesel engine emissions. While MSHA's actions to limit the concentration of dpm in underground mines are the first effort by the Federal government to deal with the special risks faced by workers exposed to diesel exhaust on the job, several states have already taken actions in this regard with respect to underground coal mines.

This section reviews some of these actions, as they were the subject of considerable discussion and comment during this rulemaking.

Pennsylvania. As indicated in section 1, Pennsylvania essentially had a ban on the use of diesel-powered equipment in underground coal mines for many years. As noted by one commenter, diesel engines were permitted provided the request was approved by the Secretary of the Department of Environmental Protection.

In 1995, one company in the State submitted a plan for approval and started negotiations with its local union representatives. This led to statewide discussions and the adoption of a new law in the State that permits the use of diesel-powered equipment in deep coal mines under certain circumstances specified in the law (Act 182). As further noted by this commenter, the drafters of the law completed their work before the issuance of MSHA's new regulation on the safe use of diesel-powered equipment in underground coal mines. The Pennsylvania law, unlike MSHA's diesel equipment rule, specifically addresses diesel particulate. The State did not set a limit on the exposure of miners to dpm, nor did it establish a limit on the concentration of dpm in deep coal mines. Rather, it approached the issue by imposing controls that will limit dpm emissions at the source.

First, all diesel engines used in underground deep coal mines in Pennsylvania must be MSHA-approved engines with an ''exhaust emissions control and conditioning system'' that meets certain tests. (Article II-A, Section 203-A, Exhaust Emission Controls). Among these are dpm emissions from each engine no greater than ''an average concentration of 0.12 mg/m^3 diluted by fifty percent of the MSHA approval plate ventilation for that diesel engine.'' In addition, any exhaust emissions

control and conditioning system must include a ''Diesel Particulate Matter (DPM) filter capable of an average of ninety-five percent or greater reduction of dpm emissions.'' It also requires the use of an oxidation catalytic converter. Thus, the Pennsylvania statute requires the use of low-emitting engines, and then the use of aftertreatment devices that significantly reduce the particulates emitted from these engines.

The Pennsylvania law also has a number of other requirements for the safe use of diesel-powered equipment in the particularly hazardous environments of underground coal mines. Many of these parallel the requirements in MSHA's diesel equipment rule. Like MSHA's requirements, they too can result in reducing miner exposure to diesel particulate—*e.g.,* regular maintenance of diesel engines by qualified personnel and equipment operator examinations. The requirements in the Pennsylvania law take into account the need to maintain the aftertreatment devices required to control diesel particulate.

While both mine operators and labor supported this approach, it remains controversial. During the hearings on this rulemaking, one commenter indicated that at the time the standards were established, it would have taken a 95% filter to reduce dpm from certain equipment to the 0.12 mg/m^3 emissions standard because 0.25 sulfur fuel was being utilized. This test reported by the commenter was completed prior to MSHA promulgating the diesel equipment rule that required the use of .05% sulfur fuel. Another commenter pointed out that as operators in the state began considering the use of newer, less polluting engines, achieving an efficiency of 95% reduction of the emissions from any such engines would become even more difficult. There was some disagreement among the commenters as to whether existing technology would permit operators to meet the 0.12 mg/m^3 emission standard in many situations. One commenter described efforts to get a small outby unit approved under Pennsylvania law. Accordingly, the industry has indicated that it would seek changes to the Pennsylvania diesel law. Commenters representing miners indicated that they were involved in these discussions.

West Virginia. Until 1997, West Virginia law banned the use of diesel-powered equipment in underground coal mines. In that year, the State created the joint labor-management West Virginia Diesel Equipment Commission (Commission) and charged it with developing regulations to permit and govern diesel engine use in underground coal mines. As explained by several commenters, the Commission, in collaboration with West Virginia University (WVU), developed a protocol for testing diesel engine exhaust controls, and the legislature appropriated more than $150,000 for WVU to test diesel exhaust controls and an array of diesel particulate filters.

There were a number of comments received by MSHA on the test protocols and results. These are discussed in part IV this preamble. One commenter noted that various manufacturers of products have been very interested in how their products compare to those of other manufacturers tested by the WVU. Another asserted that mine operators had been slowing the scheduling of tests by WVA.

Pursuant to the West Virginia law establishing the Commission, the Commission was given only a limited time to determine the applicable rules for the use of diesel engines underground, or the matter was required to be referred to an arbitrator for resolution. One commenter during the hearings noted that the Commission had not been able to reach resolution and that indeed arbitration was the next step. Other commenters described the proposal of the industry members of the Commission—0.5mg/m^3 for all equipment, as configured, before approval is granted. In this regard, the industry members of the West Virginia Commission said:

> ''We urge you to accelerate the finalization of * * * these proposed rules. We believe that will aid our cause, as well as the other states that currently don't use diesel.'' (*Id*)

Virginia. According to one commenter, diesel engine use in underground mining was legalized in Virginia in the mid-1980s. It was originally used on some heavy production equipment, but the haze it created was so thick it led to a drop in production. Thereafter, most diesel equipment has been used outby (805 pieces). The current state regulations consist of requiring that MSHA approved engines be used, and that the ''most up-to-date, approved, available diesel engine exhaust aftertreatment package'' be utilized. There are no distinctions between types of equipment. The commenter noted that more hearings were planned soon. Under a directive from the governor of Virginia, the state is reviewing its regulations and making recommendations for revisions to sections of its law on diesels.

Ohio. The record of this rulemaking contains little specific information on the restrictions on the underground use of diesel-powered equipment in Ohio. MSHA understands, however, that in practice it is not used. According to a communication with the Division of Mines and Reclamation of the Ohio Division of Natural Resources, this outcome stems from a law enacted on October 29, 1995, now codified as section 1567.35 of Ohio Revised Code Title 15, which imposes strict safety restrictions on the use of various fuels underground.

(9) History of this Rulemaking.

As discussed throughout this part, the Federal government has worked closely with the mining community to ascertain whether and how diesel-powered equipment might be used safely and healthfully in this industry. As the evidence began to grow that exposure to diesel exhaust might be harmful to miners, particularly in underground mines, formal agency actions were initiated to investigate this possibility and to determine what, if any, actions might be appropriate. These actions, including a number of non-regulatory initiatives taken by MSHA, are summarized here in chronological sequence.

Activities Prior to Proposed Rulemaking on DPM. In 1984, the National Institute for Occupational Safety and Health (NIOSH) established a standing Mine Health Research Advisory Committee to advise it on matters involving or related to mine health research. In turn, that standing body established the Mine Health Research Advisory Committee Diesel Subgroup to determine if:

> * * * there is a scientific basis for developing a recommendation on the use of diesel equipment in underground mining operations and defining the limits of current knowledge, and recommending areas of research for NIOSH, if any, taking into account other investigators' ongoing and planned research. (49 FR 37174).

In 1985, MSHA established an Interagency Task Group with NIOSH and the former Bureau of Mines (BOM) to assess the health and safety implications of the use of diesel-powered equipment in underground coal mines.

In April 1986, in part as a result of the recommendation of the Task Group, MSHA began drafting proposed regulations on the approval and use of diesel-powered equipment in underground coal mines. Also in 1986, the Mine Health Research Advisory Committee Diesel Subgroup (which, as noted above, was created by a standing NIOSH committee) summarized the evidence available at that time as follows:

> It is our opinion that although there are some data suggesting a small excess risk of adverse health effects associated with exposure to diesel exhaust, these data are not compelling enough to exclude diesels from underground mines. In cases where diesel equipment is used in mines, controls should be employed to minimize exposure to diesel exhaust.

On October 6, 1987, pursuant to Section 102(c) of the Mine Act, 30 U.S.C. 812(c), which authorizes MSHA to appoint advisory committees as he deems appropriate, the agency appointed an advisory committee ''to provide advice on the complex issues concerning the use of diesel-powered

equipment in underground coal mines.'' (52 FR 37381). MSHA appointed nine members to this committee, officially known as The Mine Safety and Health Administration Advisory Committee on Standards and Regulations for Diesel-Powered Equipment in Underground Coal Mines (hereafter the MSHA Diesel Advisory Committee). As required by section 101(a)(1) of the Mine Act, MSHA provided the MSHA Diesel Advisory Committee with draft regulations on the approval and use of diesel-powered equipment in underground coal mines. The draft regulations did not include standards setting specific limitations on diesel particulate, nor had MSHA at that time determined that such standards would be promulgated.

In July 1988, the MSHA Diesel Advisory Committee completed its work with the issuance of a report entitled ''Report of the Mine Safety and Health Administration Advisory Committee on Standards and Regulations for Diesel-Powered Equipment in Underground Coal Mines.'' It also recommended that MSHA promulgate standards governing the approval and use of diesel-powered equipment in underground coal mines. The MSHA Diesel Advisory Committee recommended that MSHA promulgate standards limiting underground coal miners' exposure to diesel exhaust.

With respect to diesel particulate, the MSHA Diesel Advisory Committee recommended that MSHA ''set in motion a mechanism whereby a diesel particulate standard can be set.'' (MSHA, 1988). In this regard, the MSHA Diesel Advisory Committee determined that because of inadequacies in the data on the health effects of diesel particulate matter and inadequacies in the technology for monitoring the amount of diesel particulate matter at that time, it could not recommend that MSHA promulgate a standard specifically limiting the level of diesel particulate matter in underground coal mines (*Id.* 64–65). Instead, the MSHA Diesel Advisory Committee recommended that MSHA ask NIOSH and the former Bureau of Mines to prioritize research in the development of sampling methods and devices for diesel particulate.

The MSHA Diesel Advisory Committee also recommended that MSHA request a study on the chronic and acute effects of diesel emissions (*Id*). In addition, the MSHA Diesel Advisory Committee recommended that the control of diesel particulate ''be accomplished through a combination of measures including fuel requirements, equipment design, and in-mine controls such as the ventilation system and equipment maintenance in conjunction with undiluted exhaust measurements.'' The MSHA Diesel Advisory Committee further recommended that particulate emissions ''be evaluated in the equipment approval process and a particulate emission index reported.'' (*Id.* at 9).

In addition, the MSHA Diesel Advisory Committee recommended that ''the total respirable particulate, including diesel particulate, should not exceed the existing two milligrams per cubic meter respirable dust standard.'' (*Id.* at 9.) It should be noted that section 202(b)(2) of the Mine Act requires that coal mine operators maintain the average concentration of respirable dust at their mines at or below two milligrams per cubic meter which effectively prohibits diesel particulate matter in excess of two milligrams per cubic meter (30 U.S.C. 842(b)(2)).

As noted, the MSHA Diesel Advisory Committee issued its report in 1988. During that year, NIOSH issued a Current Intelligence Bulletin recommending that whole diesel exhaust be regarded as a potential carcinogen and controlled to the lowest feasible exposure level (NIOSH, 1988). In its bulletin, NIOSH concluded that although the excess risk of cancer in diesel exhaust exposed workers has not been quantitatively estimated, it is logical to assume that reductions in exposure to diesel exhaust in the workplace would reduce the excess risk. NIOSH stated that ''[g]iven what we currently know, there is an urgent need for efforts to be made to reduce occupational exposures to DEP [dpm] in mines.''

Consistent with the MSHA Diesel Advisory Committee's research recommendations, MSHA, in September 1988, formally requested NIOSH to perform a risk assessment for exposure to diesel particulate. (57 FR 500). MSHA also requested assistance from NIOSH and the former BOM in developing sampling and analytical methodologies for assessing exposure to diesel particulate in mining operations. (*Id.*). In part, as a result of the MSHA Diesel Advisory Committee's recommendation, MSHA also participated in studies on diesel particulate sampling methodologies and determination of underground occupational exposure to diesel particulate.

On October 4, 1989, MSHA published a Notice of Proposed Rulemaking on approval requirements, exposure monitoring, and safety requirements for the use of diesel-powered equipment in underground coal mines. (54 FR 40950). The proposed rule followed the MSHA Diesel Advisory Committee's recommendation that MSHA promulgate regulations requiring the approval of diesel engines.

On January 6, 1992, MSHA published an Advance Notice of Proposed Rulemaking (ANPRM) (57 FR 500). In the ANPRM, MSHA, among other things, sought comment on specific reports on diesel particulate prepared by NIOSH and the former BOM. MSHA also sought comment on reports on diesel particulate which were prepared by or in conjunction with MSHA. The ANPRM also sought comments on the health effects, technological and economic feasibility, and provisions which should be considered for inclusion in a diesel particulate rule. The notice also identified five specific areas where the agency was particularly interested in comments, and about which it asked a number of detailed questions: (1) Exposure limits, including the basis thereof; (2) the validity of the NIOSH risk assessment model and the validity of various types of studies; (3) information about non-cancer risks, non-lung routes of entry, and the confounding effects of tobacco smoking; (4) the availability, accuracy and proper use of sampling and monitoring methods for diesel particulate; and (5) the technological and economic feasibility of various types of controls, including ventilation, diesel fuel, engine design, aftertreatment devices, and maintenance by mechanics with specialized training. The notice also solicited specific information from the mining community on ''the need for a medical surveillance or screening program and on the use of respiratory equipment.'' (57 FR 500). The comment period on the ANPRM closed on July 10, 1992.

While MSHA was completing a ''comprehensive analysis of the comments and any other information received'' in response to the ANPRM (57 FR 501), it took also several actions to encourage the mining community to begin to deal with the problems identified.

In 1995, MSHA sponsored three workshops ''to bring together in a forum format the U.S. organizations who have a stake in limiting the exposure of miners to diesel particulate (including) mine operators, labor unions, trade organizations, engine manufacturers, fuel producers, exhaust aftertreatment manufacturers, and academia.'' (McAteer, 1995). The sessions provided an overview of the literature and of diesel particulate exposures in the mining industry, state-of-the-art technologies available for reducing diesel particulate levels, presentations on engineering technologies toward that end, and identification of possible

strategies whereby miners' exposure to diesel particulate matter can be limited both practically and effectively.

The first workshop was held in Beckley, West Virginia on September 12 and 13, and the other two were held on October 6, and October 12 and 13, 1995, in Mt Vernon, Illinois and Salt Lake City, Utah, respectively. A transcript was made. During a speech early the next year, the Deputy Assistant Secretary for MSHA characterized what took place at these workshops:

> The biggest debate at the workshops was whether or not diesel exhaust causes lung cancer and whether MSHA should move to regulate exposures. Despite this debate, what emerged at the workshops was a general recognition and agreement that a health problem seems to exist with the current high levels of diesel exhaust exposure in the mines. One could observe that while all the debate about the studies and the level of risk was going on, something else interesting was happening at the workshops: one by one miners, mining companies, and manufacturers began describing efforts already underway to reduce exposures. Many are actively trying to solve what they clearly recognize is a problem. Some mine operators had switched to low sulfur fuel that reduces particulate levels. Some had increased mine ventilation. One company had tried a soy-based fuel and found it lowered particulate levels. Several were instituting better maintenance techniques for equipment. Another had hired extra diesel mechanics. Several companies had purchased electronically controlled, cleaner, engines. Another was testing a prototype of a new filter system. Yet another was using disposable diesel exhaust filters. These were not all flawless attempts, nor were they all inexpensive. But one presenter after another described examples of serious efforts currently underway to reduce diesel emissions. (Hricko, 1996).

In March of 1997, MSHA issued, in draft form, a publication entitled ''Practical Ways to Control Exposure to Diesel Exhaust in Mining—a Toolbox''. The draft publication was disseminated by MSHA to all underground mines known to use diesel equipment and posted on MSHA's Web site.

As explained in the publication, the Toolbox was designed to disseminate to the mining community information gained through the workshops about methods being used to reduce miner exposures to dpm. MSHA's Toolbox provided specific information about nine types of controls that can reduce dpm exposures: low emission engines; fuels; aftertreatment devices; ventilation; enclosed cabs; engine maintenance; work practices and training; fleet management; and respiratory protective equipment. Some of these approaches reduce emissions from diesel engines; others focus on reducing miner exposure to whatever emissions are present. Quotations from workshop participants were used to illustrate when and how such controls might be helpful.

As it clearly stated in its introductory section entitled ''How to Use This Publication,'' the Toolbox was not designed as a guide to existing or pending regulations. As MSHA noted in that regard:

''While the (regulatory) requirements that will ultimately be implemented, and the schedule of implementation, are of course uncertain at this time, MSHA encourages the mining community not to wait to protect miners' health. MSHA is confident that whatever the final requirements may be, the mining community will find this Toolbox information of significant value.''

On October 25, 1996, MSHA published a final rule addressing approval, exhaust monitoring, and safety requirements for the use of diesel-powered equipment in underground coal mines (61 FR 55412). The final rule addresses, and in large part is consistent with, the specific recommendations made by the MSHA Diesel Advisory Committee for limiting underground coal miners' exposure to diesel exhaust. As noted in section 7 of this part, the diesel safety rule was implemented in steps concluding in late 1999. Aspects of this diesel safety rule had a significant impact on this rulemaking.

In the Fall of 1997, following comment, MSHA's Toolbox was finalized and disseminated to the mining community. At the same time, MSHA made available to the mining community a software modeling tool developed by the Agency to facilitate dpm control. This model enables an operator to evaluate the effect which various alternative combinations of controls would have on the dpm concentration in a particular mine—before making the investment. MSHA refers to this model as ''the Estimator.'' The Estimator is in the form of a template that can be used on standard computer spreadsheet programs. As information about a new combination of controls is entered, the results are promptly displayed.

On April 9, 1998, MSHA published a proposed rule to ''reduce the risks to underground coal miners of serious health hazards that are associated with exposure to high concentrations of diesel particulate matter'' (63 FR 17492). In order to further facilitate participation by the mining community, MSHA developed as an introduction to its preamble explaining the proposed rule, a dozen ''plain language'' questions and answers.

The proposed rule to limit the concentration of dpm in underground coal mines (63 FR 17578) focused on the exclusive use of aftertreatment filters on permissible and heavy duty nonpermissible equipment to limit the concentration of dpm in underground coal mines. In its Questions and Answers, however, and throughout the preamble, MSHA presented considerable information on a number of other approaches that might have merit in limiting the concentration of dpm in underground coal mines, and drew special attention to the fact that the text of the rule being proposed represented only one of the approaches on which the agency was interested in receiving comment. Training of miners in the hazards of dpm was also proposed.

The Proposed Rule to Limit DPM Concentrations in Underground Metal and Nonmetal Mines and Related Actions. On October 29, 1998 (63 FR 58104), MSHA published a proposed rule establishing new health standards for underground metal and nonmetal mines that use equipment powered by diesel engines.

In order to further facilitate participation by the mining community, MSHA developed as an introduction to its preamble explaining the proposed rule, 30 ''plain language'' questions and answers.

The notice of proposed rulemaking reviewed and discussed the comments received in response to the ANPRM, including information on such control approaches as fuel type, fuel additives, and maintenance practices (63 FR 58134). For the convenience of the mining community, a copy of MSHA's Toolbox was also reprinted as an Appendix at the end of the notice of proposed rulemaking (63 FR 58223). A complete description of the Estimator, and several examples, were also presented in the preamble of the proposed rule.

MSHA proposed to adopt (63 FR 58104) a different rule to address dpm exposure in underground metal and nonmetal mines.

MSHA proposed a limit on the concentration of dpm to which underground metal and nonmetal miners would be exposed.

The proposed rule would have limited dpm concentrations in underground metal and nonmetal mines to about 200 micrograms per cubic meter of air. Operators would have been able to select whatever combination of engineering and work practice controls they wanted to keep the dpm concentration in the mine below this limit.

The concentration limit would have been implemented in two stages: an interim limit that would go into effect following 18 months of education and technical assistance by MSHA, and a final limit after 5 years. MSHA sampling would be used to determine compliance.

The proposal would also have required that all underground metal and nonmetal mines using diesel-powered equipment observe a set of ''best practices'' to reduce engine emissions—*e.g.,* to use low-sulfur fuel.

Additionally, the Agency also considered alternatives that would have led to a significantly lower-cost proposal, *e.g.,* establishing a less stringent concentration limit in underground metal and nonmetal mines, or increasing the time for mine operators to come into compliance. However, MSHA concluded at that time that such approaches would not be as protective, and that the approach proposed was both economically and technologically feasible.

MSHA also explored whether to permit the use of administrative controls (*e.g.,* rotation of personnel) and personal protective equipment (*e.g.,* respirators) to reduce the diesel particulate exposure of miners. It is generally accepted industrial hygiene practice, however, to eliminate or minimize hazards at the source before resorting to personal protective equipment. Moreover, such a practice is generally not considered acceptable in the case of carcinogens since it merely places more workers at risk. Accordingly, the proposal explicitly prohibited the use of such approaches, except in those limited cases where MSHA approves, due to technological constraints, a 2-year extension for an underground metal and nonmetal mine on the time to comply with the final concentration limit.

MSHA sought comments from the mining community on the proposed regulatory text as well as throughout the entire preamble.

In addition, the Agency specifically requested comments on the following issues:

(a) *Assessment of Risk/Benefits of the Rule.* The Agency welcomed comments on the significance of the material already in the record, and any information that could supplement the record. For example, information on the health risks associated with exposure to dpm—especially observations by trained observers or studies of acute or chronic effects of exposure to known levels of dpm or fine particles in general, information about pre-existing health conditions in individual miners or miners as a group that might affect their reactions to exposures to dpm or other fine particles; information about how dpm affects human health; information on the costs to miners, their families and their employers of the various health problems linked to dpm exposure, and the assumptions and approach to use in quantifying the benefits to be derived from this rule.

(b) *Proposed rule.* MSHA sought comments on specific alternative approaches discussed in Part V. The options discussed included: adjusting the concentration limit for dpm; adjusting the phase-in time for the concentration limit; and requiring that specific technology be used in lieu of establishing a concentration limit.

The Agency also requested comments on the composition of the diesel fleet, what controls cannot be utilized due to special conditions, and any studies of alternative controls using the computer spreadsheet described in the Appendix to Part V of the proposed rule preamble. The Agency also requested information about the availability and costs of various control technologies being developed (*e.g.,* high-efficiency ceramic filters), experience with the use of available controls, and information that would help the Agency evaluate alternative approaches for underground metal and nonmetal mines. In addition, the Agency requested comments from the underground coal sector on the implementation to date of diesel work practices (like the rule limiting idling, and the training of those who provide maintenance) to help evaluate related proposals for the underground metal and nonmetal sector. The Agency also asked for information about any unusual situations that might warrant the application of special provisions.

(c) *Compliance Guidance.* The Agency solicited comments on any topics on which initial guidance ought to be provided as well as any alternative practices which MSHA should accept for compliance before various provisions of the rule go into effect; and

(d) *Minimizing Adverse Impact of the Proposed Rule.* The Agency set forth assumptions about impacts (*e.g.,* costs, paperwork, and impact on smaller mines in particular) in some detail in the preamble and in the PREA. We sought comments on the methodology, and information on current operator equipment replacement planning cycles, tax, State requirements, or other information that might be relevant to purchasing new engines or control technology. The Agency also welcomed comments on the financial situation of the underground metal and nonmetal sector, including information that may be relevant to only certain commodities.

From this point on, the actions taken on the rulemakings in underground coal mines and underground metal and nonmetal mines began to overlap in chronology. There is considerable overlap between the coal and metal/nonmetal communities, and so their participation in these separate rulemakings was often intertwined.

In November 1998, MSHA held hearings on the proposed rule for underground coal mines in Salt Lake City, Utah and Beckley, West Virginia. In December 1998, hearings were held in Mt. Vernon, Illinois, and Birmingham, Alabama.

Hearings concerning the proposed rule for underground coal mines were well attended, including representatives from both the coal and metal and nonmetal sectors. Testimony was presented by individual miners, representatives of miners, mine operators, mining industry associations, representatives of engine and equipment manufacturers, and one individual manufacturer. Members of the mining community participating had an extensive opportunity to hear and respond to alternative views; some participated in several hearings. They also had an opportunity to exchange in direct dialogues with the members of MSHA's dpm rulemaking committee—responding to questions and asking questions of their own. There was extensive comment not only about the provisions of the proposed rule itself, but also about the need for diesel powered equipment in this sector, the risks associated with its use, the need for regulation in this sector, alternative approaches including those on which MSHA sought comment, and the technological and economic feasibility of various alternatives.

On February 12, 1999, (64 FR 7144) MSHA published a notice in the **Federal Register** announcing: (1) The availability of three additional studies applicable to the proposals; (2) the extension of the post-hearing comment period and close of record on the proposed rule for underground coal mines for 60 additional days, until April 30, 1999; (3) the extension of the comment period on the proposed rule for metal and nonmetal mines for an additional 60 days, until April 30, 1999; and (4) an announcement that the Agency would hold public hearings on the metal and nonmetal proposal.

On March 24, 1999, (64 FR 14200) MSHA published a notice in the **Federal Register** announcing the dates, time, and location of four public hearings for the metal and nonmetal proposed rule.

The notice also announced that the close of the post-hearing comment period would be on July 26, 1999.

On April 27, 1999, (64 FR 22592) in response to requests from the public, MSHA extended the post-hearing comment period and close of record on the proposed rule for underground coal for 90 additional days, until July 26, 1999.

In May 1999, hearings on the metal and nonmetal proposed rule were held in Salt Lake City, Ut; Albuquerque, NM; St. Louis, MO and Knoxville, TN.

Hearings were well attended and testimony was presented by both labor (miners) and industry (mining associations, coal companies) and government (NIOSH). Testimony was presented by individual mining companies, mining industry associations, mining industry consultants and the National Institute of Occupational Safety and Health. The hearings were held for MSHA to obtain specific comments on the proposed rule for diesel particulate matter exposure of metal and nonmetal miners; additional information on existing and projected exposures to diesel particulate matter and to other fine particulates in various mining operations; information on the health risk associated with exposure to diesel particulate matter; information on the cost to miners, their families and their employers of the various health problems linked to diesel particulate matter; and information on additional benefits to be expected from reducing diesel particulate matter exposure.

Members of the mining community participating, had an extensive opportunity to hear and respond to alternative views; some participated in several of the hearings. They also had an opportunity to exchange in direct dialogues with members of MSHA's dpm rulemaking committee—responding to questions and asking questions of their own. There was extensive comment not only about the provisions of the proposed rule itself, but also about potential interferences with the method used to measure dpm, the studies that MSHA used to document the risk associated with exposure to dpm, the cost estimates derived by MSHA for industry implementation, and the technology and economic feasibility of various alternatives (specifically, industry use of a tool box approach without accountability for an exposure limit).

One commenter, at the Knoxville hearing, specifically requested that the credentials and experience (related to the medical field, epidemiology, metal and nonmetal mining, mining engineering, and diesel engineering) of the hearing panelists be made a part of the public record. The commenter was informed by one of the panelists at the hearing that if this information was wanted it should be requested under the Freedom Of Information Act (FOIA). Such a request was submitted to MSHA by the commenter and appropriately responded to by the Agency.

On July 8, 1999, (64 FR 36826) MSHA published a notice in the **Federal Register** correcting technical errors in the preamble discussion on the Diesel Emission Control Estimator formula in the Appendix to Part V of the proposed rulemaking notice, and correcting Figure V–5 of the preamble. Comments on these changes were solicited. (The Estimator model was subsequently published in the literature (Haney, R.A. and Saseen, G.P., ''Estimation of diesel particulate concentrations in underground mines'', Mining Engineering, Volume 52, Number 5, April 2000)).

The rulemaking records of both rules closed on July 26, 1999, nine months after the date the proposed rule on metal and nonmetal mines was published for public notice. The post-hearing comments, like the hearings, reflected extensive participation in this effort by the full range of interests in the mining community and covered a full range of ideas and alternatives.

On June 30, 2000, the rulemaking record was reopened for 30 days in order to obtain public comment on certain additional documents which the agency determined should be placed in the rulemaking record. Those documents were the verification studies concerning NIOSH Method 5040 mentioned in section 3 of this Part. In addition, the notice provided an opportunity for comment on additional documents being placed in the rulemaking record for the related rulemaking for underground coal mines (paper filter verification investigation and recent hot gas filter test results from VERT), and an opportunity to comment on some additional documents on risk being placed in both records. In this regard, the notice reassured the mining community that any comments filed on risk in either rulemaking proceeding would be placed in both records, since the two rulemakings utilize the same risk assessment.

Part III. Risk Assessment

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Introduction

MSHA has reviewed the scientific literature to evaluate the potential health effects of occupational dpm exposures at levels encountered in the mining industry. This part of the preamble presents MSHA's review of the currently available information and MSHA's assessment of health risks associated with those exposures. All material submitted during the public comment periods was considered before MSHA drew its final conclusions.

The risk assessment begins, in Section III.1, with a discussion of dpm exposure levels observed by MSHA in the mining industry. This is followed by a review, in Section III.2, of information available to MSHA on health effects that have been studied in association with dpm exposure. Finally, in Section III.3 entitled ''Characterization of Risk,'' the Agency considers three questions that must be addressed for rulemaking under the Mine Act and relates the available information about risks of dpm exposure at current levels to the regulatory requirements.

A risk assessment must be technical enough to present the evidence and describe the main controversies surrounding it. At the same time, an overly technical presentation could cause stakeholders to lose sight of the main points. MSHA is guided by the first principle the National Research Council established for risk characterization, that the approach be:

> [a] decision driven activity, directed toward informing choices and solving problems * * * Oversimplifying the science or skewing the results through selectivity can lead to the inappropriate use of scientific information in risk management decisions, but providing full information, if it does not address key concerns of the intended audience, can undermine that audience's trust in the risk analysis.

Although the final rule covers only one sector, this portion of the preamble was intended to enable MSHA and other interested parties to assess risks throughout the coal and M/NM mining industries. Accordingly, the risk assessment includes information pertaining to all sectors of the mining industry. All public comments on the exposures of miners and the health effects of dpm exposure—whether submitted specifically for the coal rulemaking or for the metal/nonmetal rulemaking—were incorporated into the record for each rulemaking and have been considered for this assessment.

MSHA had an earlier version of this risk assessment independently peer reviewed. The risk assessment as proposed incorporated revisions made in accordance with the reviewers' recommendations, and the final version presented here contains clarifications and other responses to public comments. With regard to the risk assessment as published in the proposed preamble, the reviewers stated that:

> * * * principles for identifying evidence and characterizing risk are thoughtfully set out. The scope of the document is carefully described, addressing potential concerns about the scope of coverage. Reference citations are adequate and up to date. The document is written in a balanced fashion, addressing uncertainties and asking for additional information and comments as appropriate. (Samet and Burke, Nov. 1997).

Some commenters generally agreed with this opinion. Dr. James Weeks, representing the UMWA, found the proposed risk assessment to be ''balanced, thorough, and systematic.'' Dr. Paul Schulte, representing NIOSH, stated that ''MSHA has prepared a thorough review of the health effects associated with exposure to high concentrations of dpm, and NIOSH concurs with the published [proposed] characterization of risks associated with these exposures.'' Dr. Michael Silverstein, representing the Washington State Dept. of Labor and Industries, found MSHA's ''regulatory logic * * * thoroughly persuasive.'' He commented that ''the best available scientific evidence shows that diesel particulate exposure is associated with serious material impairment of health * * * the evidence * * * is particularly strong and certainly provides a sufficient basis for regulatory action.''

Many commenters, however, vigorously criticized various aspects of the proposed assessment and some of the scientific studies on which it was based. MSHA's final assessment, published here, was modified to respond to all of these criticisms. Also, in response to commenters' suggestions, this assessment incorporates some research studies and literature reviews not covered or inadequately discussed in the previous version.

Some commenters expressed the opinion that the proposed risk assessment should have been peer-reviewed by a group representing government, labor, industry, and independent scientists. Since the rulemaking process included a pre-hearing comment period, eight public hearings (four for coal and four for M/NM), and two post-hearing comment periods, these constituencies had ample opportunity to review and comment upon MSHA's proposed risk assessment. The length of the comment period for the Coal Dpm proposal was 15 months. The length of the comment period for the Metal/Nonmetal Dpm proposal was nine months.

1. Exposures of U.S. Miners

Information about U.S. miner exposures comes from published studies and from additional mine investigations conducted by MSHA since 1993.[1] Previously published studies of exposures to dpm among U.S. miners are: Watts (1989, 1992), Cantrell (1992, 1993), Haney (1992), and Tomb and Haney (1995). MSHA has also conducted investigations subsequent to the period covered in Tomb and Haney (1995), and the previously unpublished data through mid-1998 are included here. Both the published and unpublished studies were placed in the record with the proposal, giving MSHA's stakeholders the opportunity to analyze and comment on all of the exposure data considered.

MSHA's field studies involved measuring dpm concentrations at a total of 50 mines: 27 underground metal and nonmetal (M/NM) mines, 12 underground coal mines, and 11 surface mining operations (both coal and M/NM). At all surface mines and all underground coal mines, dpm measurements were made using the size-selective method, based on gravimetric determination of the amount of submicrometer dust collected with an impactor. With few exceptions, dpm measurements at underground M/NM mines were made using the Respirable Combustible Dust (RCD) method (with no impactor). At two of the underground M/NM mines, measurements were made using the total carbon (TC) method, and at one, RCD measurements were made in one year and TC measurements in another. Measurements at the two remaining underground M/NM mines were made using the size-selective method, as in

[1] MSHA has only limited information about miner exposures in other countries. Based on 223 personal and area samples, average exposures at 21 Canadian noncoal mines were reported to range from 170 to 1300 $\mu g/m^3$ (respirable combustible dust), with maximum measurements ranging from 1020 to 3100 $\mu g/m^3$ (Gangel and Dainty, 1993). Among 622 full shift measurements collected since 1989 in German underground noncoal mines, 91 (15%) exceeded 400 $\mu g/m^3$ (total carbon) (Dahmann et al., 1996). As explained elsewhere in this preamble, 400 $\mu g/m^3$ (total carbon) corresponds to approximately 500 $\mu g/m^3$ dpm.

coal and surface mines.[2] Weighing errors inherent in the gravimetric analysis required for both size-selective and RCD methods become statistically insignificant at the relatively high dpm concentrations observed.

According to MSHA's experience, the dpm samples reflect exposures typical of mines known to use diesel equipment for face haulage in the U.S. However, they do not constitute a random sample of mines, and care was taken in the proposed risk assessment not to characterize results as necessarily representing conditions in all mines. Several commenters objected to MSHA's use of these exposure measurements in making comparisons to exposures reported in other industries and, for M/NM, in estimating the proposed rule's impact. These objections are addressed in Sections III.1.d and III.3.b.ii(3)(c) below. Comments related to the measurement methods used in underground coal and M/NM mines are addressed, respectively, in Sections III.1.b and III.1.c.

Each underground study typically included personal dpm exposure measurements for approximately five production workers. Also, area samples were collected in return airways of underground mines to determine diesel particulate emission rates.[3] Operational information such as the amount and type of equipment, airflow rates, fuel, and maintenance was also recorded. Mines were selected to obtain a wide range of diesel equipment usage and mining methods. Mines with greater than 175 horsepower and less than 175 horsepower production equipment were sampled. Single and multiple level mines were sampled. Mine level heights ranged from eight to one-hundred feet. In general, MSHA's studies focused on face production areas of mines, where the highest concentrations of dpm could be expected; but, since some miners do not spend their time in face areas, samples were collected in other areas as well, to get a more complete picture of miner exposure. Because of potential interferences from tobacco smoke in underground M/NM mines, samples were not collected on or near smokers.

Table III–1 summarizes key results from MSHA's studies. The higher concentrations in underground mines were typically found in the haulageways and face areas where numerous pieces of equipment were operating, or where airflow was low relative to the amount of equipment operating. In production areas and haulageways of underground mines where diesel powered equipment was used, the mean dpm concentration observed was 644 μg/m^3 for coal and 808 μg/m^3 for M/NM. In travelways of underground mines where diesel powered equipment was used, the mean dpm concentration (based on 112 area samples not included in Table III–1) was 517 μg/m^3 for M/NM and 103 μg/m^3 for coal. In surface mines, the higher concentrations were generally associated with truck drivers and front-end loader operators. The mean dpm concentration observed was less than 200 μg/m^3 at all eleven of the surface mines in which measurements were made. More information about the dpm concentrations observed in each sector is presented in the material that follows.

TABLE III–1.—FULL-SHIFT DIESEL PARTICULATE MATTER CONCENTRATIONS OBSERVED IN PRODUCTION AREAS AND HAULAGEWAYS OF 50 DIESELIZED U.S. MINES

Mine type	Number of mines	Number of samples	Mean exposure (μg/m^3)	Standard error of mean (μg/m^3)	Exposure range (μg/m^3)
Surface	11	45	88	11	9–380
Underground coal	12	226	644	41	0–3,650
Underground metal and nonmetal	27	355	808	39	10–5,570

Note: Intake and return area samples are excluded.

a. Underground Coal Mines

Approximately 145 out of the 910 existing underground coal mines currently utilize diesel powered equipment. Of these 145 mines, 32 mines currently use diesel equipment for face coal haulage. The remaining mines use diesel equipment for transportation, materials handling and other support operations. MSHA focused its efforts in measuring dpm concentrations in coal mines on mines that use diesel powered equipment for face coal haulage. Twelve mines using diesel-powered face haulage were sampled. Mines with diesel powered face haulage were selected because the face is an area with a high concentration of vehicles operating at a heavy duty cycle at the furthest end of the mine's ventilation system.

Diesel particulate levels in underground mines depend on: (1) The amount, size, and workload of diesel equipment; (2) the rate of ventilation; and, (3) the effectiveness of whatever diesel particulate control technology may be in place. In the dieselized mines studied by MSHA, the sections used either two or three diesel coal haulage vehicles. In eastern mines, the haulage vehicles were equipped with a nominal 100 horsepower engine. In western mines, the haulage vehicles were equipped with a nominal 150 horsepower engine. Ventilation rates ranged from the approval plate requirement, based on the 100–75–50 percent rule (Holtz, 1960), to ten times the approval plate requirement. In most cases, the section airflow was approximately twice the approval plate requirement. Other control technology included aftertreatment filters and fuel. Two types of aftertreatment filters were used. These filters included a disposable diesel emission filter (DDEF) and a Wire Mesh Filter (WMF). The DDEF is a commercially available product; the WMF was developed by and only used at one mine. Both low sulfur and high sulfur fuels were used.

Figure III–1 displays the range of exposure measurements obtained by MSHA in the field studies it conducted in underground coal mines. A study normally consisted of collecting samples on the continuous miner operator and coal haulage vehicle

[2] The various methods of measuring dpm are explained in section 3 of Part II of the preamble to the proposed rule. This explanation, along with additional information on these methods, is also provided in section 3 of Part II of the preamble to the final M/NM rule.

[3] Since area samples in return airways do not necessarily represent locations where miners normally work or travel, they were excluded from the present analysis. A number of area samples were included, however, as described in Sections III.1.b and III.1.c. The included area samples were all taken in production areas and haulageways.

operators for two to three shifts, along with area samples in the haulageways. A total of 142 personal samples and 84 area samples were collected, excluding any area samples taken in intake or return airways.

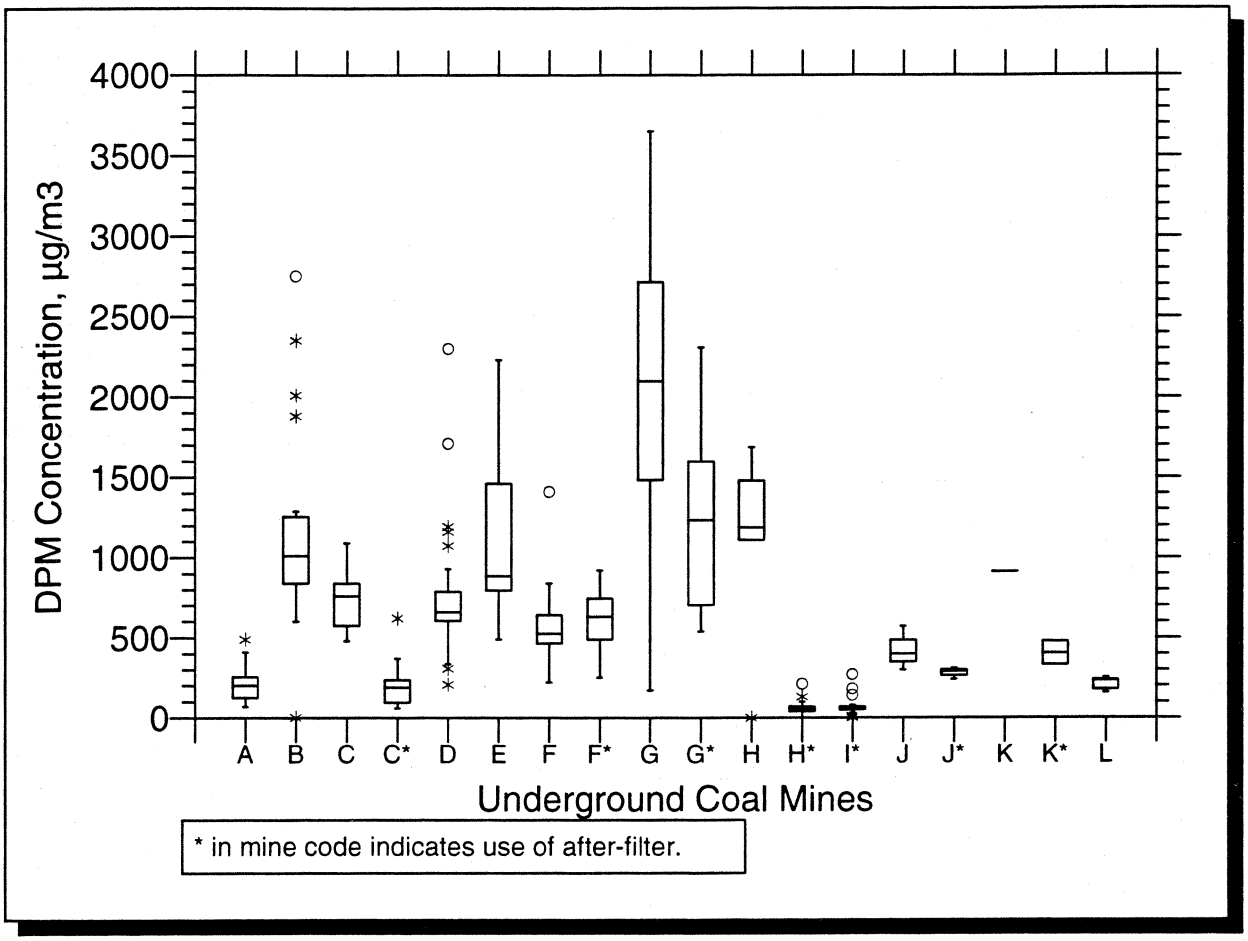

Figure 1 Box plots (Tukey, 1977) for dpm concentrations observed at 12 underground coal mines. Top and bottom of each box represent upper and lower quartiles, respectively. "Belt" inside box represents median. Vertical lines span nearly all measurements. Isolated points (either ✳ or ○) are outliers, representing unusually high or low measurements compared to other observations at the same mine. All dpm measurements were made using the size-selective method, based on gravimetric determination of the amount of submicrometer dust collected with an impactor.

As stated in the proposed risk assessment, no statistically significant difference was observed in mean dpm concentration between the personal and area samples.[4] A total of 19 individual measurements exceeded 1500 µg/m³, still excluding intake and return area samples. Although the three highest of these were from area samples, nine of the 19 measurements exceeding 1500 µg/m³ were from personal samples.

In six mines, measurements were taken both with and without use of disposable after-treatment filters, so that a total of eighteen studies, carried out in twelve mines, are displayed. Without use of after-treatment filters, average observed dpm concentrations exceeded 500 µg/m³ in eight of the twelve mines and exceeded 1000 µg/m³ in four.[5] At five of the twelve mines, all dpm measurements were 300 µg/m³ or greater in the absence of after-treatment filters.

The highest dpm concentrations observed at coal mines were collected at Mine "G." Eight of these samples were collected during employment of WMFs, and eight were collected while filters were not being employed. Without filters, the mean dpm concentration observed at Mine "G" was 2052 µg/m³ (median = 2100 µg/m³). With employment of WMFs, the mean

[4] One commenter (IMC Global) noted that MSHA had provided no data verifying this statement. For the 142 personal samples, the mean dpm concentration measurement was 608 µg/m³, with a standard error of 42.5 µg/m³. For the 84 area samples, the mean was 705 µg/m³, with a standard error of 82.1 µg/m³. The significance level (p-value) of a t-test comparing these means is 0.29 using a separate-variance test or 0.25 using a pooled-variance test. Therefore, a difference in population means cannot be inferred at any confidence level greater than 75%.

Here, and in other sections of this risk assessment, MSHA has employed standard statistical methods described in textbooks on elementary statistical inference.

[5] In coal mine E, the average as expressed by the mean exceeded 1000 µg/m³, but the median did not.

dropped to 1241 μg/m³ (median = 1235 μg/m³).

Filters were employed during three of the four studies showing median dpm concentration at or below 200 μg/m³. After adjusting for outby sources of dpm, exposures were found to be reduced by up to 95 percent in mines using the DDEF and by approximately 50 percent in the mine using the WMF.

The higher dpm concentrations observed at the mine using the WMF (Mine ''G*'') are attributable partly to the lower section airflow. The only study without filters showing a median concentration at or below 200 μg/m³ was conducted in a mine (Mine ''A'') which had section airflow approximately ten times the nameplate requirement. The section airflow at the mine using the WMF was approximately the nameplate requirement.

Some commenters [*e.g.,* WV Coal Assoc and Energy West] objected to MSHA's presentation of underground coal mine exposures based on measurements made using the size-selective method (gravimetric determination of the amount of submicrometer dust collected with an impactor). These commenters argued that the data were ''* * * collected with emissions monitoring devices discredited by MSHA itself in the preamble * * *'' and that these measurements do not reliably ''* * * distinguish it [dpm] from other particles in coal mine dust, at the critical upper end range of submicron particles.''

MSHA did not ''discredit'' use of the size-selective method for all purposes. As discussed elsewhere in this preamble, the size-selective method of measuring dpm was designed by the former BOM specifically for use in coal mines, and the size distribution of coal mine dust was taken into account in its development. Despite the recognized interference from a small fraction of coal mine dust particles, MSHA considers gravimetric size-selective measurements to be reasonably accurate in measuring dpm concentrations greater than 200 μg/m³, based on a full-shift sample, when coal mine dust concentrations are not excessive (i.e., not greater than 2.0 mg/m³). Interference from submicrometer coal mine dust is counter-balanced, to some extent, by the fraction of larger size, uncaptured dpm. Coal mine dust concentrations were not excessive when MSHA collected its size-selective samples. Therefore, even if as much as 10 percent of the coal mine dust were submicrometer, this fraction would not have contributed significantly to the high concentrations observed at the sampled mines.

At lower concentrations, or shorter sampling times, random variability in the gravimetric determination of weight gain becomes significant, compared to the weight of dust accumulated on the filter. For this reason, MSHA has rejected the use of the gravimetric size-selective method for enforcement purposes.[6] This does not mean, however, that MSHA has ''discredited'' this method for other purposes, including detection of very high dpm concentrations at coal mines (*i.e.*, greater than 500 μg/m³) and estimation of average dpm concentrations, based on multiple samples, when coal mine dust concentrations are not excessive. On the contrary, MSHA regards the gravimetric size-selective method as a useful tool for detecting and monitoring very high dpm concentrations and for estimating average exposures.

b. Underground Metal and Nonmetal Mines

Currently there are approximately 265 underground M/NM mines in the United States. Nearly all of these mines utilize diesel powered equipment, and 27 of those doing so were sampled by MSHA for dpm.[7] The M/NM studies typically included measurements of dpm exposure for dieselized production equipment operators (such as truck drivers, roof bolters, haulage vehicles) on two to three shifts. A number of area samples were also collected. None of the M/NM mines studied were using diesel particulate afterfilters.

Figure III–2 displays the range of dpm concentrations measured by MSHA in the 27 underground M/NM mines studied. A total of 275 personal samples and 80 area samples were collected, excluding intake and return area samples. Personal exposures observed ranged from less than 100 μg/m³ to more than 3500 μg/m³. Exposure measurements based on area samples ranged from less than 100 μg/m³ to more than 3000 μg/m³. With the exception of Mine ''V'', personal exposures were for face workers. Mine ''V'' did not use dieselized face equipment.

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[6] MSHA has concluded that random weighing variability would make it impractical to use the size-selective method to enforce compliance with any dpm concentration limit less than about 300 μg/m³. MSHA believes that, at such levels, single-sample noncompliance determinations based on the size-selective method could not be made at a sufficiently high confidence level.

[7] The proposal discussed data from 25 underground M/NM mines. Studies at two additional mines, carried out too late to be included in the proposal, were placed into the public record along with the earlier studies. During the proceedings, MSHA provided copies of all of these studies to stakeholders requesting them.

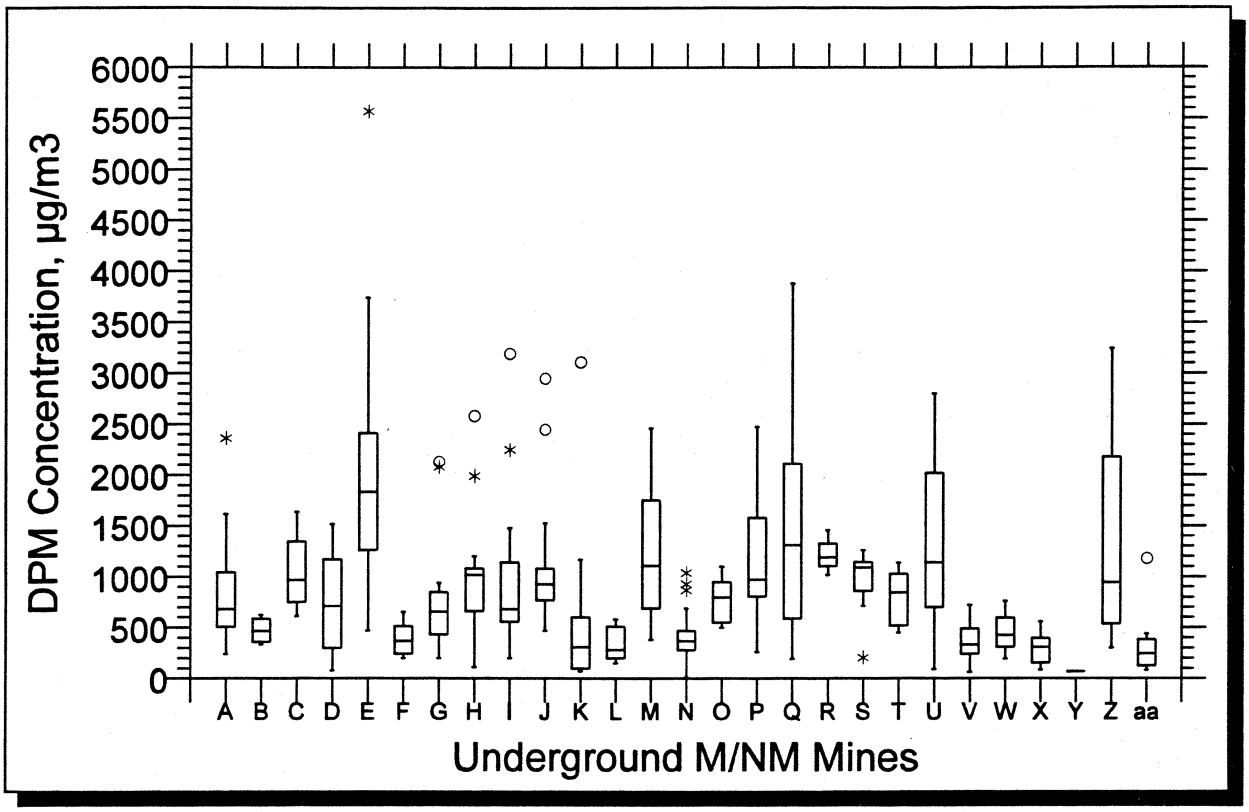

Figure 2 Box plots (Tukey, 1977) for dpm concentrations observed at 27 underground metal and nonmetal mines. Top and bottom of each box represent upper and lower quartiles, respectively. "Belt" inside box represents median. Vertical lines span nearly all measurements. Isolated points (either ✳ or ○) are outliers, representing unusually high or low measurements compared to other observations at same mine. Measurements at Mine "T" and on one visit to mine "D" were made using the size-selective method, based on gravimetric determinationof the amount of submicrometer dust collected with an impactor. Measurements on another visit to mine "D" and at Mines "Z" and "aa" were made using TC method. All other measurements were made using RCD method. Because of potential interferences from cigarette smoke, samples were not collected on or near smokers.

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As stated in the proposed risk assessment, no statistically significant difference was observed in mean dpm concentration between the personal and area samples.[8] A total of 45 individual measurements exceeded 1500 μg/m³, still excluding intake and return area samples. The three highest of these, all exceeding 3500 μg/m³, were from personal samples. Of the 45 measurements exceeding 1500 μg/m³, 30 were from personal samples and 15 were from area samples.

Average observed dpm concentrations exceeded 500 μg/m³ in 18 of the 27 underground M/NM mines and exceeded 1000 μg/m³ in 12.[9] At eight of the 27 mines, all dpm measurements exceeded 300 μg/m³. The highest dpm concentrations observed at M/NM mines were collected at Mine ''E''. Based on 16 samples, the mean dpm concentration observed at Mine ''E'' was 2008 μg/m³ (median = 1835 μg/m³). Twenty-five percent of the dpm measurements at this mine exceeded 2400 μg/m³. All four of these were based on personal samples.

As with underground coal mines, dpm levels in underground M/NM mines are related to the amount and size of equipment, to the ventilation rate, and to the effectiveness of the diesel particulate control technology employed. In the dieselized M/NM mines studied by MSHA, front-end-loaders were used either to load ore onto trucks or to haul and load ore onto belts. Additional pieces of diesel powered support equipment, such as bolters and mantrips, were also used at the mines. The typical piece of production equipment was rated at 150 to 350 horsepower. Ventilation rates in the M/NM mines studied mostly ranged from 100 to 200 cfm per horsepower of equipment. In only a few of the mines inventoried did ventilation exceed 200 cfm/hp. For single-level mines, working areas were ventilated in series (*i.e.,* the exhaust air from one area became the intake for the next working area). For multi-level mines, each level typically had a separate fresh air supply. One or two working areas could be on a level. Control technology used to reduce diesel particulate emissions in mines inventoried included oxidation catalytic converters and engine maintenance programs. Both low sulfur and high sulfur fuel were used; some mines used aviation grade low sulfur fuel.

Some commenters argued that, because of the limited number of underground M/NM mines sampled by MSHA, ''* * * results of MSHA's admittedly non-random sample cannot be extrapolated to other mines.'' [MARG] More specifically, IMC Global claimed that since only 25 [now 27] of about 260 underground M/NM mines were sampled,[10] then ''if the * * * measurements are correct, this information shows at best potential exposure problems to diesel particulate in only 10% of the miners working in the metal-nonmetal mining sector and then only for certain unlisted commodities.''[11] IMC Global went on to suggest that MSHA should ''perform sufficient additional exposure monitoring * * * to show that the diesel particulate exposures are representative of the entire industry before promulgating regulations that will be applicable to the entire industry.''

As mentioned earlier, MSHA acknowledges that the mines for which dpm measurements are available do not comprise a statistically random sample of all underground M/NM mines. MSHA also acknowledges that the results obtained for these mines cannot be extrapolated in a statistically rigorous way to the entire population of underground M/NM mines. According to MSHA's experience, however, the selected mines (and sampling locations within those mines) represent typical diesel equipment use condition at underground M/NM. MSHA believes that results at these mines, as depicted in Figure III–2, in fact fairly reflect the broad range of diesel equipment used by the industry, regardless of type of M/NM mine. Based on its extensive experience with underground mines, MSHA believes that this body of data better represents those diverse diesel equipment use conditions, with respect to dpm exposures, than any other body of data currently available.

MSHA strongly disagrees with IMC Global's contention that, ''* * * this information shows at best potential exposure problems to diesel particulate in only 10% of the miners working in the metal-nonmetal mining sector.'' IMC Global apparently drew this conclusion from the fact that MSHA sampled approximately ten percent of all underground M/NM mines. This line of argument, however, depends on an unwarranted and highly unrealistic assumption: namely, that all of the underground M/NM mines not included in the sampled group of 25 experience essentially no ''potential [dpm] exposure problems.'' MSHA certainly did not go out and, by chance or design, pick for sampling just exactly those mines experiencing the highest dpm concentrations. IMC Global's argument fails to recognize that the sampled mines could be fairly representative without being randomly chosen.

MSHA also disagrees with the premise that 27 [or 25 as in the proposal] is an inherently insufficient number of mines to sample for the purpose of identifying an industry-wide dpm exposure problem that would justify regulation. The between-mine standard deviation of the 27 mean concentrations observed within mines was 450 μg/m³. Therefore, the standard error of the estimated grand mean, based on the variability observed between mines, was $450/\sqrt{27} = 87$ μg/m³.[12] MSHA considers this degree of uncertainty to be acceptable, given that the overall mean concentration observed exceeded 800 μg/m³.

Several commenters questioned MSHA's use of the RCD and size-selective methods for measuring dpm exposures at underground M/NM mines. IMC Global indicated that MSHA's RCD measurements might systematically inflate the dpm concentrations presented in this section, because ''* * * estimates for the non-diesel particulate component of RCD actually vary between 10% to 50%, *averaging 33%.*''

MSHA considers the size-selective, gravimetric method capable of providing reasonably accurate

[8] One commenter (IMC Global) noted that MSHA had provided no data verifying this statement. For the 275 personal samples, the mean dpm concentration measurement was 770 μg/m³, with a standard error of 42.8 μg/m³. For the 80 area samples, the mean was 939 μg/m³, with a standard error of 86.6 μg/m³. The significance level (p-value) of a t-test comparing these means is 0.08 using a separate-variance test or 0.07 using a pooled-variance test. Therefore, a difference in population means cannot be inferred at a 95% confidence level.

[9] At M/NM mines C, I, J, P, and Z the average as expressed by the mean exceeded 1000 μg/m³ but the median did not. At M/NM mines H and S, the median exceeded 1000 μg/m³ but the mean did not. At M/NM mine K, the mean exceeded 500 μg/m³, but the median did not.

[10] Three underground M/NM mine surveys, carried out too late to be included in the discussion, were placed into the public record and provided to interested stakeholders. These surveys contained data from two additional underground M/NM mines (''Z'' and ''aa'') and additional data for a mine (''d'') that had previously been surveyed. The risk assessment has now been updated to include these data, representing a total of 27 underground M/NM mines.

[11] A breakdown by commodity is given at the end of this subsection.

[12] This quantity, 87 μg/m³, differs from the standard error of the mean of individual measurements for underground M/NM mines, presented in Table III–1. The tabled value is based on 355 measurements whose standard deviation is 727μg/m³. Therefore, the standard error of the mean of all individual measurements is $727/\sqrt{355} = 39$ μg/m³, as shown in the table. Similarly, the mean of all individual measurements (listed in Table III–1 as 808 μg/m³) differs from the grand mean of individual mean concentrations observed within mines, which is 838 μg/m³.

measurements when the dpm concentration is greater than 200 μg/m³, interferences are adequately limited, and the measurement is based on a full-shift sample. Relatively few M/NM measurements were made using this method, and none at the mines showing the highest dpm concentrations. No evidence was presented that the size distribution of coal mine dust (for which the impactor was specifically developed) differs from that of other mineral dusts in a way that significantly alters the impactor's performance. Similarly, MSHA considers the RCD method, when properly applied, to be capable of providing reasonably accurate dpm measurements at concentrations greater than 200 μg/m³. As with the size selective method, however, random weighing errors can significantly reduce the precision of even full-shift RCD measurements at lower dpm concentrations. For this reason, in order to maintain a sufficiently high confidence level for its noncompliance determinations, MSHA will not use the RCD method for enforcement purposes. This does not mean, however, that MSHA has ''discredited'' the RCD measurements for all other purposes, including detection of very high dpm concentrations (i.e., greater than 300 μg/m³) and estimation of average concentrations based on multiple samples. On the contrary, MSHA considers the RCD method to be a useful tool for detecting and monitoring very high dpm concentrations in appropriate environments and for estimating average exposures when those exposures are excessive.

MSHA did not employ an impactor in its RCD measurements, and it is true that some of these measurements may have been subject to interference from lubrication oil mists. However, MSHA believes that the high estimates sometimes made of the non-dpm component of RCD (cited by IMC Global) do not apply to the RCD measurements depicted in Figure III–2. MSHA has three reasons for believing these RCD measurements consisted almost entirely of dpm:

(1) MSHA took special care to sample only environments where interferences would not be significant. No samples were taken near pneumatic drills or smoking miners.

(2) There was no interference from carbonates. The RCD analysis was performed at 500° C, and carbonates are not released below 1000° C. (Gangel and Dainty, 1993)

(3) Although high sulphur fuel was used in some mines, thereby adding sulfates to the RCD measurement, these sulfates are considered part of the dpm, as explained in section 2 of Part II of this preamble. Sulfates should not be regarded as an interference in RCD measurements of dpm.

Commenters presented no evidence that there were substantial interferences in MSHA's RCD measurements, and, as stated above, MSHA was careful to avoid them. Therefore, MSHA considers it reasonable, in the context of this risk assessment, to assume that all of the RCD was in fact dpm. Moreover, in the majority of underground M/NM mines sampled, even if the RCD measurements were reduced by ⅓, the mine's average would still be excessive: it would still exceed the maximum exposure level reported for non-mining occupations presented in section III.1.d.

The breakdown, as suggested by IMC Global, of sampled underground M/NM mines by commodity is as follows:

Commodity	Number of mines
Copper	2
Gold	1
Lead/Zinc	6
Limestone	6
Potash	2
Salt	6
Trona (soda ash)	2
Other Nonmetal	2
Total	27

c. Surface Mines

Currently, there are approximately 12,620 surface mining operations in the United States. The total consists of approximately 1,550 coal mines and 11,070 M/NM mines. Virtually all of these mines utilize diesel powered equipment.

MSHA conducted dpm studies at eleven surface mining operations: eight coal mines and three M/NM mines. MSHA deliberately directed its surface sampling efforts toward occupations likely to experience high dpm concentrations. To help select such occupations, MSHA first made a visual examination (based on blackness of the filter) of surface mine respirable dust samples collected during a November 1994 study of surface coal mines. This preliminary screening of samples indicated that relatively high surface mine dpm concentrations are typically associated with front-end-loader operators and haulage-truck operators; accordingly, sampling focused on these operations. A total of 45 samples was collected.

Figure III–3 displays the range of dpm concentrations measured at the eleven surface mines. The average dpm concentration observed was less than 200 μg/m³ at all mines sampled. The maximum dpm concentration observed was less than or equal to 200 μg/m³ in 8 of the 11 mines (73%). The surface mine studies suggest that even when sampling is performed at the areas of surface mines believed most likely to have high exposures, dpm concentrations are generally likely to be less than 200 μg/m³.

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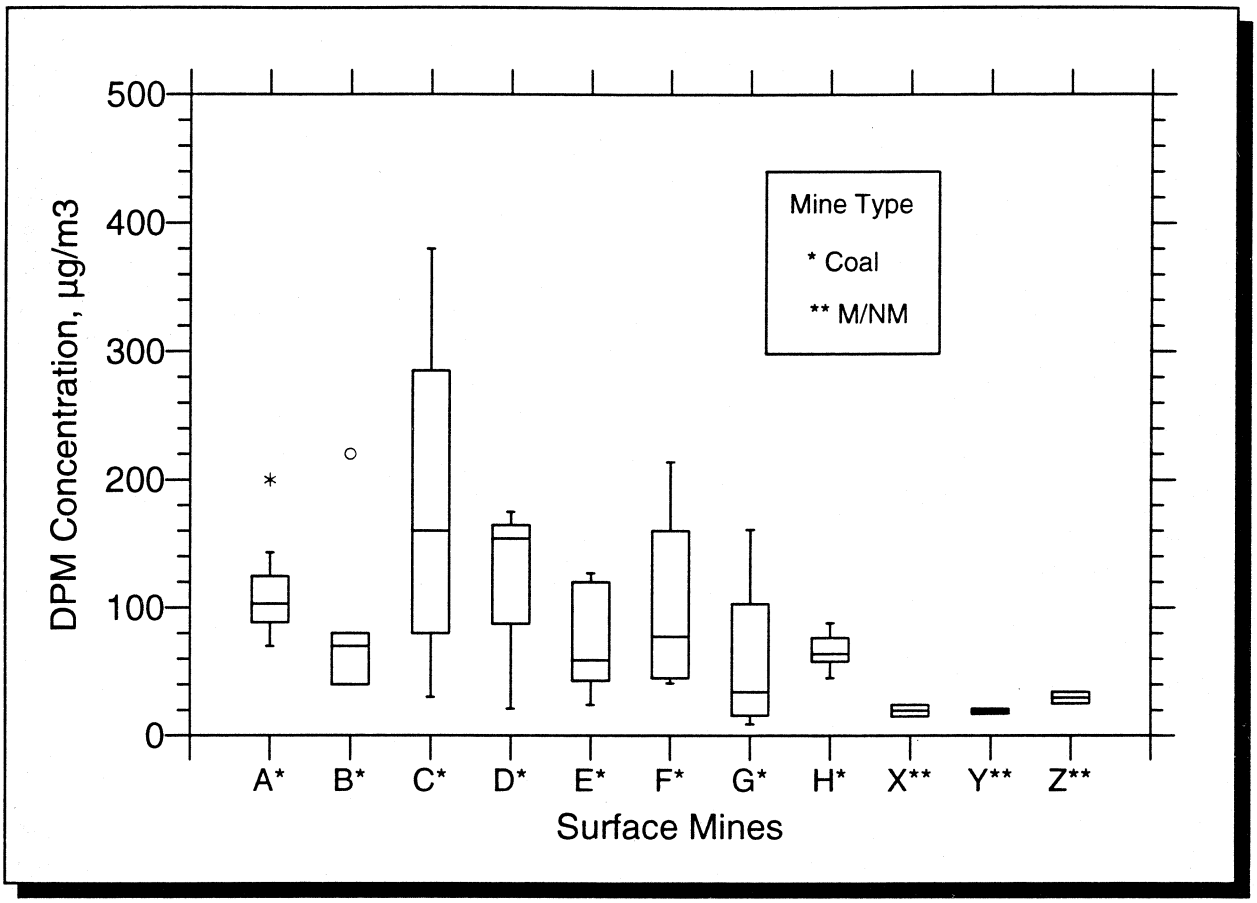

Figure 3 Box plots (Tukey, 1977) for dpm concentrations observed at 11 surface mines. Top and bottom of each box represent upper and lower quartiles, respectively. "Belt" inside box represents median. Vertical lines span nearly all measurements. Isolated points (either ✳ or ○) are outliers, representing unusually high or low measurements compared to other observations at the same mine. All dpm measurements were made using the size-selective method, based on gravimetric determination of the amount of submicrometer dust collected with an impactor. Because of potential interferences from cigarette smoke, samples were not collected on smokeres who worked inside enclosures.

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d. Miner Exposures Compared to Exposures of Other Groups

Occupational exposure to diesel particulate primarily originates from industrial operations employing equipment powered with diesel engines. Diesel engines are used to power ships, locomotives, heavy duty trucks, heavy machinery, as well as a small number of light-duty passenger cars and trucks. NIOSH has estimated that approximately 1.35 million workers are occupationally exposed to the combustion products of diesel fuel in approximately 80,000 workplaces in the United States. (NIOSH 1988) Workers who are likely to be exposed to diesel emissions include: mine workers; bridge and tunnel workers; railroad workers; loading dock workers; truck drivers; fork-lift drivers; farm workers; and, auto, truck, and bus maintenance garage workers (NIOSH, 1988). Besides miners, groups for which occupational exposures have been reported and health effects have been studied include loading dock workers, truck drivers, and railroad workers.

As estimated by the reported geometric mean,[13] the median site-specific occupational exposures for loading dock workers operating or otherwise exposed to unfiltered diesel fork lift trucks ranged from 23 to 55 μg/m³, as measured by submicrometer elemental carbon (EC) (NIOSH, 1990). Reported geometric mean concentrations of submicrometer EC ranged from 2.0 to 7.0 μg/m³ for truck drivers and from 4.8 to 28 μg/m³ for truck mechanics, depending on weather conditions (Zaebst et al., 1991).

Because these exposure averages, unlike those for railroad workers and miners, were reported in terms of EC, it is necessary, for purposes of comparison, to convert them to estimates of total dpm. Watts (1995) states that ''elemental carbon generally accounts for about 40% to 60% of diesel particulate mass.'' Therefore, in earlier versions of this risk assessment, a 2.0 conversion factor was assumed for dock workers, truck drivers, and truck mechanics, based on the midpoint of the 40–60% range proposed by Watts.

Some commenters objected to MSHA's use of this conversion factor. IMC Global, for example, asserted that Watts' ''* * * 40 to 60% relationship between elemental carbon and diesel particulate mass * * * applies only to underground coal mines where diesel haulage equipment is used.'' IMC Global, and other commenters, also objected to MSHA's use of a single conversion factor for ''* * * different types of diesel engines under different duty cycles with different fuels and different types of emission control devices (if any) subjected to varying degrees of maintenance.''

MSHA's quotation from Watts (1995) was taken from the ''Summary'' section of his paper. That paper covers a variety of occupational environments, and the summary makes no mention of coal mines. The sentence immediately preceding the quoted passage refers to the ''occupational environment'' in general, and there is no indication that Watts meant to restrict the 40- to 60-percent range to any specific environment. It seems clear that the 40- to 60-percent range refers to average values across a spectrum of occupational environments.

IMC Global mistakenly attributed to MSHA ''the blanket statement'' that the same ratio of elemental carbon to dpm applies ''for all diesel engines in different industries for all patterns of use.'' MSHA made no such statement. On the contrary, MSHA agrees with Watts (and IMC Global) that ''the percentage of elemental carbon in total diesel particulate matter fluctuates'' depending on ''engine type, duty cycle, fuel, lube oil consumption, state of engine maintenance, and the presence or absence of an emission control device.'' (Watts, op cit.) Indeed, MSHA acknowledges that, because of these factors, the percentage on a particular day in a particular environment may frequently fall outside the stated range. But MSHA is not applying a single conversion factor to individual elemental carbon measurements and claiming knowledge of the total dpm corresponding to each separate measurement. Instead, MSHA is applying an average conversion factor to an average of measurements in order to derive an estimate of an average dpm exposure. Averages are always less widely dispersed than individual values.

[13] Median concentrations were not reported. The geometric mean provides a smoothed estimate of the median.

Still, MSHA agrees with IMC Global that better estimates of dpm exposure levels are attainable by applying conversion factors more specifically related to the separate categories within the trucking industry: dock workers, truck drivers, and truck mechanics. Based on a total of 63 field measurements, the mean ratios (in percent) of EC to total carbon (TC) reported for these three categories were 47.3, 36.6, and 34.2, respectively (Zaebst et al., 1991).[14] As explained elsewhere in this preamble, TC amounts to approximately 80 percent, by weight, of total dpm. Therefore, each of these ratios must be multiplied by 0.8 in order to estimate the corresponding percentage of EC in dpm.

It follows that the median mass concentration of dpm can be estimated as 2.64 (i.e., 1/(0.473×0.8)) times the geometric mean EC reported for dock workers, 3.42 times the geometric mean EC for truck drivers, and 3.65 times the geometric mean EC for truck mechanics. Applying the 2.64 conversion factor to the range of geometric mean EC concentrations reported for dock workers (i.e, 23 to 55 μg/m^3) results in an estimated range of 61 to 145 μg/m^3 in median dpm concentrations at various docks. Similarly, the estimated range of median dpm concentrations is calculated to be 6.8 to 24 μg/m^3 for truck drivers and 18 to 102 μg/m^3 for truck mechanics. It should be noted that MSHA is using conversion factors only for those occupational groups whose geometric mean exposures have been reported in terms of EC measurements.

Average exposures of railroad workers to dpm were estimated by Woskie et al. (1988) and Schenker et al. (1990). As measured by total respirable particulate matter other than cigarette smoke, Woskie et al. reported geometric mean concentrations for various occupational categories of exposed railroad workers ranging from 49 to 191 μg/m^3.

For comparison with the exposures reported for these other industries, median dpm exposures measured within sampled mines were calculated directly from the data described in subsections a, b, and c above. The median within each mine is shown as the horizontal ''belt'' plotted for the mine in Figures III–1, III–2, and III–3.

Figure III–4 compares the range of median dpm concentrations observed for mine workers within different mines to a range of dpm exposure levels estimated for urban ambient air and to the ranges of median dpm concentrations estimated for loading dock workers operating or otherwise exposed to diesel fork lift trucks, truck drivers, truck mechanics, and railroad workers. The range for ambient air, 1 to 10 μg/m^3, was obtained from Cass and Gray (1995). For dock workers, truck drivers, truck mechanics, and railroad workers, the estimated ranges of median dpm exposures are, respectively: 61 to 145 μg/m^3, 6.8 to 24 μg/m^3, 18 to 102 μg/m^3 and 49 to 191 μg/m^3. The range of median dpm concentrations observed at different underground coal mines is 55 to 2100 μg/m^3, with filters employed at mines showing the lower concentrations.[15] For underground M/NM mines, the corresponding range is 68 to 1835 μg/m^3, and for surface mines it is 19 to 160 μg/m^3. Since each range plotted is a range of median values or (for ambient air) mean values, the plots do not encompass all of the individual measurements reported.

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[14] MSHA calculated the ratio for truck drivers by taking a weighted average of the ratios reported for ''local drivers'' and ''road drivers.''

[15] One commenter misinterpreted the tops of the ranges plotted in Figure III–4. This commenter apparently mistook the top of the range depicted for underground coal mines as the mean or median dpm exposure concentration measured across all underground coal mines. The top of this range (at 2100 μg/m^3, actually represents the highest median concentration at any of the coal mines sampled. It corresponds to the ''belt'' plotted for Mine ''G'' (with no after-filters) in Figure III–1. The bottom of the same bar, at 55 μg/m^3, corresponds to the ''belt'' plotted for Mine H* (with after-filters) in Figure III–1.

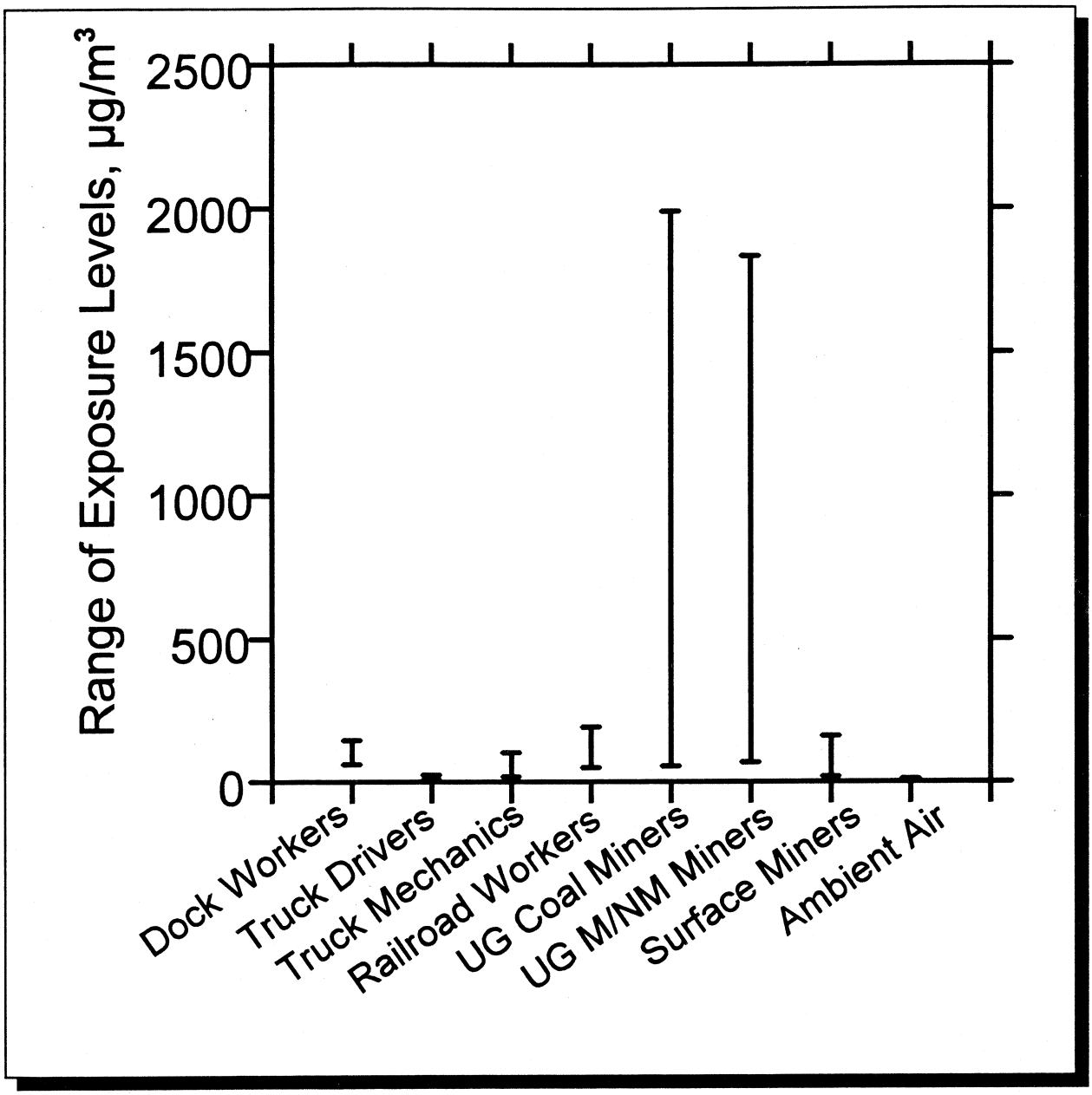

Figure III-4. — Range of median dpm exposure levels observed within various mines for underground and surface miners compared to range of median Dpm exposure levels estimated for other occupations. Range of dpm exposure levels for ambient air is for urban environments only and is based on the monthly mean for different months and locations in Southern California. Range for ambient air is roughly 1 to 10 $\mu g/m^3$.

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As shown in Figure III–4, some miners are exposed to far higher concentrations of dpm than are any other populations for which exposure data have been reported. Indeed, median dpm concentrations observed in some underground mines are up to 200 times as high as mean environmental exposures in the most heavily polluted urban areas,[16] and up to 10 times as high as median exposures estimated for the most heavily exposed workers in other occupational groups.

Several commenters objected to Figure III–4 and, more generally, to MSHA's comparison of dpm exposure levels for miners against the levels reported for other occupations. The objections to MSHA's method of estimating ranges of median dpm exposure for job categories within the trucking industry have already been discussed and addressed above. Other objections to the comparison were based on claims of insufficient accuracy in the RCD and gravimetric size selective measurements MSHA used to measure dpm levels for miners. MSHA considers its use of these methods appropriate for purposes of this comparison and has responded to criticisms of the dpm measurements for miners in Subsections 1.a and 1.b of this risk assessment.[17]

Some commenters objected to MSHA's basing a characterization of dpm exposures to miners on data spanning a ten-year period. These commenters contended that, in at least some M/NM mines, dpm levels had improved substantially during that period. No data were submitted, however, to support the premise that dpm exposures throughout the mining industry have declined to the levels reported for other occupations. As stated in the proposal and emphasized above, MSHA's dpm measurements were not technically designed as a random or statistically representative sample of the industry. They do show, however, that very high exposures have recently occurred in some mines. For example, as shown in Figure III–2, more than 25 percent of MSHA's dpm measurements exceeded 2000 μg/m^3 at underground M/NM mines ''U'' and ''Z''—and these measurements were made in 1996–7. In M/NM mines where exposures are actually commensurate with other industries already, little or nothing would need to be changed to meet the exposure limits.

IMC Global further objected to Figure III–4 on the grounds that ''* * * the assumptions that MSHA used to develop that figure are grossly inaccurate and do not do make sense in the context of a dose-response relationship between lung cancer and dpm exposure.'' IMC Global suggested that the comparison in Figure III–4 be deleted for this reason. MSHA believes that the comparison is informative and that empirical evidence should be used, when it is available, even though the evidence was not generated under ideal, theoretical dose-response model conditions. The issue of whether Figure III–4 is consistent with an exposure-response relationship for dpm is addressed in Subsection 3.a.iii(4) of this risk assessment.

2. Health Effects Associated With DPM Exposures

This section reviews the various health effects (of which MSHA is aware) that may be associated with dpm exposures. The review is divided into three main sections: acute effects, such as diminished pulmonary function and eye irritation; chronic effects, such as lung cancer; and mechanisms of toxicity. Prior to that review, however, the relevance of certain types of information will be considered. This discussion will address the relevance of health effects observed in animals, health effects that are reversible, and health effects associated with fine particulate matter in the ambient air.

Several commenters described medical surveillance studies that NIOSH and/or the former Bureau of Mines had carried out in the late 1970s and early 1980s on underground miners employed in western, dieselized coal mines. These commenters urged MSHA to make these studies available and to consider the results in this rulemaking. Some of these commenters also suggested that these data would provide a useful baseline for pulmonary function and lung diseases among miners exposed to dpm, and recommended that follow-up examinations now be conducted to evaluate the possible effects of chronic dpm exposure.

In response to such comments presented at some of the public hearings, another commenter wrote:

> First of all, MSHA is not a research agency, it is a regulatory agency, so that it would be inappropriate for MSHA to initiate research. MSHA did request that NIOSH conduct a risk assessment on the health effects of diesel exhaust and encouraged NIOSH and is currently collaborating with NIOSH (and NCI) on research of other underground miners exposed to diesel exhaust. And third, research on the possible carcinogenicity of diesel particulate matter was not undertaken on coal miners in the West or anywhere else because of the confounding exposure to crystalline silica, also considered a carcinogen, because too few coal miners have been exposed, and for too short a time to conduct a valid study. It was not arbitrariness or indifference on MSHA's part that it did not initiate research on coal miners; it was not within their mandate and it is inappropriate in any event. [UMWA]

Three reports summarizing and presenting results from these medical surveillance studies related to dpm exposures in coal mines were, in fact, utilized and cited in the proposed risk assessment (Ames et al., 1982; Reger et al., 1982; Ames et al., 1984). Ames et al. (1982) evaluated acute respiratory effects, and their results are considered in Subsection 2.b.ii of this risk assessment. Reger et al. (1982) and Ames et al. (1984) evaluated chronic effects, and their results are considered in Subsection 2.c.i(1).

A fourth report (Glenn et al., 1983) summarized results from the overall research program of which the coal mine studies were a part. This health and environmental research program included not only coal miners, but also workers at potash, trona, salt, and metal mines. All subjects were given chest radiographs and spirometric tests and were questioned about respiratory symptoms, smoking and occupational history. In conjunction with these medical evaluations, industrial hygiene surveys were conducted to characterize the mine environments where diesel equipment was used. Diesel exhaust exposure levels were characterized by area and personal samples of NO_2 (and, in some cases, additional gasses), aldehydes, and both respirable and total dust. For the evaluations of acute effects, exposure measures were based on the shift concentrations to which the examined workers were exposed. For the evaluations of chronic effects, exposures were usually estimated by summing the products of time spent in various locations by each miner by concentrations estimated for the various locations. Results of studies on acute effects in salt mines were reported by Gamble et al. (1978) and are considered

[16] It should be noted, however, that 24-hour environmental exposures for a full lifetime are not directly comparable with workday exposures over an occupational lifetime. If it is assumed that air inhaled during a work shift comprises half the total air inhaled during a 24-hour day, then the amount of air inhaled over the course of a 70-year lifetime is approximately 4.7 times the amount inhaled over a 45-year occupational lifetime with 240 working days per year.

[17] One commenter pointed out that the measurements for miners included both area and personal samples but provided no evidence that this would invalidate the comparison. As pointed out in Subsections 1.a and 1.b, area samples did not dominate the upper end of MSHA's dpm measurements. Furthermore, Figure III–4 presents a comparison of medians rather than means or individual measurements, so inclusion of the area samples has very little impact on the results.

in Subsection 2.b.ii of this risk assessment. Attfield (1979), Attfield et al. (1982), and Gamble et al. (1983) evaluated effects in M/NM mines, and their results are considered in Subsection 2.c.i(1). The general summary provided by Glenn et al. (1983) was among the reports that one commenter (MARG) listed as having received inadequate attention in the proposed risk assessment. In that context, the general results summarized in this report are discussed, under the heading of ''Counter-Evidence,'' in Subsection 2.c.i(2)(a) of this risk assessment.

a. Relevancy Considerations

i. Animal Studies. Since the lungs of different species may react differently to particle inhalation, it is necessary to treat the results of animal studies with some caution. Evidence from animal studies can nevertheless be valuable—both in helping to identify potential human health hazards and in providing a means for studying toxicological mechanisms. Respondents to MSHA's ANPRM who addressed the question of relevancy urged consideration of all animal studies related to the health effects of diesel exhaust.

Unlike humans, laboratory animals are bred to be homogeneous and can be randomly selected for either non-exposure or exposure to varying levels of a potentially toxic agent. This permits setting up experimental and control groups of animals that exhibit relatively little biological variation prior to exposure. The consequences of exposure can then be determined by comparing responses in the experimental and control groups. After a prescribed duration of deliberate exposure, laboratory animals can also be sacrificed, dissected, and examined. This can contribute to an understanding of mechanisms by which inhaled particles may exert their effects on health. For this reason, discussion of the animal evidence is placed in the section entitled ''Mechanisms of Toxicity'' below.

Animal evidence also can help isolate the cause of adverse health effects observed among humans exposed to a variety of potentially hazardous substances. If, for example, the epidemiologic data are unable to distinguish between several possible causes of increased risk of disease in a certain population, then controlled animal studies may provide evidence useful in suggesting the most likely explanation—and provide that information years in advance of definitive evidence from human observations.

Furthermore, results from animal studies may also serve as a check on the credibility of observations from epidemiologic studies of human populations. If a particular health effect is observed in animals under controlled laboratory conditions, this tends to corroborate observations of similar effects in humans.

One commenter objected to MSHA's reference to using animal studies as a ''check'' on epidemiologic studies. This commenter emphasized that animal studies provide far more than just corroborative information and that researchers use epidemiologic and animal studies ''* * * to help understand different aspects of the carcinogenic process.'' [18] MSHA does not dispute the utility of animal studies in helping to provide an understanding of toxicological processes and did not intend to belittle their importance for this purpose. In fact, MSHA places the bulk of its discussion of these studies in a section entitled ''Mechanisms of Toxicity.'' However, MSHA considers the use of animal studies for corroborating epidemiologic associations to be also important—especially with respect to ruling out potential confounding effects and helping to establish causal linkages. Animal studies make possible a degree of experimental design and statistical rigor that is not attainable in human studies.

Other commenters disputed the relevance of at least some animal data to human risk assessment. For example, The West Virginia Coal Association indicated the following comments by Dr. Peter Valberg:

> * * * scientists and scientific advisory groups have treated the rat bioassay for inhaled particles as unrepresentative of human lung-cancer risks. For example, the Presidential/Congressional Commission on Risk Assessment and Risk Management (''CCRARM'') noted that the response of rat lungs to inhaled particulate in general is not likely to be predictive of human cancer risks. More specific to dpm, the Clean Air Scientific Advisory Committee (''CASAC''), a peer-review group for the U.S. EPA, has commented on two drafts (1995 and 1998) of the EPA's Health Assessment Document on Diesel Exhaust. On both occasions, CASAC emphasized that the data from rats are not relevant for human risk assessment. Likewise, the Health Effects Institute also has concluded that rat data should not be used for assessing human lung cancer risk.

Similarly, the NMA commented that the 1998 CASAC review ''makes it crystal clear that the rat studies cited by MSHA should not be relied upon as legitimate indicators of the carcinogenicity of Dpm in humans.'' The Nevada Mining Association, endorsing Dr. Valberg's comments, added:

> * * * to the extent that MSHA wishes to rest its case on rat studies, Dr. Valberg, among others, has impressively demonstrated that these studies are worthless for human comparison because of rats' unique and species-specific susceptibility to inhaled insoluble particles.

However, neither Dr. Valberg nor the Nevada Mining Association provided evidence that rats' susceptibility to inhaled insoluble particles was ''unique'' and that humans, for example, were not also susceptible to lung overload at sufficiently high concentrations of fine particles. Even if (as has apparently been demonstrated) some species (such as hamsters) do not exhibit susceptibility similar to rats, this by no means implies that rats are the only species exhibiting such susceptibility.

These commenters appear at times to be saying that, because studies of lung cancer in rats are (in the commenters' view) irrelevant to humans, MSHA should completely ignore all animal studies related to dpm. To the extent that this was the position advocated, the commenters' line of reasoning neglects several important points:

1. The animal studies under consideration are not restricted to studies of lung cancer responses in rats. They include studies of bioavailability and metabolism as well as studies of immunological and genotoxic responses in a variety of animal species.

2. The context for the determinations cited by Dr. Valberg was risk assessment at ambient levels, rather than the much higher dpm levels to which miners are exposed. The 1995 HEI report to which Dr. Valberg alludes acknowledged a potential mechanism of lung overload in humans at dpm concentrations exceeding 500 $\mu g/m^3$ (HEI, 1995). Since miners may concurrently be exposed to concentrations of mineral dusts significantly exceeding 500 $\mu g/m^3$, evidence related to the consequences of lung overload has special significance for mining environments.

3. The scientific authorities cited by Dr. Valberg and other commenters objected to using existing animal studies for quantitative human risk assessment. MSHA has not proposed doing that. There is an important distinction between extrapolating results from the rat studies to human populations and using them to confirm epidemiologic findings and to identify and explore potential mechanisms of toxicity.

[18] This risk assessment is not limited to cancer effects, but the commenter's point can be generalized.

MSHA by no means ''wishes to rest its case on rat studies,'' and it has no intention of doing so. MSHA does believe, however, that judicious consideration of evidence from animal studies is appropriate. The extent to which MSHA utilizes such evidence to help draw specific conclusions will be clarified below in connection with those conclusions.

ii. *Reversible Health Effects.* Some reported health effects associated with dpm are apparently reversible—*i.e.,* if the worker is moved away from the source for a few days, the symptoms dissipate. A good example is eye irritation.

In response to the ANPRM, questions were raised as to whether so-called ''reversible'' effects can constitute a ''material'' impairment. For example, a predecessor constituent of the National Mining Association (NMA) argued that ''it is totally inappropriate for the agency to set permissible exposure limits based on temporary, reversible sensory irritation'' because such effects cannot be a ''material'' impairment of health or functional capacity within the definition of the Mine Act (American Mining Congress, 87–0–21, Executive Summary, p. 1, and Appendix A).

MSHA does not agree with this categorical view. Although the legislative history of the Mine Act is silent concerning the meaning of the term ''material impairment of health or functional capacity,'' and the issue has not been litigated within the context of the Mine Act, the statutory language about risk in the Mine Act is similar to that under the OSH Act. A similar argument was dispositively resolved in favor of the Occupational Safety and Health Administration (OSHA) by the 11th Circuit Court of Appeals in *AFL–CIO* v. *OSHA,* 965 F.2d 962, 974 (1992).

In that case, OSHA proposed new limits on 428 diverse substances. It grouped these into 18 categories based upon the primary health effects of those substances: *e.g.,* neuropathic effects, sensory irritation, and cancer. (54 FR 2402). Challenges to this rule included the assertion that a ''sensory irritation'' was not a ''material impairment of health or functional capacity'' which could be regulated under the OSH Act. Industry petitioners argued that since irritant effects are transient in nature, they did not constitute a ''material impairment.'' The Court of Appeals decisively rejected this argument.

The court noted OSHA's position that effects such as stinging, itching and burning of the eyes, tearing, wheezing, and other types of sensory irritation can cause severe discomfort and be seriously disabling in some cases. Moreover, there was evidence that workers exposed to these sensory irritants could be distracted as a result of their symptoms, thereby endangering other workers and increasing the risk of accidents. (*Id.* at 974). This evidence included information from NIOSH about the general consequences of sensory irritants on job performance, as well as testimony by commenters on the proposed rule supporting the view that such health effects should be regarded as material health impairments. While acknowledging that ''irritation'' covers a spectrum of effects, some of which can be minor, OSHA had concluded that the health effects associated with exposure to these substances warranted action—to ensure timely medical treatment, reduce the risks from increased absorption, and avoid a decreased resistance to infection (*Id* at 975). Finding OSHA's evaluation adequate, the Court of Appeals rejected petitioners' argument and stated the following:

> We interpret this explanation as indicating that OSHA finds that although minor irritation may not be a material impairment, there is a level at which such irritation becomes so severe that employee health and job performance are seriously threatened, even though those effects may be transitory. We find this explanation adequate. OSHA is not required to state with scientific certainty or precision the exact point at which each type of sensory or physical irritation becomes a material impairment. Moreover, section 6(b)(5) of the Act charges OSHA with addressing all forms of ''material impairment of health or functional capacity,'' and not exclusively ''death or serious physical harm'' or ''grave danger'' from exposure to toxic substances. See 29 U.S.C. 654(a)(1), 655(c). [*Id.* at 974].

In its comments on the proposed rule, the NMA claimed that MSHA had overstated the court's holding. In making this claim, the NMA attributed to MSHA an interpretation of the holding that MSHA did not put forth. In fact, MSHA agrees with the NMA's interpretation as stated in the following paragraph and takes special note of the NMA's acknowledgment that transitory or reversible effects can sometimes be so severe as to seriously threaten miners' health and safety:

> NMA reads the Court's decision to mean (as it stated) that ''minor irritation may not be a material impairment'' * * * but that irritation can reach ''a level at which [it] becomes so severe that employee health and job performance are seriously threatened even though those effects may be transitory.'' * * * AMC in 1992 and NMA today are fully in accord with the view of the 11th Circuit that when health effects, transitory or otherwise, become so ''severe'' as to ''seriously threaten'' a miner's health or job performance, the materiality threshold has been met.

The NMA, then, apparently agrees with MSHA that sensory irritations and respiratory symptoms can be so severe that they cross the material impairment threshold, regardless of whether they are ''reversible.'' Therefore, as MSHA has maintained, such health effects are highly relevant to this risk assessment—especially since impairments of a miner's job performance in an underground mining environment could seriously threaten the safety of both the miner and his or her co-workers. Sensory irritations may also impede miners' ability to escape during emergencies.

The NMA, however, went on to emphasize that ''* * * federal appeals courts have held that 'mild discomfort' or even 'moderate irritation' do not constitute 'significant' or 'material' health effects'':

> In International Union v. Pendergrass, 878 F. 2d 389 (1989), the D.C. Circuit upheld OSHA's formaldehyde standard against a challenge that it did not adequately protect against significant noncarcinogenic health effects, even though OSHA had found that, at the permissible level of exposure, ''20% of workers suffer 'mild discomfort', while 30% more experience 'slight discomfort','' *Id.* at 398. Likewise, in Texas Independent Ginners Ass'n. v. Marshall, 630 F, 2d 398 (1980), the Fifth Circuit Court of Appeals held that minor reversible symptoms do not constitute material impairment unless OSHA shows that those effects might develop into chronic disease. *Id.* at 408–09.

MSHA is fully aware of the distinction that courts have made between mild discomfort or irritation and transitory health effects that can seriously threaten a miner's health and safety. MSHA's position, after reviewing the scientific literature, public testimony, and comments, is that all of the health effects considered in this risk assessment fall into the latter category.

iii. Health Effects Associated with $PM_{2.5}$ in Ambient Air. There have been many studies in recent years designed to determine whether the mix of particulate matter in ambient air is harmful to health. The evidence linking particulates in air pollution to health problems has long been compelling enough to warrant direction from the Congress to limit the concentration of such particulates (see part II, section 5 of this preamble). In recent years, the evidence of harmful effects due to airborne particulates has increased, suggesting that ''fine'' particulates (*i.e.,* particles less than 2.5 μm in diameter) are more strongly associated than ''coarse'' respirable particulates (*i.e.,* particles greater than 2.5 μm but less

than 10 μm in diameter) with the adverse health effects observed (EPA, 1996).

MSHA recognizes that there are two difficulties involved in utilizing the evidence from such studies in assessing risks to miners from occupational dpm exposures. First, although dpm is a fine particulate, ambient air also contains fine particulates other than dpm. Therefore, health effects associated with exposures to fine particulate matter in air pollution studies are not associated specifically with exposures to dpm or any other one kind of fine particulate matter. Second, observations of adverse health effects in segments of the general population do not necessarily apply to the population of miners. Since, due to age and selection factors, the health of miners differs from that of the public as a whole, it is possible that fine particles might not affect miners, as a group, to the same degree as the general population.

Some commenters reiterated these two points, recognized by MSHA in the proposal, without addressing MSHA's stated reasons for including health effects associated with fine particulates in this risk assessment. There are compelling reasons why MSHA considered this body of evidence in this rulemaking.

Since dpm is a type of respirable particle, information about health effects associated with exposures to respirable particles, and especially to fine particulate matter, is certainly relevant, even if difficult to apply directly to dpm exposures. Adverse health effects in the general population have been observed at ambient atmospheric particulate concentrations well below the dpm concentrations studied in occupational settings. The potency of dpm differs from the total fine particulate found in ambient air. This makes it difficult to establish a specific exposure-response relationship for dpm that is based on fine particle results. However, this does not mean that these results should be ignored in a dpm risk assessment. The available evidence of adverse health effects associated with fine particulates is still highly relevant for dpm hazard identification. Furthermore, as shown in Subsection 3.c.ii of this risk assessment, the fine particle research findings can be used to construct a rough exposure-response relationship for dpm, showing significantly increased risks of material impairment among exposed miners. MSHA's estimates are based on the best available epidemiologic evidence and show risks high enough to warrant regulatory action.

Moreover, extensive scientific literature shows that occupational dust exposures contribute to the development of Chronic Obstructive Pulmonary Diseases (COPD), thereby compromising the pulmonary reserve of some miners. Miners experience COPD at a significantly higher rate than the general population (Becklake 1989, 1992; Oxman 1993; NIOSH 1995). In addition, many miners also smoke tobacco. This places affected miners in subpopulations specifically identified as susceptible to the adverse health effects of respirable particle pollution (EPA, 1996). Some commenters (*e.g.,* MARG) repeated MSHA's observation that the population of miners differs from the general population but failed to address MSHA's concern for miners' increased susceptibility due to COPD incidence and/or smoking habits. The Mine Act requires that standards ''* * * most adequately assure on the basis of the best available evidence that *no miner* suffer material impairment of health or functional capacity * * *'' (Section 101(a)(6), emphasis added). This most certainly authorizes MSHA to protect miners who have COPD and/or smoke tobacco.

MARG also submitted the opinion that if ''* * * regulation of fine particulate matter is necessary, it [MSHA] should propose a rule dealing specifically with the issue of concern, rather than a rule that limits total airborne carbon or arbitrarily singles out diesel exhaust * * *.'' MSHA's concern is not with ''total airborne carbon'' but with dpm, which consists mostly of submicrometer airborne carbon. At issue here, however, are the adverse health effects associated with dpm exposure. Dpm is a type of fine particulate, and there is no evidence to suggest that the dpm fraction contributes less than other fine particulates to adverse health effects linked to exposures in ambient air.

For this reason, and because miners may be especially susceptible to fine particle effects, MSHA has concluded, after considering the public comments, that the body of evidence from air pollution studies is highly relevant to this risk assessment. The Agency is, therefore, taking that evidence fully into account.

b. Acute Health Effects

Information pertaining to the acute health effects of dpm includes anecdotal reports of symptoms experienced by exposed miners, studies based on exposures to diesel emissions, and studies based on exposures to particulate matter in the ambient air. These will be discussed in turn. Subsection 2.a.iii of this risk assessment addressed the relevance to dpm of studies based on exposures to particulate matter in the ambient air.

Only the evidence from human studies will be addressed in this section. Data from genotoxicity studies and studies on laboratory animals will be discussed later, in Subsection 2.d on mechanisms of toxicity. Section 3.a and 3.b contain MSHA's interpretation of the evidence relating dpm exposures to acute health hazards.

i. Symptoms Reported by Exposed Miners. Miners working in mines with diesel equipment have long reported adverse effects after exposure to diesel exhaust. For example, at the dpm workshops conducted in 1995, a miner reported headaches and nausea experienced by several operators after short periods of exposure (dpm Workshop; Mt. Vernon, IL, 1995). Another miner reported that smoke from poorly maintained equipment, or from improper fuel use, irritates the eyes, nose, and throat. ''We've had people sick time and time again * * * at times we've had to use oxygen for people to get them to come back around to where they can feel normal again.'' (dpm Workshop; Beckley, WV, 1995). Other miners (dpm Workshops; Beckley, WV, 1995; Salt Lake City, UT, 1995), reported similar symptoms in the various mines where they worked.

At the 1998 public hearings on MSHA's proposed dpm rule for coal mines, one miner, with work experience in a coal mine utilizing diesel haulage equipment at the face, testified that

> * * * unlike many, I have not experienced the headaches, the watering of the eyes, the cold-like symptoms and walking around in this cloud of smoke. Maybe it's because of the maintenance programs. Maybe it's because of complying with ventilation. * * * after 25 years, I have not shown any effects. [SLC, 1998].

Other miners working at dieselized coal mines testified at those hearings that they had personally experienced eye irritation and/or respiratory ailments immediately after exposure to diesel exhaust, and they attributed these ailments to their exposure. For example, one miner attributed a case of pneumonia to a specific episode of unusually high exposure. (Birm., 1998) The safety and training manager of the mining company involved noted that ''there had been a problem recognized in review with that exhaust system on that particular piece of equipment'' and that the pneumonia may have developed due to ''idiosyncracy of his lungs that respond to any type of a respiratory irritant.'' The manager suggested that this incident should not

be generalized to other situations but provided no evidence that the miner's lungs were unusually susceptible to irritation.[19]

Another miner, who had worked at the same underground mine before and after diesel haulage equipment was introduced, indicated that he and his co-workers began experiencing acute symptoms after the diesel equipment was introduced. This miner suggested that these effects were linked to exposure, and referring to a co-worker stated:

> * * * had respiratory problems, after * * * diesel equipment was brought into that mine—he can take off for two weeks vacation, come back—after that two weeks, he felt pretty good, his respiratory problems would straighten up, but at the very instant that he gets back in the face of diesel-powered equipment, it starts up again, his respiratory problems will flare up again, coughing, sore throat, numerous problems in his chest. (Birm., 1998).

Several other underground miners asserted there was a correlation between diesel exposure levels and the frequency and/or intensity of respiratory symptoms, eye irritations, and chest ailments. One miner, for example, stated:

> I've experienced [these symptoms] myself. * * * other miners experience the same kind of distresses * * * Some of the stresses you actually can feel—you don't need a gauge to measure this—your burning eyes, nose, throat, your chest irritation. The more you're exposed to, the higher this goes. This includes headaches and nausea and some lasting congestion, depending on how long you've been exposed per shift or per week.
>
> The men I represent have experienced more cold-like symptoms, especially over the past, I would say, eight to ten years, when diesel has really peaked and we no longer really use much of anything else. [SLC, 1998].

Kahn et al. (1988) conducted a study of the prevalence and seriousness of such complaints, based on United Mine Workers of America records and subsequent interviews with the miners involved. The review involved reports at five underground coal mines in Utah and Colorado between 1974 and 1985. Of the 13 miners reporting symptoms: 12 reported mucous membrane irritation, headache and light-headiness; eight reported nausea; four reported heartburn; three reported vomiting and weakness, numbness, and tingling in extremities; two reported chest tightness; and two reported wheezing (although one of these complained of recurrent wheezing without exposure). All of these incidents were severe enough to result in lost work time due to the symptoms (which subsided within 24 to 48 hours).

In comments submitted for this rulemaking, the NMA pointed out, as has MSHA, that the evidence presented in this subsection is anecdotal. The NMA, further, suggested that the cited article by Kahn et al. typified this kind of evidence in that it was ''totally devoid of any correlation to actual exposure levels.'' A lack of concurrent exposure measurements is, unfortunately, not restricted to anecdotal evidence; and MSHA must base its evaluation on the available evidence. MSHA recognizes the scientific limitations of anecdotal evidence and has, therefore, compiled and considered it separately from more formal evidence. MSHA nevertheless considers such evidence potentially valuable for identifying acute health hazards, with the understanding that confirmation requires more rigorous investigation.[20]

With respect to the same article (Kahn et al., 1988), and notwithstanding the NMA's claim that the article was totally devoid of any correlation to exposure levels, the NMA also stated that MSHA:

> * * * neglects to include in the preamble the article's description of the conditions under which the ''overexposures'' occurred, *e.g.,* ''poor engine maintenance, poor maintenance of emission controls, prolonged idling of machinery, engines pulling heavy loads, use of equipment during times when ventilation was disrupted (such as during a move of longwall machinery), use of several pieces of equipment exhausting into the fresh-air intake, and use of poor quality fuel.

The NMA asserted that these conditions, cited in the article, ''have been addressed by MSHA's final standards for diesel equipment in underground coal mines issued October 25, 1996.''[21] Furthermore, despite its reservations about anecdotal evidence:

> NMA is mindful of the testimony of several miners in the coal proceeding who complained of transient irritation owing to exposure to diesel exhaust * * * the October 1996 regulations together with the phased-in introduction of catalytic converters on all outby equipment and the introduction of such devices on permissible equipment when such technology becomes available will address the complaints raised by the miners.

The NMA provided no evidence, however, that elimination of the conditions described by Kahn et al., or implementation of the 1996 diesel regulations for coal mines, would reduce dpm levels sufficiently to prevent the sensory irritations and respiratory symptoms described. Nor did the NMA provide evidence that these are the only conditions under which complaints of sensory irritations and respiratory symptoms occur, or explain why eliminating them would reduce the need to prevent excessive exposure under other conditions.

In the proposal for the present rule, MSHA requested additional information about such effects from medical personnel who have treated miners. IMC Global submitted letters from four healthcare practitioners in Carlsbad, NM, including three physicians. None of these practitioners attributed any cases of respiratory problems or other acute symptoms to dpm exposure. Three of the four practitioners noted that they had observed respiratory symptoms among exposed miners but attributed these symptoms to chronic lung conditions, smoking, or other factors. One physician stated that ''[IMC Global], which has used diesel equipment in its mining operations for over 20 years, has never experienced a single case of injury or illness caused by exposures to diesel particulates.''

ii. Studies Based on Exposures to Diesel Emissions. Several experimental and statistical studies have been conducted to investigate acute effects of exposure to diesel emissions. These more formal studies provide data that are more scientifically rigorous than the anecdotal evidence presented in the preceding subsection. Unless otherwise indicated, diesel exhaust exposures were determined qualitatively.

In a clinical study (Battigelli, 1965), volunteers were exposed to three concentrations of diluted diesel exhaust and then evaluated to determine the effects of exposure on pulmonary resistance and the degree of eye irritation. The investigators stated that ''levels utilized for these controlled exposures are comparable to realistic values such as those found in railroad shops.'' No statistically significant change in pulmonary function was detected, but exposure for ten minutes to diesel exhaust diluted to the middle level produced ''intolerable'' irritation in some subjects while the average irritation score was midway between ''some'' irritation and a ''conspicuous but tolerable'' irritation level. Diluting

[19] MSHA realizes the incidents related in this subsection are anecdotal and draws no statistical conclusions from them. Since they pertain to specific experiences, however, they can be useful in identifying a potential hazard.

[20] MSHA sees potential value in anecdotal evidence when it relates to immediate experiences. MSHA regards anecdotal evidence to be less appropriate for identifying chronic health effects, since chronic effects cannot readily be linked to specific experiences. Accordingly, this risk assessment places little weight on anecdotal evidence for the chronic health hazards considered.

[21] The 1996 regulations to which the NMA was referring do not apply to M/NM mines.

the concentration by 50% substantially reduced the irritation. At the highest exposure level, more than 50 percent of the volunteers discontinued the experiment before 10 minutes because of ''intolerable'' eye irritation.

A study of underground iron ore miners exposed to diesel emissions found no difference in spirometry measurements taken before and after a work shift (Jörgensen and Svensson 1970). Similarly, another study of coal miners exposed to diesel emissions detected no statistically significant relationship between exposure and changes in pulmonary function (Ames et al. 1982). However, the authors noted that the lack of a statistically significant result might be due to the low concentrations of diesel emissions involved.

Gamble et al. (1978) observed decreases in pulmonary function over a single shift in salt miners exposed to diesel emissions. Pulmonary function appeared to deteriorate in relation to the concentration of diesel exhaust, as indicated by NO_2; but this effect was confounded by the presence of NO_2 due to the use of explosives.

Gamble et al. (1987a) assessed response to diesel exposure among 232 bus garage workers by means of a questionnaire and before- and after-shift spirometry. No significant relationship was detected between diesel exposure and change in pulmonary function. However, after adjusting for age and smoking status, a significantly elevated prevalence of reported symptoms was found in the high-exposure group. The strongest associations with exposure were found for eye irritation, labored breathing, chest tightness, and wheeze. The questionnaire was also used to compare various acute symptoms reported by the garage workers and a similar population of workers at a lead acid battery plant who were not exposed to diesel fumes. The prevalence of work-related eye irritations, headaches, difficult or labored breathing, nausea, and wheeze was significantly higher in the diesel bus garage workers, but the prevalence of work-related sneezing was significantly lower.

Ulfvarson et al. (1987) studied effects over a single shift on 47 stevedores exposed to dpm at particle concentrations ranging from 130 $\mu g/m^3$ to 1000 $\mu g/m^3$. Diesel particulate concentrations were determined by collecting particles on glass fiber filters of unspecified efficiency. A statistically significant loss of pulmonary function was observed, with recovery after 3 days of no occupational exposure.

To investigate whether removal of the particles from diesel exhaust might reduce the ''acute irritative effect on the lungs'' observed in their earlier study, Ulfvarson and Alexandersson (1990) compared pulmonary effects in a group of 24 stevedores exposed to unfiltered diesel exhaust to a group of 18 stevedores exposed to filtered exhaust, and to a control group of 17 occupationally unexposed workers. The filters used were specially constructed from 144 layers of glass fiber with ''99.97% degrees of retention of dioctylphthalate mist with particle size 0.3 μm.'' Workers in all three groups were nonsmokers and had normal spirometry values, adjusted for sex, age, and height, prior to the experimental workshift.

In addition to confirming the earlier observation of significantly reduced pulmonary function after a single shift of occupational exposure, the study found that the stevedores in the group exposed only to filtered exhaust had 50–60% less of a decline in forced vital capacity (FVC) than did those stevedores who worked with unfiltered equipment. Similar results were observed for a subgroup of six stevedores who were exposed to filtered exhaust on one shift and unfiltered exhaust on another. No loss of pulmonary function was observed for the unexposed control group. The authors suggested that these results ''support the idea that the irritative effect of diesel exhausts [sic] to the lungs is the result of an interaction between particles and gaseous components and not of the gaseous components alone.'' They concluded that ''* * * it should be a useful practice to filter off particles from diesel exhausts in work places even if potentially irritant gases remain in the emissions'' and that ''removal of the particulate fraction by filtering is an important factor in reducing the adverse effect of diesel exhaust on pulmonary function.''

Rudell et al. (1996) carried out a series of double-blind experiments on 12 healthy, non-smoking subjects to investigate whether a particle trap on the tailpipe of an idling diesel engine would reduce acute effects of diesel exhaust, compared with exposure to unfiltered exhaust. Symptoms associated with exposure included headache, dizziness, nausea, tiredness, tightness of chest, coughing, and difficulty in breathing. The most prominent symptoms were found to be irritation of the eyes and nose, and a sensation of unpleasant smell. Among the various pulmonary function tests performed, exposure was found to result in significant changes only as measured by increased airway resistance and specific airway resistance. The ceramic wall flow particle trap reduced the number of particles by 46 percent, but resulted in no significant attenuation of symptoms or lung function effects. The authors concluded that diluted diesel exhaust caused increased irritant symptoms of the eyes and nose, unpleasant smell, and bronchoconstriction, but that the 46-percent reduction in median particle number concentration observed was not sufficient to protect against these effects in the populations studied.

Wade and Newman (1993) documented three cases in which railroad workers developed persistent asthma following exposure to diesel emissions while riding immediately behind the lead engines of trains having no caboose. None of these workers were smokers or had any prior history of asthma or other respiratory disease. Asthma diagnosis was based on symptoms, pulmonary function tests, and measurement of airway hyperreactivity to methacholine or exercise.

Although MSHA is not aware of any other published report directly relating diesel emissions exposures to the development of asthma, there have been a number of recent studies indicating that dpm exposure can induce bronchial inflammation and respiratory immunological allergic responses in humans. Studies published through 1997 are reviewed in Peterson and Saxon (1996) and Diaz-Sanchez (1997).

Diaz-Sanchez et al.(1994) challenged healthy human volunteers by spraying 300 μg dpm into their nostrils.[22] Immunoglobulin E (IgE) binds to mast cells where it binds antigen leading to secretion of biologically active amines (*e.g.,* histamine) causing dilation and increased permeability of blood vessels. These amines are largely responsible for clinical manifestations of such allergic reactions as hay fever, asthma, and hives. Enhanced IgE levels were found in nasal washes in as little as 24 hours, with peak production observed 4 days after the dpm was administered.[23] No effect was observed on the levels of other immunoglobulin proteins. The selective enhancement of local IgE production was demonstrated by a dramatic increase in IgE-secreting cells. The authors suggested that dpm may augment human allergic disease

[22] Assuming that a working miner inhales approximately 1.25 m^3 of air per hour, this dose corresponds to a 1-hour exposure at a dpm concentration of 240 $\mu g/m^3$.

[23] IgE is one of five types of immunoglobulin, which are proteins produced in response to allergens. Cytokine (mentioned later) is a substance involved in regulating IgE production.

responses by enhancing the production of IgE antibodies. Building on these results, Diaz-Sanchez et al.(1996) measured cytokine production in nasal lavage cells from healthy human volunteers challenged with 150 μg dpm sprayed into each nostril. Based on the responses observed, including a broad increase in cytokine production, along with the results of the 1994 paper, the authors concluded that dpm exposure contributes to enhanced local IgE production and thus plays a role in allergic airway disease.

Salvi et al. (1999) exposed healthy human volunteers to diluted diesel exhaust at a dpm concentration of 300 $\mu g/m^3$ for one hour with intermittent exercise. Although there were no changes in pulmonary function, there were significant increases in various markers of allergic response in airway lavage fluid. Bronchial biopsies obtained six hours after exposure also showed significant increases in markers of immunologic response in the bronchial tissue. Significant increases in other markers of immunologic response were also observed in peripheral blood following exposure. A marked cellular inflammatory response in the airways was reported. The authors concluded that ''at high ambient concentrations, acute short-term DE [diesel exhaust] exposure produces a well-defined and marked systemic and pulmonary inflammatory response in healthy human volunteers, which is underestimated by standard lung function measurements.''

iii. Studies Based on Exposures to Particulate Matter in Ambient Air. Due to an incident in Belgium's industrial Meuse Valley, it was known as early as the 1930s that large increases in particulate air pollution, created by winter weather inversions, could be associated with large simultaneous increases in mortality and morbidity. More than 60 persons died from this incident, and several hundred suffered respiratory problems. The mortality rate during the episode was more than ten times higher than normal, and it was estimated that over 3,000 sudden deaths would occur if a similar incident occurred in London. Although no measurements of pollutants in the ambient air during the episode are available, high PM levels were obviously present (EPA, 1996).

A significant elevation in particulate matter (along with SO_2 and its oxidation products) was measured during a 1948 incident in Donora, PA. Of the Donora population, 42.7 percent experienced some acute adverse health effect, mainly due to irritation of the respiratory tract. Twelve percent of the population reported difficulty in breathing, with a steep rise in frequency as age progressed to 55 years (Schrenk, 1949).

Approximately as projected by Firket (1931), an estimated 4,000 deaths occurred in response to a 1952 episode of extreme air pollution in London. The nature of these deaths is unknown, but there is clear evidence that bronchial irritation, dyspnea, bronchospasm, and, in some cases, cyanosis occurred with unusual prevalence (Martin, 1964).

These three episodes ''left little doubt about causality in regard to the induction of serious health effects by very high concentrations of particle-laden air pollutant mixtures'' and stimulated additional research to characterize exposure-response relationships (EPA, 1996). Based on several analyses of the 1952 London data, along with several additional acute exposure mortality analyses of London data covering later time periods, the U.S. Environmental Protection Agency (EPA) concluded that increased risk of mortality is associated with exposure to combined particulate and SO_2 levels in the range of 500–1000 $\mu g/m^3$. The EPA also concluded that relatively small, but statistically significant increases in mortality risk exist at particulate (but not SO_2) levels below 500 $\mu g/m^3$, with no indications of a specific threshold level yet indicated at lower concentrations (EPA, 1986).

Subsequently, between 1986 and 1996, increasingly sophisticated techniques of particulate measurement and statistical analysis have enabled investigators to address these questions more quantitatively. The studies on acute effects carried out since 1986 are reviewed in the 1996 EPA Air Quality Criteria for Particulate Matter, which forms the basis for the discussion below (EPA, 1996).

At least 21 studies have been conducted that evaluate associations between acute mortality and morbidity effects and various measures of fine particulate levels in the ambient air. These studies are identified in Tables III–2 and III–3. Table III–2 lists 11 studies that measured primarily fine particulate matter using filter-based optical techniques and, therefore, provide mainly qualitative support for associating observed effects with fine particles. Table III–3 lists quantitative results from 10 studies that reported gravimetric measurements of either the fine particulate fraction or of components, such as sulfates, that serve as indicators or surrogates of fine particulate exposures.

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Table III-2. —Studies of acute health effects using filter based optical indicators of fine particles in the ambient air.

City	Study Years	Indicator*	Reference†
Acute Mortality			
London	1963-1972 (winters) 1965-1972 (winters)	BS	Thurston et al., 1989 Ito et al., 1993
Athens	1975-1987 July, 1987 1984-1988	BS	Katsouyanni et al., 1990 Katsouyanni et al., 1993 Touloumi et al., 1994
Los Angeles	1970-1979 1970-1979	KM	Shumway et al., 1988 Kinney and Ozkaynak, 1991
Santa Clara	1980-1986 (winters)	COH	Fairley, 1990
Increased Hospitalization			
Barcelona	1985-1989	BS	Sunyer et al., 1993
Acute Change in Pulmonary Function			
Wageningen, Netherlands		BS	Hoek and Brunkreef, 1993
Netherlands		BS	Roemer et al., 1993

† All references are from EPA, 1996

*BS (black smoke), KM (carbonaceous material), and COH (coefficient of haze) are optical measurements that are most directly related to elemental carbon concentrations, but only indirectly to mass. Site specific calibrations and/or comparisons of such optical measurements with gravimetric mass measurements in the same time and city are needed to make inferences about particle mass. However, all three of these indicators preferentially measure carbon particles found in the fine fraction of total airborne particulate matter. (EPA, 1996).

Table III-3. —Studies of acute health effects using gravimetric indicators of fine particles in the ambient air.

Study	Indicator	RR per 25 $\mu g/m^3$ $PM_{2.5}$ Increase (95% Confidence Interval)	Mean $PM_{2.5}$ Levels (Min/Max)†
Acute Mortality			
Six Cities[A] (overall)	$PM_{2.5}$	1.038 (1.026, 1.055)	
Portage, WI	$PM_{2.5}$	1.030 (0.993, 1.071)	11.2 (±7.8)
Topeka, KS	$PM_{2.5}$	1.020 (0.951, 1.092)	12.2 (±7.4)
Boston, MA	$PM_{2.5}$	1.056 (1.038, 1.071)	15.7 (±9.2)
St. Louis, MO	$PM_{2.5}$	1.028 (1.010, 1.043)	18.7 (±10.5)
Kingston/Knoxville, TN	$PM_{2.5}$	1.035 (1.005, 1.066)	20.8 (±9.6)
Steubenville, OH	$PM_{2.5}$	1.025 (0.998, 1.053)	29.6 (±21.9)
Increased Hospitalization			
Ontario, CAN[B]	$SO_4^=$	1.03 (1.02, 1.04)	Min/Max = 3.1 - 8.2
Ontario, CAN[C]	$SO_4^=$	1.03 (1.02, 1.04)	Min/Max = 2.0 - 7.7
	O_3	1.03 (1.02, 1.05)	
NYC/Buffalo, NY[D]	$SO_4^=$	1.05 (1.01, 1.10)	NR
Toronto, CAN[D]	H^+(Nmol/m^3)	1.16 (1.03, 1.30)*	28.8 (NR, 391)
	$SO_4^=$	1.12 (1.00, 1.24)	7.6 (NR, 48.7)
	$PM_{2.5}$	1.15 (1.02, 1.78)	18.6 (NR, 66.0)
Increased Respiratory Symptoms			
Southern California[F]	$SO_4^=$	1.48 (1.14, 1.91)	R = 2 - 37
Six Cities[G] (Cough)	$PM_{2.5}$	1.19 (1.01, 1.42)**	18.0 (7.2, 37)***
	$PM_{2.5}$ Sulfur	1.23 (0.95, 1.59)**	2.5 (3.1, 61)***
	H^+	1.06 (0.87, 1.29)**	18.1 (0.8, 5.9)***
Six Cities[G] (Lower Resp. Symp.)	$PM_{2.5}$	1.44 (1.15 - 1.82)**	18.0 (7.2, 37)***
	$PM_{2.5}$ Sulfur	1.82 (1.28 - 2.59)**	2.5 (0.8, 5.9)***
	H^+	1.05 (0.25 - 1.30)**	18.1 (3.1, 61)***
Denver, CO[P] (Cough, adult asthmatics)	$PM_{2.5}$	0.0012 (0.0043)****	0.41 - 73
	$SO_4^=$	0.0042 (0.00035)****	0.12 - 12
	H^+	0.0076 (0.0038)****	2.0 - 41
Decreased Lung Function			
Uniontown, PA[E]	$PM_{2.5}$	PEFR 23.1 (-0.3,36.9) (per 25 $\mu g/m^3$)	25/88 (NR/88)
Seattle, WA[Q] (Asthmatics)	$b_{ext.}$ calibrated by $PM_{2.5}$	FEV1 42 ml (12,73)	5/45
		FVC 45 ml (20,70)	

References from EPA, 1996, Staff Report

[A] Schwartz et al. (1996a)

[B] Burnett et al. (1994)

[C] Burnett et al. (1995) O_3

[D] Thurston et al. (1992, 1994)

[E] Neas et al. (1995)

[F] Ostro et al. (1993)

[G] Schwartz et al. (1994)

[P] Ostro et al. (1991)

[Q] Koenig et al. (1993)

† Min/Max 24-hr PM indicator level shown in parentheses unless otherwise noted as (±S.D.), 10 and 90 percentile (10,90).

* Change per 100 nmoles/m^3.

** Change per 20 $\mu g/m^3$ for $PM_{2.5}$; per 5 $\mu g/m^3$ for $PM_{2.5}$ sulfur; per 25 nmoles/m^3 for H^+.

*** 50th percentile value (10,90 percentile).

**** Coefficient and SE in parenthesis.

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A total of 38 studies examining relationships between short-term particulate levels and increased mortality, including nine with fine particulate measurements, were published between 1988 and 1996 (EPA, 1996). Most of these found statistically significant positive associations. Daily or several-day elevations of particulate concentrations, at average levels as low as 18–58 μ/m^3, were associated with increased mortality, with stronger relationships observed in those with preexisting respiratory and cardiovascular disease. Overall, these studies suggest that an increase of 50 $\mu g/m^3$ in the 24-hour average of PM_{10} is associated with a 2.5 to 5-percent increase in the risk of mortality in the general population, excluding accidents, suicides, and homicides. Based on Schwartz et al. (1996), the relative risk (RR) of mortality in the general population increases by about 2.6 to 5.5 percent per 25 $\mu g/m^3$ of fine particulate ($PM_{2.5}$) (EPA, 1996). More specifically, Schwartz et al. (1996) reported significantly elevated risks of mortality due to pneumonia, chronic obstructive pulmonary disease (COPD), and ischemic heart disease (IHD). For these three causes of death, the estimated increases in risk per incremental increase of 10 $\mu g/m^3$ in the concentration of $PM_{2.5}$ were 4.0 percent, 3.3 percent, and 2.1 percent, respectively. Each of these three results was statistically significant at a 95-percent confidence level.

A total of 22 studies were published on associations between short-term particulate levels and hospital admissions, outpatient visits, and emergency room visits for respiratory disease, Chronic Obstructive Pulmonary Disease (COPD), pneumonia, and heart disease (EPA, 1996). Fifteen of these studies were focused on the elderly. Of the seven that dealt with all ages (or in one case, persons less than 65 years old), all showed positive results. All of the five studies relating fine particulate measurements to increased hospitalization, listed in Tables III–2 and III–3, dealt with general age populations and showed statistically significant associations. The estimated increase in risk ranges from 3 to 16 percent per 25 $\mu g/m^3$ of fine particulate. Overall, these studies are indicative of acute morbidity effects being related to fine particulate matter and support the mortality findings.

Most of the 14 published quantitative studies on ambient particulate exposures and acute respiratory diseases were restricted to children (EPA, 1996, Table 12–12). Although they generally showed positive associations, and may be of considerable biological relevance, evidence of toxicity in children is not necessarily applicable to adults. The few studies on adults have not produced statistically significant evidence of a relationship.

Thirteen studies since 1982 have investigated associations between ambient particulate levels and loss of pulmonary function (EPA, 1996, Table 12–13). In general, these studies suggest a short term effect, especially in symptomatic groups such as asthmatics, but most were carried out on children only. In a study of adults with mild COPD, Pope and Kanner (1993) found a 29±10 ml decrease in 1-second Forced Expiratory Volume (FEV_1) per 50 $\mu g/m^3$ increase in PM_{10}, which is similar in magnitude to the change generally observed in the studies on children. In another study of adults, with PM_{10} ranging from 4 to 137 $\mu g/m^3$, Dusseldorp et al. (1995) found 45 and 77 ml/sec decreases, respectively, for evening and morning Peak Expiratory Flow Rate (PEFR) per 50 $\mu g/m^3$ increase in PM_{10} (EPA, 1996). In the only study carried out on adults that specifically measured fine particulate ($PM_{2.5}$), Perry et al. (1983) did not detect any association of exposure with loss of pulmonary function. This study, however, was conducted on only 24 adults (all asthmatics) exposed at relatively low concentrations of $PM_{2.5}$ and,therefore, had very little power to detect any such association.

c. Chronic Health Effects

During the 1995 dpm workshops, miners reported observable adverse health effects among those who have worked a long time in dieselized mines. For example, a miner (dpm Workshop; Salt Lake City, UT, 1995), stated that miners who work with diesel ''have spit up black stuff every night, big black—what they call black (expletive) * * * [they] have the congestion every night * * * the 60-year-old man working there 40 years.'' Similarly, in comments submitted in response to MSHA's proposed dpm regulations, several miners reported cancers and chronic respiratory ailments they attributed to dpm exposure.

Scientific investigation of the chronic health effects of dpm exposure includes studies based specifically on exposures to diesel emissions and studies based more generally on exposures to fine particulate matter in the ambient air. Only the evidence from human studies will be addressed in this section of the risk assessment. Data from genotoxicity studies and studies on laboratory animals will be discussed later, in Subsection 2.d on mechanisms of toxicity. Subsection 3.a(iii) contains MSHA's interpretation of the evidence relating dpm exposures to one chronic health hazard: lung cancer.

i. Studies Based on Exposures to Diesel Emissions. The discussion will (1) summarize the epidemiologic literature on chronic effects other than cancer, and then (2) concentrate on the epidemiology of cancer in workers exposed to dpm.

(1) Chronic Effects other than Cancer

A number of epidemiologic studies have investigated relationships between diesel exposure and the risk of developing persistent respiratory symptoms (i.e., chronic cough, chronic phlegm, and breathlessness) or measurable loss in lung function. Three studies involved coal miners (Reger et al., 1982; Ames et al., 1984; Jacobsen et al., 1988); four studies involved metal and nonmetal miners (Jörgenson & Svensson, 1970; Attfield, 1979; Attfield et al., 1982; Gamble et al., 1983). Three studies involved other groups of workers—railroad workers (Battigelli et al., 1964), bus garage workers (Gamble et al., 1987), and stevedores (Purdham et al., 1987).

Reger et al. (1982) examined the prevalence of respiratory symptoms and the level of pulmonary function among more than 1,600 underground and surface U.S. coal miners, comparing results for workers (matched for smoking status, age, height, and years worked underground) at diesel and non-diesel mines. Those working at underground dieselized mines showed some increased respiratory symptoms and reduced lung function, but a similar pattern was found in surface miners who presumably would have experienced less diesel exposure. Miners in the dieselized mines, however, had worked underground for less than 5 years on average.

In a study of 1,118 U.S. coal miners, Ames et al. (1984) did not detect any pattern of chronic respiratory effects associated with exposure to diesel emissions. The analysis, however, took no account of baseline differences in lung function or symptom prevalence, and the authors noted a low level of exposure to diesel-exhaust contaminants in the exposed population.

In a cohort of 19,901 British coal miners investigated over a 5-year period, Jacobsen et al. (1988) found increased work absence due to self-reported chest illness in underground workers exposed to diesel exhaust, as compared to surface workers, but found no correlation with their estimated level of exposure.

Jörgenson & Svensson (1970) found higher rates of chronic productive bronchitis, for both smokers and nonsmokers, among Swedish underground iron ore miners exposed to diesel exhaust as compared to surface workers at the same mine. No significant difference was found in spirometry results.

Using questionnaires collected from 4,924 miners at 21 U.S. metal and nonmetal mines, Attfield (1979) evaluated the effects of exposure to silica dust and diesel exhaust and obtained inconclusive results with respect to diesel exposure. For both smokers and non-smokers, miners occupationally exposed to diesel for five or more years showed an elevated prevalence of persistent cough, persistent phlegm, and shortness of breath, as compared to miners exposed for less than five years, but the differences were not statistically significant. Four quantitative indicators of diesel use failed to show consistent trends with symptoms and lung function.

Attfield et al. (1982) reported on a medical surveillance study of 630 white male miners at 6 U.S. potash mines. No relationships were found between measures of diesel use or exposure and various health indices, based on self-reported respiratory symptoms, chest radiographs, and spirometry.

In a study of U.S. salt miners, Gamble and Jones (1983) observed some elevation in cough, phlegm, and dyspnea associated with mines ranked according to level of diesel exhaust exposure. No association between respiratory symptoms and estimated cumulative diesel exposure was found after adjusting for differences among mines. However, since the mines varied widely with respect to diesel exposure levels, this adjustment may have masked a relationship.

Battigelli et al. (1964) compared pulmonary function and complaints of respiratory symptoms in 210 U.S. railroad repair shop employees, exposed to diesel for an average of 10 years, to a control group of 154 unexposed railroad workers. Respiratory symptoms were less prevalent in the exposed group, and there was no difference in pulmonary function; but no adjustment was made for differences in smoking habits.

In a study of workers at four diesel bus garages in two U.S. cities, Gamble et al. (1987b) investigated relationships between job tenure (as a surrogate for cumulative exposure) and respiratory symptoms, chest radiographs, and pulmonary function. The study population was also compared to an unexposed control group of workers with similar socioeconomic background. After indirect adjustment for age, race, and smoking, the exposed workers showed an increased prevalence of cough, phlegm, and wheezing, but no association was found with job tenure. Age- and height-adjusted pulmonary function was found to decline with duration of exposure, but was elevated on average, as compared to the control group. The number of positive radiographs was too small to support any conclusions. The authors concluded that the exposed workers may have experienced some chronic respiratory effects.

Purdham et al. (1987) compared baseline pulmonary function and respiratory symptoms in 17 exposed Canadian stevedores to a control group of 11 port office workers. After adjustment for smoking, there was no statistically significant difference in self-reported respiratory symptoms between the two groups. However, after adjustment for smoking, age, and height, exposed workers showed lower baseline pulmonary function, consistent with an obstructive ventilatory defect, as compared to both the control group and the general metropolitan population.

In a review of these studies, Cohen and Higgins (1995) concluded that they did not provide strong or consistent evidence for chronic, nonmalignant respiratory effects associated with occupational exposure to diesel exhaust. These reviewers stated, however, that ''several studies are suggestive of such effects * * * particularly when viewed in the context of possible biases in study design and analysis.'' Glenn et al (1983) noted that the studies of chronic respiratory effects carried out by NIOSH researchers in coal, salt, potash, and trona mines all ''revealed an excess of cough and phlegm in the diesel exposed group.'' IPCS (1996) noted that ''[a]lthough excess respiratory symptoms and reduced pulmonary function have been reported in some studies, it is not clear whether these are long-term effects of exposure.'' Similarly, Morgan et al. (1997) concluded that while there is ''some evidence that the chronic inhalation of diesel fumes leads to the development of cough and sputum, that is chronic bronchitis, it is usually impossible to show a cause and effect relationship * * *.'' MSHA agrees that these dpm studies considers them to be suggestive of adverse chronic, non-cancerous respiratory effects.

(2) Cancer

Because diesel exhaust has long been known to contain carcinogenic compounds (*e.g.,* benzene in the gaseous fraction and benzopyrene and nitropyrene in the dpm fraction), a great deal of research has been conducted to determine if occupational exposure to diesel exhaust actually results in an increased risk of cancer. Evidence that exposure to dpm increases the risk of developing cancer comes from three kinds of studies: human studies, genotoxicity studies, and animal studies. In this risk assessment, MSHA has placed the most weight on evidence from the human epidemiologic studies and views the genotoxicity and animal studies as lending support to the epidemiologic evidence.

In the epidemiologic studies, it is generally impossible to disassociate exposure to dpm from exposure to the gasses and vapors that form the remainder of whole diesel exhaust. However, the animal evidence shows no significant increase in the risk of lung cancer from exposure to the gaseous fraction alone (Heinrich et al., 1986, 1995; Iwai et al., 1986; Brightwell et al., 1986). Therefore, dpm, rather than the gaseous fraction of diesel exhaust, is usually assumed to be the agent associated with any excess prevalence of lung cancer observed in the epidemiologic studies. Subsection 2.d of this risk assessment contains a summary of evidence supporting this assumption.

(a) Lung Cancer

MSHA evaluated 47 epidemiologic studies examining the prevalence of lung cancer within groups of workers occupationally exposed to dpm. This includes four studies not included in MSHA's risk assessment as originally proposed.[24] The earliest of these studies was published in 1957 and the latest in 1999. The most recent published reviews of these studies are by Mauderly (1992), Cohen and Higgins (1995), Muscat and Wynder (1995), IPCS (1996), Stöber and Abel (1996), Cox (1997), Morgan et al. (1997), Cal-EPA (1998), ACGIH (1998), and U.S. EPA (1999). In response to both the ANPRM and the 1998 proposals, several commenters also provided MSHA with their own reviews of many of these studies. In arriving at its conclusions, MSHA considered all of these reviews,

[24] One of these studies (Christie et al., 1995) was cited in the discussion on mechanisms of toxicity but not considered in connection with studies involving dpm exposures. Several commenters advocated that it be considered. The other three were published in 1997 or later. Johnston et al. (1997) was introduced to these proceedings in 64FR7144. Säverin et al. (1999) is the published English version of a German study submitted as part of the public comments by NIOSH on May 27, 1999. The remaining study is Brüske-Hohlfeld et al. (1999).

including those of the commenters, as well as the 47 source studies available to MSHA.

In addition, MSHA relied on two comprehensive statistical ''meta-analyses'' [25] of the epidemiologic literature: Lipsett and Campleman (1999)[26] and Bhatia et al. (1998).[27] These meta-analyses, which weight, combine, and analyze data from the various epidemiologic studies, were themselves the subject of considerable public comment and are discussed primarily in Subsection 3.a.iii of this risk assessment. The present section tabulates results of the studies and addresses their individual strengths and weaknesses. Interpretation and evaluation of the collective evidence, including discussion of potential publication bias or any other systematic biases, is deferred to Subsection 3.a.iii.

Tables III–4 (27 cohort studies) and III–5 (20 case-control studies) identify all 47 known epidemiologic studies that MSHA considers relevant to an assessment of lung cancer risk associated with dpm exposure.[28] These tables include, for each of the 47 studies listed, a brief description of the study and its findings, the method of exposure assessment, and comments on potential biases or other limitations. Presence or absence of an adjustment for smoking habits is highlighted, and adjustments for other potentially confounding factors are indicated when applicable. Although MSHA constructed these tables based primarily on its own reading of the 48 source publications, the tables also incorporate strengths and weaknesses noted in the literature reviews and/or in the public comments submitted.

Some degree of association between occupational dpm exposure and an excess prevalence of lung cancer was reported in 41 of the 47 studies reviewed by MSHA: 22 of the 27 cohort studies and 19 of the 20 case-control studies. Despite some commenters' use of conflicting terminology, which will be addressed below, MSHA refers to these 41 studies as ''positive.'' The 22 positive cohort studies in Table III–4 are identified as those reporting a relative risk (RR) or standardized mortality ratio (SMR) exceeding 1.0. The 19 positive case-control studies in Table III–5 are identified as those reporting an RR or odds ratio (OR) exceeding 1.0. A study does not need to be statistically significant (at the 0.05 level) or meet all criteria described, in order to be considered a ''positive'' study. The six remaining studies were entirely negative: they reported a deficit in the prevalence of lung cancer among exposed workers, relative to whatever population was used in the study as a basis for comparison. These six negative studies are identified as those reporting no relative risk (RR), standard mortality ratio (SMR), or odds ratio (OR) greater than 1.0.[29]

MSHA recognizes that these 47 studies are not of equal importance for determining whether dpm exposure leads to an increased risk of lung cancer. Some of the studies provide much better evidence than others. Furthermore, since no epidemiologic study can be perfectly controlled, the studies exhibit various strengths and weaknesses, as described by both this risk assessment and a number of commenters. Several commenters, and some of the reviewers cited above, focused on the weaknesses and argued that none of the existing studies is conclusive. MSHA, in accordance with other reviewers and commenters, maintains: (1) that the weaknesses identified in both negative and positive studies mainly cause underestimation of risks associated with high occupational dpm exposure; (2) that it is legitimate to base conclusions on the combined weight of all available evidence and that, therefore, it is not necessary for any individual study to be conclusive; and (3) that even though the 41 positive studies vary a great deal in strength, nearly all of them contribute something to the weight of positive evidence.

TABLE III–4.—SUMMARY OF INFORMATION FROM 27 COHORT STUDIES ON LUNG CANCER AND OCCUPATIONAL EXPOSURE TO DIESEL EXHAUST

Study	Occupation	Number of subjects	Follow-up period	Exposure assessment	Smk. adj.	Findings [a]	Stat. sig. [b]	Comments
Ahlberg et al. (1981).	Male truck drivers	35,883	1961–73	Occupation only		RR = 1.33 for drivers of ''ordinary'' trucks.	(*)	Risk relative to males employed in trades thought to have no exposure to ''petroleum products or other chemicals.'' Comparison controlled for age and province of residence (Sweden). Based on comparison of smoking habits between truck drivers and general Stockholm population, authors concluded that excess rate of lung cancer could not be entirely attributed to smoking.

[25] MSHA restricts the term ''meta-analysis'' to formal, statistical analyses of the pooled data taken from several studies. Some commenters (and Cox in the article itself) referred to the review by Cox (op.cit.) as a meta-analysis. Although this article seeks to identify characteristics of the individual studies that might account for the general pattern of results, it performs no statistical analysis on the pooled epidemiologic data. For this reason, MSHA does not regard the Cox article as a meta-analysis in the same sense as the two studies so identified. MSHA does, however, recognize that the Cox article evaluates and rejects the collective evidence for causality, based on the common characteristics identified. In that context, Cox's arguments and conclusions are addressed in Subsection 3.a.iii. Cox also presents a statistical analysis of data from one of the studies, and that portion of the article is considered here, along with his observations about other individual studies.

[26] MSHA's risk assessment as originally proposed cited an unpublished version, attributed to Lipsett and Alexexeff (1998), of essentially the same meta-analysis. Both the 1999 and 1998 versions are now in the public record.

[27] Silverman (1998) reviewed the meta-analysis by Bhatia et al. (op cit.) and discussed, in general terms, the body of available epidemiologic evidence on which it is based. Some commenters stated that MSHA had not sufficiently considered Silverman's views on the limitations of this evidence. MSHA has thoroughly considered these views and addresses them in Subsection 3.a.(iii).

[28] For simplicity, the epidemiologic studies considered here are placed into two broad categories. A *cohort study* compares the health of persons having different exposures, diets, etc. A *case-control study* starts with two defined groups known to differ in health and compares their exposure characteristics.

[29] The six entirely negative studies are: Kaplan (1959); DeCoufle et al. (1977); Waller (1981); Edling et al. (1987); Bender et al. (1989); Christie et al. (1995).

TABLE III–4.—SUMMARY OF INFORMATION FROM 27 COHORT STUDIES ON LUNG CANCER AND OCCUPATIONAL EXPOSURE TO DIESEL EXHAUST—Continued

Study	Occupation	Number of subjects	Follow-up period	Exposure assessment	Smk. adj.	Findings [a]	Stat. sig. [b]	Comments
Ahlman et al. (1991).	Underground sulfide ore miners.	597	1968–86	Job histories from personnel records. Measurements of alpha energy concentration from radon daughters at each mine worked.		RR = 1.45 overall. RR = 2.9 for 45–64 age group (calculated by MSHA).		Age-adjusted relative risk compared to males living in same area of Finland. No excess observed among 338 surface workers at same mines, with similar smoking and alcohol consumption, based on questionnaire. Based on calculation of expected lung cancers due to radon, excess risk attributed by author partly to radon exposure and partly to diesel exhaust & silica exposure.
Balarajan & McDowall (1988).	Professional drivers.	3,392	1950–84	Occupation only		SMR = 0.86 for taxi drivers.. SMR = 1.42 for bus drivers.. SMR = 1.59 for truck drivers.	(*)	Possibly higher rates of smoking among bus and truck drivers than among taxi drivers.
Bender et al. (1989).	Highway maintenance workers.	4,849	1945–84	Occupation only		SMR = 0.69		No adjustment for healthy worker effect.
Boffetta et al. (1988).	Railroad workers Truck drivers Heavy Eq. Op's Miners	2,973 16,208 855 2,034	1982–84	Occupation and diesel exposure by questionnaire.		RR = 1.24 for truck drivers. RR = 1.59 for railroad workers RR = 2.60 for heavy Eq. Op's RR = 2.67 for miners	(*) (*)	Risk relative to reporting that they never worked in these four occupations and were never occupationally exposed to diesel exhaust. Adjusted for age and smoking only.
Do	All workers	476,648	1982–84	Occupation and diesel exposure by questionnaire.		RR = 1.05 for 1–15 years. RR = 1.21 for 16+ years.		Based on self-reported exposure, relative to unexposed workers. Adjusted for occupational exposures to asbestos, coal and stone dusts, coal tar & pitch, and gasoline exhaust (in addition to age and smoking). Possible biases due to volunteered participation and elevated lung cancer rate among 98,026 subjects with unknown dpm exposure.
Christie et al. (1994, 1995).	Coal miners	23,630	1973–92	Occupation only		SMR = 0.76		No adjustment for healthy worker effect. Cohort includes workers who entered workforce up through 1992. SMR reported to be greater than for occupationally unexposed petroleum workers.
Dubrow & Wegman (1984).	Truck & tractor drivers.	Not reported	1971–73	Occupation only		sMOR = 1.73 based on 176 deaths.	(*)	Excess cancers observed over the entire respiratory system and upper alimentary tract.
Edling et al. (1987)	Bus workers	694	1951–83	Occupation only		SMR = 0.7 for overall cohort.		Small size of cohort lacks statistical power to detect excess risk of lung cancer. No adjustment for healthy worker effect.
Garshick et al. (1988, 1991).	Railroad workers	55,395 (1991 report).	1959–80	Job in 1959 & years of diesel exposure since 1959.		RR = 1.31 for 1–4 years. RR = 1.28 for 5–9 years. RR = 1.19 for 10–14 years. RR = 1.40 for 15 or more years.	(*) (*) (*) .	Adjusted for attained age (1991 report). Cumulative diesel exposure-years lagged by 5 years. Subjects with likely asbestos exposure excluded from cohort. Statistically significant results corroborated if 12,872 shopworkers and hostlers possibly exposed to asbestos are also excluded. Missing 12% of death certificates. Cigarette smoking judged to be uncorrelated with diesel exposure within cohort. Higher RR for each exposure group if shopworkers and hostlers are excluded.
Guberan et al (1992).	Professional drivers.	1,726	1961–86	Occupation only		SMR = 1.50	(*)	Approximately 1/3 to 1/4 of cohort reported to be long-haul truck drivers. SMR based on regional lung cancer mortality rate.
Gustafsson et al. (1986).	Dock workers	6,071	1961–80	Occupation only		SMR = 1.32 (mortality). SMR = 1.68 (morbidity)	(*) (*)	No adjustment for healthy worker effect.

TABLE III–4.—SUMMARY OF INFORMATION FROM 27 COHORT STUDIES ON LUNG CANCER AND OCCUPATIONAL EXPOSURE TO DIESEL EXHAUST—Continued

Study	Occupation	Number of subjects	Follow-up period	Exposure assessment	Smk. adj.	Findings [a]	Stat. sig. [b]	Comments
Gustavsson et al. (1990).	Bus garage workers.	708	1952–86	Semi-quantitative, based on job history & exposure intensity estimated for each job.		SMR = 1.22 for overall cohort. SMR = 1.27 for highest-exposed subgroup.		Lack of statistical significance may be attributed to small size of cohort.
Hansen (1993)	Truck drivers	14,225	1970–80	Occupation only		SMR = 1.60 for overall cohort. Some indication of increasing SMR with age (i.e., greater cumulative exposure).	(*)	Compared to unexposed control group of 38,301 laborers considered to "resemble the group of truck drivers in terms of work-related demands on physical strength and fitness, educational background, social class, and life style." Correction for estimated differences in smoking habits between cohort and control group reduces SMR from 1.60 to 1.52. Results judged "unlikely *** [to] have been seriously confounded by smoking habit differences."
Howe et al. (1983)	Railroad workers	43,826	1965–77	Jobs classified by diesel exposure.		RR = 1.20 for "possibly exposed.".	(*)	Risk is relative to unexposed subgroup of cohort. Similar results obtained for coal dust exposure.
						RR = 1.35 for "probably exposed.".	(*)	Possible confounding with asbestos and coal dust.
Johnston et al. (1997).	Underground coal miners.	18,166	1950–85	Quantitative, based on detailed job history & surrogate dpm measurements.		Mine-adjusted model: RR = 1.156 per g-hr/m^3.		Risk is relative to unexposed workers in coal miners based on cohort. Adjusted for age, smoking habit & intensity, mine site, and cohort entry date. Mine site highly correlated with dpm exposure.
						Mine-unadjusted model: RR = 1.227 per g-hr/m^3.		Both models lag exposure by 15 years.
Kaplan (1959)	Railroad workers	Approx. 32000	1953–58	Jobs classified by diesel exposure.		SMR=0.88 for operationally exposed.		No adjustment for healthy worker effect. Clerks (in rarely exposed group) found more likely to have had urban residence than occupationally exposed workers.
						SMR = 0.72 for somewha exposed SMR = 0.80 for rarely exposed.		No attempt to distinguish between diesel and coal-fired locomotives. Results may be attributable to short duration of exposure and/or inadequate follow-up time.
Leupker & Smith (1978).	Truck drivers	183,791	May–July, 1976	Occupation only		SMR = 1.21		Lack of statistical significance may be due to inadequate follow-up period. Retirees excluded from cohort, so lung cancers occurring after retirement were not included.
Lindsay et al. (1933).	Truck drivers	Not reported	1965–79	Occupation only		SMR = 1.15	(*)	
Menck & Henderson (1976).	Truck drivers	34,800 estimated	1968–73	Occupation only		SMR = 1.65	(*)	Number of subjects in cohort estimated from census data.
Raffle (1957)	Transport engineers.	2,666 estimated from manyears at risk.	1950–55	Occupation only		SMR = 1.42		SMR calculated by combining data presented for four quadrants of London. Excluded from most retirees and lung cancers occurring after retirement.
Rafnsson & Gunnarsdottir (1991).	Truck drivers	868	1951–88	Occupation only		SMR = 2.14	(*)	No trend of increasing risk with increased duration of employment or increased follow-up time. Based on survey of smoking habits in cohort compared to general male population, and fact that there were fewer than expected deaths from respiratory disease, authors concluded that differences in smoking habits were unlikely to be enough to explain excess rate of lung cancer. However, not all trucks were diesel prior to 1951, and there is possible confounding by asbestos exposure.

TABLE III–4.—SUMMARY OF INFORMATION FROM 27 COHORT STUDIES ON LUNG CANCER AND OCCUPATIONAL EXPOSURE TO DIESEL EXHAUST—Continued

Study	Occupation	Number of subjects	Follow-up period	Exposure assessment	Smk. adj.	Findings [a]	Stat. sig. [b]	Comments
Rushton et al. (1983).	Bus maintenamce workers.	8,480	5.9 yrs (mean)	Occupation only		SMR = 1.01 for overall cohort. SMR = 1.33 for "general hand" subgroup.	(*)	Short follow-up period. SMR based on comparison to national rates, with no adjustment for regional or socioeconomic differences, which could account for excess lung cancers observed among general hands. No adjustment for healthy worker effect.
Säverin et al. (1999).	Underground potash miners.	5,536	1970–94	Quantitative, based on TC measurements & detailed job history.		RR = 2.17 for highest compared to least exposed categories. RR = 1.03 to 1.225 per mg-yr/m^3, depending on statistical model & inclusion criteria.		Based on routine measurements, miners determined to have had no occupational exposure to radon progeny. Authors judged asbestos exposure minor, with negligible effects. Cigarette smoking determined to be uncorrelated with cumulative TC exposure within cohort.
Schenker et al. (1984).	Railroad workers	2,519	1967–79	Job histories, with exposure classified as unexposed, high, low, or undefined.		RR = 1.50 for low exposure subgroup. RR = 2.77 for high exposure subgroup.		Risk relative to unexposed subgroup. Jobs considered to have similar socioeconomic status. Differences in smoking calculated to be insufficient to explain findings. Possible confounding by asbestos exposure.
Waller (1981)	Bus workers	16,828 Est. from manyears at risk.	1950–74	Occupation only		SMR = 0.79 for overall cohort.		Lung cancers occurring after retirement or resignation from London Transport Authority were not counted. No adjustment for healthy worker effect.
Waxweiler et al. (1973).	Potash miners	3,886	1941–67	Miners classified as underground or surface.		SMR = 1.1 for both underground and surface miners. SMR = 0.99 for overall cohort. SMR = 1.07 for ≥20 yr member SMR = 1.12 for ≥20 yr. latency.		No adjustment for healthy worker effect. SMR based on national lung cancer mortality, which is about 1/3 higher than lung cancer mortality rate in New Mexico, where miners resided. Authors judged this to be balanced by smoking among miners. A substantial percentage of the underground subgroup may have had little or no occupational exposure to diesel exhaust.
Wong et al. (1973)	Heavy equipment operators.	34,156	1964–78	Job histories, latency, & years of union membership.		SMR = 1.30 for 4,075 "normal" retirees.	(*)	Increasing trend in SMR with latency and (up to 15 yr) with duration of union membership. No adjustment for healthy worker effect.
						SMR = 3.43 for "high exposure" dozer operators with 15–19 yr union membership & ≥20 yr latency.	(*)	

[a] RR = Relative Risk; SMR = Standardized Mortality Ratio. Values greater than 1.0 indicate excess prevalence of lung cancer associated with diesel exposure.
[b] An asterisk (*) indicates statistical significance based on 2-tailed test at confidence level of at least 95%.

TABLE III–5.—SUMMARY OF PUBLISHED INFORMATION FROM 20 CASE-CONTROL STUDIES ON LUNG CANCER AND EXPOSURE TO DIESEL EXHAUST

Study	Cases	Controls	Number of cases	Number of controls	Exposure assessment	Matching		Findings [a]	Stat. sig. [b]	Comments
						Smk.	Additional			
Benhamou et al. (1988).	Histologically confirmed lung cancers.	Non-tobacco released diseases.	1,625	3,091	Occupational history by questionnaire.	√	sex, age at diagnosis, hospital, interviewer.	RR=2.14 for miners.	(*)	Mine type not reported.

TABLE III–5.—SUMMARY OF PUBLISHED INFORMATION FROM 20 CASE-CONTROL STUDIES ON LUNG CANCER AND EXPOSURE TO DIESEL EXHAUST—Continued

Study	Cases	Controls	Number of cases	Number of controls	Exposure assessment	Matching		Findings [a]	Stat. sig.[b]	Comments
						Smk.	Additional			
								RR=1.42 for professional drivers.	(*)	No evidence of an increase in risk with duration of exposure.
Boffetta et al. (1990).	Hospitalized males with histologically confirmed lung cancer.	Hospitalized males with no tobacco related disease.	2,584	5,099	Occupation classified by probability of diesel exposure.	√	Sex, age within 2 yr, hospital, year of interview.	OR=0.95 for 13 jobs with probable exposure. OR=1.49 for more than 30 yr in "probable" jobs.		Adjusted for race, asbestos exposure, education, & number of cigarettes per day.
Do			477	846	Occupational history & duration of diesel exposure by interview.	√	.....do	OR=1.21 for any self-reported diesel exposure. OR=2.39 for more than 30 yr of self-reported diesel exposure..		
Brüske-Hohlfeld et al. (1999).	Cytologically and/or histologically confirmed lung cancers.	Randomly selected from compulsory registries of residents.	3,498	3,541	Occupational history by interview; total duration of diesel exposure compiled from individual job episodes.	√	Sex, age, region of residence.	OR=1.43 for any occupational diesel exposure during lifetime. OR=1.56 for West German professional drivers post-1955. OR=2.88 for > 20 yr in "traffic-related" jobs other than driving. OR=6.81 for > 30 yr as full-time driver of farm tractors. OR=4.30 for > 20 yr as heavy equipment operator.	(*) (*) (*) (*) (*)	Adjusted for cumulative smoking & asbestos exposure. All interviews conducted directly with cases and controls. Lack of elevated risk for East German professional drivers attributed to relatively low traffic density & low proportion of vehicles with diesel engines in East Germany. Non-driving "traffic-related jobs" include switchmen & operators of diesel locomotives & forklifts.
Buiatti et al. (1985).	Histologically confirmed lung cancers.	Patients at same hospital.	376	892	Occupational history from interview.	√	Sex, age, admission date.	OR=1.8 for taxi drivers.		Adjusted for current and past smoking patterns and for asbestos exposure.
Coggon et al. (1984).	Lung cancer deaths of males under 40.	Deaths from other causes in males under 40.	598	1,180	Occupation from death certificate, classified as high, low, or no diesel exposure.		Sex, death year, region, and birth year (approx.).	RR=1.3 for all jobs with diesel exposure. RR=1.1 for jobs classified as high exposure.	(*)	Only most recent full-time occupation recorded on death certificate.
Damber & Larsson (1985).	Male patients with lung cancer.	One living and one deceased without lung cancer.	604	1,071	Job, with tenure, from mailed questionnaire.	√	Sex, death year, age, municipality.	RR=1.9 for non-smoking truck drivers aged <70 yr. RR=4.5 for non-smoking truck drivers aged ≥70 yr.	(*)	Ex-smokers who did not smoke for at least last 10 years included with non-smokers.

TABLE III–5.—SUMMARY OF PUBLISHED INFORMATION FROM 20 CASE-CONTROL STUDIES ON LUNG CANCER AND EXPOSURE TO DIESEL EXHAUST—Continued

Study	Cases	Controls	Number of cases	Number of controls	Exposure assessment	Matching		Findings [a]	Stat. sig.[b]	Comments
						Smk.	Additional			
DeCoufle et al. (1997).	Male patients with lung cancer.	Non-neoplastic disease patients.	6,434	([c])	Occupation only, from questionnaire.	√	Unmatched	RR=0.92 for bus, taxi, and truck drivers. RR=0.94 for locomotive engineers.		Selected occupation compared to clerical workers. Positive associations found before smoking adjustment.
Emmelin et al. (1993).	Deaths from primary lung cancer among dock workers.	Dock workers without lung cancer.	50	154	Semi-quantitative from work history & records of diesel fuel usage.	√	Date of birth, port, and survival to within 2 years of case's diagnosis of lung cancer.	RR = 1.6 for "medium" duration of exposure.. RR = 2.9 for "high" duration of exposure.		Increasing relative risk also observed using exposure estimates based on machine usage & diesel fuel consumption. Confounding from asbestos may be significant.
Garshick et al. (1987).	Deaths with primary lung cancer among railroad workers.	Deaths from other than cancer, suicide, accidents, or unknown causes.	1,256	2,385	Job history and tenure combined with current exposure levels measured for each job.	√	Date of birth and death.	RR = 1.41 for 20+ diesel-years in workers aged ≤ 64 yr.. RR = 0.91 for 20+ diesel-years in workers aged ≥ 65 yr.	(*)	Adjusted for asbestos exposure. Older workers had relatively short diesel exposure, or none.
Gustavsson et al. (1990).	Deaths from lung cancer among bus garage workers.	Non-cases within cohort mortality study.	20	120	Semi-quantitative based on job, tenure, & exposure class for each job.		Born within two years of case.	RR = 1.34, 1.81, and 2.43 for increasing cumulative diesel exposure categories, relative to lowest exposure category.	(*)	Authors judged smoking habits to be similar for different exposure categories. RR did not increase with increasing asbestos exposure.
Hall & Wynder (1984).	Hospitalized males with lung cancer.	Hospitalized males with no tobacco-related diseases.	502	502	Usual occupation by interview.	√	Age, race, hospital, and hospital room status.	RR = 1.4 for jobs with diesel exposure.. RR = 1.9 for heavy equipment operators & repairmen.		Confounding with other occupational exposures possible.
Hayes et al. (1989).	Lung cancer deaths pooled from 3 studies.	Various—lung disease excluded.	2,291	2,570	Occupational history by interview.	√	Sex, age, and either race or area of residence.	OR = 1.5 for ≥ 10 yr truck driving. OR = 2.1 for ≥ 10 yr operating heavy equipment. OR = 1.7 for ≥ 10 yr bus driving.	(*)	OR adjusted for birth-year cohort and state of residence (FL, NJ, or LA), in addition to average cigarette use. Smaller OR for < 10 yr in these jobs.
Lerchen et al. (1987).	New Mexico residents with lung cancer.	Medicare recipients.	506	771	Occupational history, industry, & self-reported exposure, by interview.	√	Sex, age, ethnicity.	OR = 0.6 for ≥ 1 yr occupational exposure to diesel exhaust.. OR = 2.1 for underground non-uranium mining.		Small number of cases and controls in diesel-exposed jobs. Possibly insufficient exposure duration. Not matched on date of birth or death.

TABLE III–5.—SUMMARY OF PUBLISHED INFORMATION FROM 20 CASE-CONTROL STUDIES ON LUNG CANCER AND EXPOSURE TO DIESEL EXHAUST—Continued

Study	Cases	Controls	Number of cases	Number of controls	Exposure assessment	Matching		Findings [a]	Stat. sig.[b]	Comments
						Smk.	Additional			
Milne et al. (1983).	Lung cancer deaths.	Deaths from any other cancer.	925	6,565	Occupation from death certificate.		None	OR = 3.5 for bus drivers. OR = 1.6 for truck drivers.	(*)	Inadequate latency allowance.
Morabia et al. (1992).	Male lung cancer patients.	Patients without lung cancer or other tobacco-related condition.	1,793	3,228	Job, with coal and asbestos exposure durations, by interview.	√	Race, age, hospital, and smoking history.	OR=2.3 for miners.. OR=1.1 for bus drivers.. OR=1.0 for truck or tractor drivers.		Mine type not specified. Potential confounding by other occupational exposures for miners.
Pfluger and Minder (1994).	Professional drivers.	Workers in occupational categories with no known excess lung cancer risk.	284	1,301	Occupation only, from death certificate.		None	OR=1.48 for professional drivers.	(*)	Stratified by age. Indirectly adjusted for smoking, based on smoking-rate for occupation.
Siemiatycki et al. (1988).	Squamous cell lung cancer patients by type of lung cancer.	Other cancer patients.	359	1,523	Semi-quantitative, from occupational history by interview, & exposure class for each job.	√	None	OR=1.2 for diesel exposure;. OR=2.8 for mining.		Stratified by age, socioeconomic status, ethnicity, and blue- vs. white-collar job history. Examination of files indicated that most miners ''were exposed to diesel exhaust for short periods of time.'' Mining included quarrying, so result is likely to be confounded by silica exposure.
Steenland et al. (1990, 1992, 1998).	Deaths from lung CA among Teamsters.	Deaths other than lung or bladder cancer or motor vehicle accidents.	996	1,085	Occupational history and tenure from next-of-kin, supplemented by IH data.	√	Time of death within 2 years.	OR=1.27 for diesel truck drivers with 1–24 yr tenure.. OR=1.26 for diesel truck drivers with 25–34 yr tenure.. OR=1.89 for diesel truck drivers with ≥35 yr tenure.. OR=1.50 for truck mechanics with ≥18 yr tenure after 1959.	(*)	Years of tenure not necessarily all at main job (i.e., diesel truck driver). OR adjusted for asbestos exposure.

TABLE III–5.—SUMMARY OF PUBLISHED INFORMATION FROM 20 CASE-CONTROL STUDIES ON LUNG CANCER AND EXPOSURE TO DIESEL EXHAUST—Continued

Study	Cases	Controls	Number of cases	Number of controls	Exposure assessment	Matching		Findings [a]	Stat. sig.[b]	Comments
						Smk.	Additional			
Swanson et al. (1993) See also Burns & Swanson (1991).	Histologically confirmed Detroit metro area lung cancers.	Colon or rectal cancer cases.	[d] 3,792 [e] 5,935	[d] 1,966 [e] 3,956	Occupational history from interview.	√	None	OR = 1.4 for heavy truck drivers with 1–9 yr tenure. OR = 1.6 for heavy truck drivers with 10–19 yr tenure OR = 2.5 for heavy truck drivers with ≥20 yr tenure	(*)	OR for truck drivers & RR workers is for white males, relative to corresponding group with < 1 yr tenure, adjusted for age at diagnosis. Pattern of increasing risk with duration of employment also reported for black male railroad workers, based on fewer cases. (1993 report).
								OR = 1.2 for railroad workers with 1–9 yr tenure. OR = 2.5 for railroad workers with ≧10 yr tenure	(*)	
								OR = 2.98 for mining industry workers.	(*)	OR for mining machinery operators and mining is for all males, adjusted for race and age at diagnosis. Type of mining not reported. Potential confounding by.
								OR = 5.03 for mining machinery operators	(*)	
Williams et al. (1977).	Male lung cancer patients.	Other male cancer patients.	432	2,817	Main lifetime occupation from interview.	√	Sex	OR = 1.52 for male truck drivers.		Controlled for age, race, alcohol use, and socioeconomic status. Unexplained discrepancies in reported number of controls.

[a] RR = Relative Risk; OR = Odds Ratio. Values greater than 1.0 indicate excess prevalence of lung cancer associated with diesel exposure.
[b] An asterisk (*) indicates statistical significance based on 2-tailed test at confidence level of at least 95%.
[c] Not reported. [d] Males. [e] Total.

(i) Evaluation Criteria. Several commenters contended that MSHA paid more attention to positive studies than to negative ones and indicated that MSHA had not sufficiently explained its reasons for discounting studies they regarded as providing negative evidence. MSHA used five principal criteria to evaluate the strengths and weaknesses of the individual studies:

(1) power of the study to detect an exposure effect;

(2) composition of comparison groups;

(3) exposure assessment;

(4) statistical significance; and

(5) potential confounders.

These criteria are consistent with those proposed by the HEI Diesel Epidemiology Expert Panel (HEI, 1999). To help explain MSHA's reasons for valuing some studies over others, these five criteria will now be discussed in turn.

Power of The Study

There are several factors that contribute to a study's power, or ability to detect an increased risk of lung cancer in an exposed population. First is the study's size—i.e., the number of subjects in a cohort or the number of lung cancer cases in a case-control study. If few subjects or cases are included, then any statistical relationships are likely to go undetected. Second is the duration and intensity of exposure among members of the exposed group. The greater the exposure, the more likely it is that the study will detect an effect if it exists. Conversely, a study in which few members of the exposed group experienced cumulative exposures

significantly greater than the background level is unlikely to detect an exposure effect. Third is the length of time the study allows for lung cancer to exhibit a statistical impact after exposure begins. This involves a latency period, which is the time required for lung cancer to develop in affected individuals, or (mainly pertaining to cohort studies) a follow-up period, which is the time allotted, including latency, for lung cancers in affected individuals to show up in the study. It is generally acknowledged that lung cancer studies should, at the very minimum, allow for a latency period of at least 10 years from the time exposure begins and that it is preferable to allow for latency periods of at least 20 years. The shorter the latency allowance, the less power the study has to detect any increased risk of lung cancer that may be associated with exposure.

As stated above, six of the 47 studies did not show positive results: One of these studies (Edling et al.) was based on a small cohort of 694 bus workers, thus having little statistical power. Three other of these studies (DeCoufle, Kaplan, and Christie) included exposed workers for whom there was an inadequate latency allowance (i.e., less than 10 years). The entire period of follow-up in the Kaplan study was 1953–1958. The Christie study was designed in such a way as to provide for neither a minimum period of exposure nor a minimum period of latency: the report covers lung cancers diagnosed only through 1992, but the ''exposed'' cohort includes workers who may have entered the work force (and thus begun their exposure) as late as Dec. 31, 1992. Such workers would not be expected to develop lung cancer during the study period. The remaining two negative studies (Bender, 1989 and Waller, 1981) appear to have been included a reasonably adequate number of exposed workers and to have allowed for an adequate latency period.

Some of the 41 positive studies also had little power, either because they included relatively few exposed workers (*e.g.,* Lerchen et al., 1987, Ahlman et al., 1991; Gustavsson et al., 1990) or an inadequate latency allowance or follow-up period (*e.g.,* Leupker and Smith (1978); Milne, 1983; Rushton et al., 1983). In those based on few exposed workers, there is a strong possibility that the positive association arose merely by chance.[30] The other studies, however, found increased prevalence of lung cancer despite the relatively short periods of latency and follow-up time involved. It should be noted that, for reasons other than lack of power, MSHA places very little weight on the Milne and Rushton studies. As mentioned in Table III–4, the Rushton study compared the cohort to the national population, with no adjustment for regional or socioeconomic differences. This may account for the excess rate of lung cancers reported for the exposed ''general hand'' job category. The Milne study did not control for potentially important ''confounding'' variables, as explained below in MSHA's discussion of that criterion.

Composition of Comparison Groups

This criterion addresses the question of how equitable is the comparison between the exposed and unexposed populations in a cohort study, or between the subjects with lung cancer (i.e., the ''cases'') and the subjects without lung cancer (i.e., the ''controls'') in a case-control study. MSHA includes bias due to confounding variables under this criterion if the groups differ systematically with respect to such factors as age or exposure to non-diesel carcinogens. For example, unless adequate adjustments are made, comparisons of underground miners to the general population may be systematically biased by the miners' greater exposure to radon gas. Confounding not built into a study's design or otherwise documented is considered potential rather than systematic and is considered under a separate criterion below. Other factors included under the present criterion are systematic (i.e., ''differential'') misclassification of those placed into the ''exposed'' and ''unexposed'' groups, selection bias, and bias due to the ''healthy worker effect.''

In several of the studies, a group identified with diesel exposure may have systematically included workers who, in fact, received little or no occupational diesel exposure. For example, a substantial percentage of the ''underground miner'' subgroup in Waxweiler et al. (1973) worked in underground mines with no diesel equipment. This would have diluted any effect of dpm exposure on the group of underground miners as a whole.[31] Similarly, the groups classified as miners in Benhamou et al. (1988), Boffetta et al. (1988), and Swanson et al. (1993) included substantial percentages of miners who were probably not occupationally exposed to diesel emissions. Potential effects of exposure misclassification are discussed further under the criterion of ''Exposure Assessment'' below.

Selection bias refers to systematic differences in characteristics of the comparison groups due to the criteria and/or methods used to select those included in the study. For example, three of the cohort studies (Raffle, 1957; Leupker and Smith, 1976; Waller, 1981) systematically excluded retirees from the cohort of exposed workers—but not from the population used for comparison. Therefore, cases of lung cancer that developed after retirement were counted against the comparison population but not against the cohort. This artificially reduced the SMR calculated for the exposed cohort in these three studies.

Another type of selection bias may occur when members of the control group in a case-control study are non-randomly selected. This happens when cases and controls are selected from the same larger population of patients or death certificates, and the controls are simply selected (prior to case matching) from the group remaining after those with lung cancer are removed. Such selection can lead to a control group that is biased with respect to occupation and smoking habits. Specifically, ''* * * a severely distorted estimate of the association between exposure to diesel exhaust and lung cancer, and a severely distorted picture of the direction and degree of confounding by cigarette smoking, can come from case-control studies in which the controls are a collection of 'other deaths' '' when the cause of most 'other deaths' is itself correlated with smoking or occupational choice (HEI, 1999). This selection bias can distort results in either direction.

MSHA judged that seven of the 20 available case-control studies were susceptible to this type of selection bias because controls were drawn from a population of ''other deaths'' or ''other patients.''[32] These control groups were likely to have over-represented cases of cardiovascular disease, which is known to be highly correlated with smoking and is possibly also correlated with

[30] As noted in Table III–4, the underground sulfide ore miners studied by Ahlman et al. (1991) were exposed to radon in addition to diesel emissions. The total number of lung cancers observed, however, was greater than what was attributable to the radon exposure, based on a calculation by the authors. Therefore, the authors attributed a portion of the excess risk to diesel exposure.

[31] Furthermore, as pointed out in comments submitted by Dr. Peter Valberg through the NMA, the subgroup of underground miners working at mines with diesel engines was small, and the exposure duration in one of the mines with diesel engines was only ten years. Therefore, the power of the study was inadequate to detect an excess risk of lung cancer for that subgroup by itself.

[32] These were: Buiatti et al. (1985), Coggan et al. (1984), DeCoufle et al. (1977), Garshick et al. (1987), Hayes et al. (1989), Lerchen et al. (1987), and Steenland et al. (1990).

occupation. The only case-control study not reporting a positive result (DeCoufle et al., 1977) fell into this group of seven. The remaining 13 case-control studies all reported positive results.

It is ''well established that persons in the work force tend to be 'healthier' than persons not employed, and therefore healthier than the general population. Worker mortality tends to be below average for all major causes of death.'' (HEI, 1999) Because workers tend to be healthier than non-workers, the prevalence of disease found among workers exposed to a toxic substance may be lower than the rate prevailing in the general population, but higher than the rate occurring in an unexposed population of similar workers. This phenomenon is called the ''healthy worker effect.''

All five cohort studies reporting entirely negative results drew comparisons against the general population and made no adjustments to take the healthy worker effect into account. (Kaplan, 1959; Waller (1981); Edling et al. (1987); Bender et al. (1989); Christie et al. (1995). The sixth negative study (DeCoufle, 1977) was a case-control study in which vehicle drivers and locomotive engineers were compared to clerical workers. As mentioned earlier, this study did not meet the criterion for a minimum 10-year latency period. All other studies in which exposed workers were compared against similar but unexposed workers reported some degree of elevated lung cancer risk for exposed workers.

Many of the 41 positive studies also drew comparisons against the general population with no compensating adjustment for the healthy worker effect. But the healthy worker effect can influence results even when the age-adjusted mortality or morbidity rate observed among exposed workers is greater than that found in the general population. In such studies, comparison with the general population tends to reduce the excess risk attributable to the substance being investigated. For example, Gustafsson et al. (1986), Rushton et al. (1983), and Wong et al. (1985) each reported an unadjusted SMR exceeding 1.0 for lung cancer in exposed workers and an SMR significantly less than 1.0 for all causes of death combined. Since the SMR for all causes is less than 1.0, there is evidence of a healthy worker effect. Therefore, the SMR reported for lung cancer was probably lower than if the comparison had been made against a more similar population of unexposed workers. Bhatia et al. (1998) constructed a simple estimate of the healthy worker effect evident in these studies, based on the SMR for all causes of death except lung cancer. This estimate was then used to adjust the SMR reported for lung cancer. For the three positive studies mentioned, the adjustment raised the SMR from 1.29 to 1.48, from 1.01 to 1.23, and from 1.07 to 1.34, respectively.[33]

Exposure Assessment

Many commenters suggested that a lack of concurrent exposure measurements in available studies limits their utility for quantitative risk assessment (QRA). MSHA is fully aware of these limitations but also recognizes that less desirable surrogates of exposure must frequently be employed out of practical necessity. As stated by HEI's expert panel on diesel epidemiology:

> Quantitative measures of exposures are important in any epidemiologic study used for QRA. The greater the detail regarding specific exposure, including how much, for how long, and at what concentration, the more useful the study is for this purpose. Frequently, however, individual measurements are not available, and surrogate measures or markers are used. For example, the most general surrogate measures of exposure in occupational epidemiologic studies are job classification and work location. (HEI, 1999)

It is important to distinguish, moreover, between studies used to identify a hazard (i.e., to establish that dpm exposure is associated with an excess risk of lung cancer) and studies used for QRA (i.e., to quantify the amount of excess risk corresponding to a given level of exposure). Although detailed exposure measurements are desirable in any epidemiologic study, they are more important for QRA than for identifying and characterizing a hazard. Conversely, epidemiologic studies can be highly useful for purposes of hazard identification and characterization even if a lack of personal exposure measurements renders them less than ideal for QRA.

Still, MSHA agrees that the quality of exposure assessment affects the value of a study for even hazard identification. Accordingly, MSHA has divided the 47 studies into four categories, depending on the degree to which exposures were quantified for the specific workers included. This ranking refers only to exposure assessment and does not necessarily correspond to the overall weight MSHA places on any of the studies.

The highest rank, with respect to this criterion, is reserved for studies having quantitative, concurrent exposure measurements for specific workers or for specific jobs coupled with detailed work histories. Only two studies (Johnston et al., 1997 and Säverin et al., 1999) fall into this category.[34] Both of these recent cohort studies took smoking habits into account. These studies both reported an excess risk of lung cancer associated with dpm exposure.

The second rank is defined by semi-quantitative exposure assessments, based on job history and an estimated exposure level for each job. The exposure estimates in these studies are crude, compared to those in the first rank, and they are subject to many more kinds of error. This severely restricts the utility of these studies for QRA (i.e., for quantifying the change in risk associated with various specified exposure levels). For purposes of hazard identification and characterization, however, crude exposure estimates are better than no exposure estimates at all. MSHA places two cohort studies and five case-control studies into this category.[35] All seven of these studies reported an excess risk of lung cancer risk associated with diesel exposure. Thus, results were positive in all nine studies with quantitative or semi-quantitative exposure assessments.

The next rank belongs to those studies with only enough information on individual workers to construct estimates of exposure duration. Although these studies present no data relating excess risk to specific exposure levels, they do provide excess risk estimates for those working a specified minimum number of years in a job associated with diesel exposure. One cohort study and five case-control studies fall into this category, and all six of them reported an excess risk of lung cancer.[36] With one exception

[33] A similar adjustment was applied to the SMR for lung cancer reported in one of the negative studies (Edling et al., 1987). This raised the SMR from 0.67 to 0.80. Because of insufficient data, Bhatia et al. did not carry out the adjustment for the three other studies they considered with potentially important healthy worker effects. (Bhatia et al., 1998)

[34] The study of German potash miners by Säverin et al. was introduced by NIOSH at the Knoxville public hearing prior to publication. The study, as cited, was later published in English. Although the dpm measurements (total carbon) were all made in one year, the authors provide a justification for assuming that the mining technology and type of machinery used did not change substantially during the period miners were exposed (ibid., p.420).

[35] The cohort studies are Garshick et al. (1988) and Gustavsson et al. (1990). The case-control studies are Emmelin et al. (1993), Garshick et al. (1997), Gustavsson et al. (1990), Siemiatycki et al. (1988), and Steenland et al. (1990, 1992).

[36] The cohort study is Wong et al. (1985). The case-control studies are Brüske-Hohlfeld et al. (1999), Benhamou et al. (1988), Boffetta et al. (1990), Hayes et al. (1989), and Swanson et al. (1993).

(Benhamou et al. 1988), these studies also presented evidence of increased age-adjusted risk for workers with longer exposures and/or latency periods.

The bottom rank, with respect to exposure assessment, consists of studies in which no exposure information was collected for individual workers. These studies used only job title to distinguish between exposed and unexposed workers. The remaining 32 studies, including five of the six with entirely negative results, fall into this category.

Studies basing exposure assessments on only a current job title (or even a history of job titles) are susceptible to significant misclassification of exposed and unexposed workers. Unless the study is poorly designed, this misclassification is ''nondifferential''—i.e., those who are misclassified are no more and no less likely to develop lung cancer (or to have been exposed to carcinogens such as tobacco smoke) than those who are correctly classified. If workers are sometimes misclassified nondifferentially, then this will tend to mask or dilute any excess risk attributable to exposure. Furthermore, differential misclassification in these studies usually consists of systematically including workers with little or no diesel exposure in a job category identified as ''exposed.'' This too would generally mask or dilute any excess risk attributable to exposure. Therefore, MSHA assumes that in most of these studies, more rigorous and detailed exposure assessments would have resulted in somewhat higher estimates of excess risk.

IMC Global, MARG, and some other commenters expressed special concern about potential exposure misclassification and suggested that such misclassification might be partly responsible for results showing excess risk. IMC Global, for example, quoted a textbook observation that, contrary to popular misconceptions, nondifferential exposure misclassification can sometimes bias results away from the null. MSHA recognizes that this can happen under certain special conditions. However, there is an important distinction between ''can sometimes'' and ''can frequently.'' There is an even more important distinction between ''can sometimes'' and ''in this case does.'' As noted by the HEI Expert Panel on Diesel Epidemiology (HEI, 1999, p. 48), ''* * * nondifferential misclassification most often leads to an overall underestimation of effect.'' Similarly, Silverman (1998) noted, specifically with respect to the diesel studies, that ''* * * this [exposure misclassification] bias is most likely to be nondifferential, and the effect would probably have been to bias point estimates [of excess risk] toward the null value.''

Statistical Significance

A ''statistically significant'' finding is a finding unlikely to have arisen by chance in the particular group, or statistical sample, of persons being studied. An association arising by chance would have no predictive value for exposed workers outside the sample. However, a specific epidemiologic study may fail to achieve statistical significance for two very different reasons: (1) there may be no real difference in risk between the two groups being compared, or (2) the study may lack the power needed to detect whatever difference actually exists. As described earlier, a lack of sufficient power comes largely from limitations such as a small number of subjects in the sample, low exposure and/or duration of exposure, or too short a period of latency or follow-up time. Therefore, a lack of statistical significance in an individual study does not demonstrate that the results of that study were due merely to chance—only that the study (viewed in isolation) is statistically inconclusive.

As explained earlier, MSHA classifies a reported RR, SMR, or OR (*i.e.,* the point estimate of relative risk) as ''positive'' if it exceeds 1.0 and ''negative'' if it is less than or equal to 1.0. By common convention, a positive result is considered statistically significant if its 95-percent confidence interval does not overlap 1.0. If all other relevant factors are equal, then a statistically significant positive result provides stronger evidence of an underlying relationship than one that is not statistically significant. On the other hand, a study must meet two requirements in order to provide statistically significant evidence of no positive relationship: (1) the upper limit of its 95-percent confidence interval must not exceed 1.0 by an appreciable amount[37] and (2) it must have allowed for sufficient exposure, latency, and follow-up time to have detected an existing relationship.

As shown in Tables III–4 and III–5, statistically significant positive results were reported in 25 of the 47 studies: 11 of the 19 positive case-control studies and 14 of the 22 positive cohort studies. In 16 of the 41 studies showing a positive association, the association observed was not statistically significant. Results in five of the six negative studies were not statistically significant. One of the six negative studies (Christie *et al.,* 1995, in full version), reported a statistically significant deficit in lung cancer for miners. This study, however, provided for no minimum period of exposure or latency and, therefore, lacked the power necessary to provide statistically significant evidence.[38]

Whether or not a study provides statistically significant evidence is dependent upon many variables, such as study size, adequate follow-up time (to account for enough exposure and latency), and adequate case ascertainment. In the ideal world, a sufficiently powerful study that failed to demonstrate a statistically significant positive relationship would, by its very failure, provide statistically significant evidence that an underlying relationship between an exposure and a specific disease was unlikely. It is important to note that MSHA regards a real 10-percent increase in the risk of lung cancer (*i.e.,* a relative risk of 1.1) as constituting a clearly significant health hazard. Therefore, ''sufficiently powerful'' in this context means that the study would have to be of such scale and quality as to detect a 10-percent increase in risk if it existed. The outcome of such a study could plausibly be called ''negative'' even if the estimated RR slightly exceeded 1.0—so long as the lower confidence limit did not exceed 1.0 and the upper confidence limit did not exceed 1.05. Rarely does an epidemiological study fall into this ''ideal'' study category. MSHA reviewed the dpm epidemiologic studies to determine which of them could plausibly be considered to be negative.

For example, one study (Waxweiller *et al.,* 1973) reported positive but statistically non-significant results corresponding to an RR of about 1.1. Among the studies MSHA counts as positive, this is the one that is numerically closest to being ''negative''. This study, however, relied on a relatively small cohort containing an indeterminate but probably substantial percentage of occupationally unexposed workers. Furthermore, there was no minimum latency allowance for the exposed workers. Therefore, even if MSHA were to use 1.1 rather than 1.05 as a threshold for significant relative risk, the study had insufficient statistical power to merit ''negative'' status.

One commenter (Dr. James Weeks, representing the UMWA) argued that ''MSHA's reliance on * * * statistical

[37] As a matter of practicality, MSHA places the threshold at 1.05.

[38] More detailed discussion of this study appears later in this subsection.

significance is somewhat misplaced. Results that are not significant statistically * * * can nevertheless indicate that the exposure in question caused the outcome.'' MSHA agrees that an otherwise sound study may yield positive (or negative) results that provide valuable evidence for (or against) an underlying relationship but fail, because of an insufficient number of exposed study subjects, to achieve statistical significance. In the absence of other evidence to the contrary, a single positive but not statistically significant result could even show that a causal relationship is more likely than not. By definition, however, such a result would not be conclusive at a high level of confidence. A finding of even very high excess risk in a single, well-designed study would be far from conclusive if based on a very small number of observed lung cancer cases or if it were in conflict with evidence from toxicity studies.

MSHA agrees that evidence should not be ignored simply because it is not conclusive at a conventional but arbitrary 95-percent confidence level. Lower confidence levels may represent weaker but still important evidence. Nevertheless, to rule out chance effects, the statistical significance of individual studies merits serious consideration when only a few studies are available. That is not the case, however, for the epidemiology literature relating lung cancer to diesel exposure. Since many studies contribute to the overall weight of evidence, the statistical significance of individual studies is far less important than the statistical significance of all findings combined. Statistical significance of the combined findings is addressed in Subsection 3.a.iii of this risk assessment.

Potential Confounders

There are many variables, both known and unknown, that can potentially distort the results of an epidemiologic study. In studies involving lung cancer, the most important example is tobacco smoking. Smoking is highly correlated with the development of lung cancer. If the exposed workers in a study tend to smoke more (or less) than the population to which they are being compared, then smoking becomes what is called a ''confounding variable'' or ''confounder'' for the study. In general, any variable affecting the risk of lung cancer potentially confounds observed relationships between lung cancer and diesel exposure. Conspicuous examples are age, smoking habits, and exposure to airborne carcinogens such as asbestos or radon progeny. Diet and other lifestyle factors may also be potential confounders, but these are probably less important for lung cancer than for other forms of cancer, such as bladder cancer.

There are two ways to avoid distortion of study results by a potential confounder: (1) design the study so that the populations being compared are essentially equivalent with respect to the potentially confounding variable; or (2) allow the confounding to take place, but adjust the results to compensate for its effects. Obviously, the second approach can be applied only to known confounders. Since no adjustment can be made for unknown confounders, it is important to minimize their effects by designing the comparison groups to be as similar as possible.

The first approach requires a high degree of control over the two groups being compared (exposed and unexposed in a cohort study; with and without lung cancer in a case-control study). For example, the effects of age in a case-control study can be controlled by matching each case of lung cancer with one or more controls having the same year of birth and age in year of diagnosis or death. Matching on age is never perfect, because it is generally not feasible to match within a day or even a month. Similarly, the effects of smoking in a case-control study can be imperfectly controlled by matching on smoking habits to the maximum extent possible.[39] In a cohort study, there is no confounding unless the exposed cohort and the comparison group differ with respect to a potential confounder. For example, if both groups consist entirely of never-smokers, then smoking is not a confounder in the study. If both groups contain the same percentage of smokers, then smoking is still an important confounder to the extent that smoking intensity and history differ between the two groups. In an attempt to minimize such differences (along with potentially important differences in diet and lifestyle) some studies restrict comparisons to workers of similar socioeconomic status and area of residence. Studies may also explicitly investigate smoking habits and histories and forego any adjustment of results if these factors are found to be homogeneously distributed across comparison groups. In that case, smoking would not actually appear to function as a confounder, and a smoking adjustment might not be required or even desirable. Nevertheless, a certain amount of smoking data is still necessary in order to check or verify homogeneity. The study's credibility may also be an important consideration. Therefore, MSHA agrees with the HEI's expert panel that even when smoking appears not to be a confounder,

> * * * a study is open to criticism if no smoking data are collected and the association between exposure and outcome is weak. * * * When the magnitude of the association of interest is weak, uncontrolled confounding, particularly from a strong confounder such as cigarette smoking, can have a major impact on the study's results and on the credibility of their use. [HEI, 1999]

However, this does not mean that a study cannot, by means of an efficient study design and/or statistical verification of homogeneity, demonstrate adequate control for smoking without applying a smoking adjustment.

The second approach to dealing with a confounder requires knowledge or estimation both of the differences in group composition with respect to the confounder and of the effect that the confounder has on lung cancer. Ideally, this would entail specific, quantitative knowledge of how the variable affects lung cancer risk for each member of both groups being compared. For example, a standardized mortality ratio (SMR) can be used to adjust for age differences when a cohort of exposed workers with known birth dates is compared to an unexposed reference population with known, age-dependent lung cancer rates.[40] In practice, it is not usually possible to obtain detailed information, and the effects of smoking and other known confounders cannot be precisely quantified.

Stöober and Abel (1996) argue, along with Morgan *et al.* (1997) and some commenters, that even in those epidemiologic studies that are adjusted for smoking and show a statistically significant association, the magnitude of relative or excess risk observed is too small to demonstrate any causal link between dpm exposure and cancer. Their reasoning is that in these studies, errors in the collection or interpretation of smoking data can create a bias in the results larger than any potential contribution attributable to diesel particulate. They propose that studies

[39] If cases and controls cannot be closely matched on smoking or other potentially important confounder, then a hybrid approach is often taken. Cases and controls are matched as closely as possible, differences are quantified, and the study results are adjusted to account for the differences.

[40] Since these rates may vary by race, geographic region, or other factors, the validity of this adjustment depends heavily on choice of an appropriate reference population. For example, Waxweiler *et al.* (1973) based SMRs for a New Mexico cohort on national lung cancer mortality rates. Since the national age-adjusted rate of lung cancer is about 1/3 higher than the New Mexico rate, the reported SMRs were roughly 3/4 of what they would have been if based on rates specific to New Mexico.

failing to account for smoking habits should be disqualified from consideration, and that evidence of an association from the remaining, smoking-adjusted studies should be discounted because of potential confounding due to erroneous, incomplete, or otherwise inadequate characterization of smoking histories.

It should be noted, first of all, that five of the six negative studies neither matched nor adjusted for smoking.[41] But more importantly, MSHA concurs with IARC (1989), Cohen and Higgins (1995), IPCS (1996), CAL–EPA (1998), ACGIH (1998), Bhatia *et al.* (1998), and Lipsett and Campleman (1999) in not accepting the view that studies should automatically be disqualified from consideration because of potential confounders. MSHA recognizes that unknown exposures to tobacco smoke or other human carcinogens can distort the results of some lung cancer studies. MSHA also recognizes, however, that it is not possible to design a human epidemiologic study that perfectly controls for all potential confounders. It is also important to note that a confounding variable does not necessarily inflate an observed association. For example, if the exposed members of a cohort smoke less than the reference group to which they are compared, then this will tend to reduce the apparent effects of exposure on lung cancer development. In the absence of evidence to the contrary, it is reasonable to assume that a confounder is equally likely to inflate or to deflate the results.

As shown in Tables III–4 and III–5, 18 of the published epidemiologic studies involving lung cancer did, in fact, control or adjust for exposure to tobacco smoke, and five of these 18 also controlled or adjusted for exposure to asbestos and other carcinogenic substances (Garshick *et al.*, 1987; Boffetta *et al.*, 1988; Steenland *et al.*, 1990; Morabia *et al.*, 1992; Brüske-Hohlfeld *et al.*, 1999). These results are less likely to be confounded than results from most of the studies with no adjustment. All but one of these 18 studies reported some degree of excess risk associated with occupational exposure to diesel particulate, with statistically significant results reported in eight.

In addition, several of the studies with no smoking adjustment took the first approach described above for preventing or substantially mitigating potential confounding by smoking habits: they drew comparisons against internal control groups or other control groups likely to have similar smoking habits as the exposed groups (*e.g.,* Garshick *et al.*, 1988; Gustavsson *et al.*, 1990; Hansen, 1993; and Säverin *et al.*, 1999). Therefore, MSHA places more weight on these studies than on studies drawing comparisons against dissimilar groups with no smoking controls or adjustments. This emphasis is in accordance with the conclusion by Bhatia *et al.* (1998) that smoking homogeneity typically exists within cohorts and is associated with a uniform lifestyle and social class. Although it was not yet available at the time Bhatia *et al.* performed their analysis, an analysis of smoking patterns by Säverin *et al.* (op cit.) within the cohort they studied also supports this conclusion.

IMC Global and MARG objected to MSHA's position on potential confounders and submitted comments in general agreement with the views of Morgan *et al.* (op cit.) and Stöbel and Abel (op cit.). Specifically, they suggested that studies reporting relative risks solely between 1.0 and 2.0 should be discounted because of potential confounders. Of the 41 positive studies considered by MSHA, 22 fall into this category (16 cohort and 6 case-control). In support of their suggestion, IMC Global quoted Speizer (1986), Muscat and Wynder (1995), Lee (1989), WHO (1980), and NCI (1994). These authorities all urged great caution when interpreting the results of such studies, because of potential confounders. MSHA agrees that none of these studies, considered individually, is conclusive and that each result must be considered with due caution. None of the quoted authorities, however, proposed that such studies should automatically be counted as ''negative'' or that they could not add incrementally to an aggregate body of positive evidence.

IMC Global also submitted the following reference to two Federal Court decisions pertaining to estimated relative risks less than 2.0:

> The Ninth Circuit concluded in Daubert v. Merrell Dow Pharmaceuticals'' that ''for an epidemiologic study to show causation * * * the relative risk * * * arising from the epidemiologic data will, at a minimum, have to exceed 2.'' Similarly, a District Court stated in Hall v. Baxter Healthcare Corp. 49: The threshold for concluding that an agent was more likely the cause of the disease than not is relative risk greater than 2.0. Recall that a relative risk of 1.0 means that the agent has no affect on the incidence of disease. When the relative risk reaches 2.0. the agent is responsible for an equal number of cases of disease as all other background causes. Thus a relative risk of 2.0 implies a 50% likelihood that an exposed individual's disease was caused by the agent. [IMC Global]

In contrast with the two cases cited, the purpose of this risk assessment is not to establish civil liabilities for personal injury. MSHA's concern is with reducing the risk of lung cancer, not with establishing the specific cause of lung cancer for an individual miner. The excess risk of an outcome, given an excessive exposure, is not the same thing as the likelihood that an excessive exposure caused the outcome in a given case. To understand the difference, it may be helpful to consider two analogies: (1) The likelihood that a given death was caused by a lightning strike is relatively low, yet exposure to lightning is rather hazardous; (2) a specific smoker may not be able to prove that his or her lung cancer was ''more likely than not'' caused by radon exposure, yet radon exposure significantly increases the risk—especially for smokers. Lung cancer has a variety of alternative causes, but this fact does not reduce the risk associated with any one of them.

Furthermore, there is ample precedent for utilizing epidemiologic studies reporting relative risks less than 2.0 in making clinical and public policy decisions. For example, the following table contains the RR for death from cardiovascular disease associated with cigarette smoking reported in several prospective epidemiologic studies:

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[41] The exception is DeCoufle *et al.* (1977), a case-control study that apparently did not match or otherwise adjust for age.

Study on cigarette smoking	Estimate of RR of death from cardiovascular disease
British doctors	1.6
Males in 25 states	
ages 45-64	2.08
ages 65-79	1.36
U.S. Veterans	1.74
Japanese study	1.96
Canadian veterans	1.6
Males in nine states	1.70
Swedish males	1.7
Swedish females	1.3
California occupations	2.0

Source: U.S. Department of Health and Human Services (1989)

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By IMC Global's rule of thumb, all but one or two of these studies would be discounted as evidence of increased risk attributable to smoking. These studies, however, have not been widely discounted by scientific authorities. To the contrary, they have been instrumental in establishing that cigarette smoking is a principal cause of heart disease.

A second example is provided by the increased risk of lung cancer found to be caused by residential exposure to radon progeny. As in the case of dpm, tobacco smoking has been an important potential confounder in epidemiological studies used to investigate whether exposures to radon concentrations at residential levels can cause lung cancer. Yet, in the eight largest residential epidemiological studies used to help establish the reality of this now widely accepted risk, the reported relative risks were all less than 2.0. Based on a meta-analysis of these eight studies, the combined relative risk of lung cancer attributable to residential radon exposure was 1.14. This elevation in the risk of lung cancer, though smaller than that reported in most studies of dpm effects, was found to be statistically significant at a 95-percent confidence level (National Research Council, 1999, Table G–25).

(ii) Studies Involving Miners. In the proposed risk assessment, MSHA identified seven epidemiologic studies reporting an excess risk of lung cancer among miners thought to have been exposed occupationally to diesel exhaust. As stated in the proposal, two of these studies specifically investigated miners, and the other five treated miners as a subgroup within a larger population of workers.[42] MSHA placed two additional studies specific to exposed coal miners (Christie *et al.,* 1995; Johnston *et al.,* 1997) into the public record with its Feb. 12, 1999 **Federal Register** notice. Another study,[43] investigating lung cancer in exposed potash miners, was introduced by NIOSH at the Knoxville public hearing on May 27, 1999 and later published as Säverin *et al.,* 1999. Finally, one study reporting an excess risk of lung cancer for presumably exposed miners was listed in Table III–5 as originally published, and considered by MSHA in its overall assessment, but inadvertently left out of the discussion on studies involving miners in the previous version of this risk assessment.[44] There are, therefore, available to MSHA a total of 11 epidemiologic studies addressing the risk of lung cancer for miners, and five of these studies are specific to miners.

Five cohort studies (Waxweiler *et al.,* 1973; Ahlman *et al.,* 1991; Christie *et al.,* 1996; Johnston *et al.,* 1997; Säverin *et al.,* 1999) were performed specifically on groups of miners, and one (Boffetta *et al.,* 1988) addressed miners as a subgroup of a larger population. Except for the study by Christie *et al.,* the cohort studies all showed elevated lung cancer rates for miners in general or for the most highly exposed miners within a cohort. In addition, all five case-control studies reported elevated rates of lung cancer for miners (Benhamou *et al.,* 1988; Lerchen *et al.,* 1987; Siemiatycki *et al.,* 1988; Morabia *et al.,* 1992; Burns and Swanson, 1991).

Despite the risk assessment's emphasis on human studies, some members of the mining community apparently believed that the risk assessment relied primarily on animal studies and that this was because studies on miners were unavailable. Canyon Fuels, for example, expressed concerns about relying on animal studies instead of studies on western diesel-exposed miners:

> Since there are over a thousand miners here in the West that have fifteen or more years of exposure to diesel exhaust, why has there been no study of the health status of those miners? Why must we rely on animal studies that are questionable and inconclusive?

Actually, western miners were involved in several studies of health effects other than cancer, as described earlier in this risk assessment. With respect to lung cancer, there are many reasons why workers from a particular group of mines might not be selected for study. Lung cancer often takes considerably more than 15 years to develop, and a valid study must allow not only for adequate duration of exposure but also for an adequate period of latency following exposure. Furthermore, many mines contain radioactive gases and/or respirable silica dust, making it difficult to isolate the effects of a potential carcinogen.

Similarly, at the public hearing in Albuquerque on May 13, 1999, a representative of Getchell Gold stated that he thought comparing miners to rats was irrational and that ''there has not been a study on these miners as to what the effects are.'' To correct the impression that MSHA was basing its risk assessment primarily on laboratory animal studies, an MSHA panelist pointed out Tables III–4 and III–5 of the proposed preamble and identified six studies pertaining to miners that were listed in those tables. However, he placed no special weight on these studies and cited them only to illustrate the existence of epidemiologic studies reporting an elevated risk of lung cancer among miners.

With their post-hearing comments, the NMA and MARG submitted critiques by Dr. Peter Valberg and Dr. Jonathan Borak of six reports involving miners (see Footnote 42). Drs. Valberg and Borak both noted that the six studies reviewed lacked information on diesel exposure and were vulnerable to confounders and exposure misclassification. For these reasons, Dr. Valberg judged them ''particularly poor in identifying what specific role, if any, diesel exhaust plays in lung cancer for miners.'' He concluded that they do not ''implicate diesel exposure per se as

[42] In the proposed risk assessment, the studies identified as specifically investigating miners were Waxweiler *et al.* (1973) and Ahlman *et al.* (1991). At the Albuquerque public hearing, Mr. Bruce Watzman, representing the NMA, asked a member of the MSHA panel (Mr. Jon Kogut) to list six studies involving miners that he had cited earlier in the hearing and to identify those that were specific to miners. In both his response to Mr. Watzman, and in his earlier remarks, Mr. Kogut noted that the studies involving miners were listed in Tables III–4 and III–5. However, he inadvertently neglected to mention Ahlman *et al.* (op cit.) and Morabia *et al.* (1992). (The latter study addressed miners as a subgroup of a larger population.)

In his response to Mr. Watzman, Mr. Kogut cited Swanson *et al.* (1993) but not Burns and Swanson (1991), which he had mentioned earlier in the hearing in connection with the same study. These two reports are listed under a single entry in Table III–5 (Swanson *et al.*) because they both report findings based on the same body of data. Therefore, MSHA considers them to be two parts of the same study. The 5.03 odds ratio for mining machine operators mentioned by Mr. Kogut during the hearing was reported in Burns and Swanson (1991).

Only the six studies specified by Mr. Kogut in his response to Mr. Watzman were included in separate critiques by Dr. Peter Valberg and Dr. Jonathan Borak later submitted by the NMA and by MARG, respectively. Dr. Valberg did not address Burns and Swanson (1991), and he addressed a different report by Siemiatycki than the one listed in Table III–5 and cited during the hearing (*i.e.,* Siemiatycki *et al.,* 1988). Neither Dr. Valberg nor Dr. Borak addressed Ahlman *et al.* (op cit.) or Morabia *et al.* (op cit.). Also excluded were two additional miner-specific studies placed into the record on Feb. 12, 1999 (Fed. Reg. 64:29 at 59258). Mr. Kogut did not include them in his response to Mr. Watzman, or in his prior remarks, because he was referring only to studies listed in Tables III–4 and III–5 of the published proposals. Mr. Kogut also did not include a study specific to German potash miners submitted by NIOSH at a subsequent public hearing, and this too was left out of both critiques. A published version of the study (Säverin *et al.,* 1999) was placed into the record on June 30, 2000. All of the studies involving miners are in the public record and have been available for comment by interested parties throughout the posthearing comment periods.

[43] Some commenters suggested that MSHA ''overlooked'' a recently published study on NSW miners, Brown *et al.,* 1997. This study evaluated the occurrence of forms of cancer other than lung cancer in the same cohort studied by Christie *et al.* (1995).

[44] This study was published in two separate reports on the same body of data: Burns and Swanson (1991) and Swanson *et al.* (1993). Both published reports are listed in Table III–5 under the entry for Swanson *et al.*

strongly associated with lung cancer risk in miners.'' Similarly, Dr. Borak suggested that, since they do not relate adverse health effects in miners to any particular industrial exposure, ''the strongest conclusion that can be drawn from these six studies is that the miners in the studies had an increased risk of lung cancer.''

MSHA agrees with Drs. Valberg and Borak that none of the studies they reviewed provides direct evidence of a link between dpm exposure and the excess risk of lung cancer reported for miners. (A few disagreements on details of the individual studies will be discussed below). As MSHA said at the Albuquerque hearing, the lack of exposure information on miners in these studies led MSHA to rely more heavily on associations reported for other occupations. MSHA also noted the limitations of these studies in the proposed risk assessment. MSHA explicitly stated that other epidemiologic studies exist which, though not pertaining specifically to mining environments, contain better diesel exposure information and are less susceptible to confounding by extraneous risk factors.

Inconclusive as they may be on their own, however, even studies involving miners with only presumed or sporadic occupational diesel exposure can contribute something to the weight of evidence. They can do this by corroborating evidence of increased lung cancer risk for other occupations with likely diesel exposures and by providing results that are at least consistent with an increased risk of lung cancer among miners exposed to dpm. Moreover, two newer studies pertaining specifically to miners do contain dpm exposure assessments based on concurrent exposure measurements (Johnston *et al., op cit.;* Säverin *et al., op cit.*). The major limitations pointed out by Drs. Valberg and Borak with respect to other studies involving miners do not apply to these two studies.

Case-Control Studies

Five case-control studies, all of which adjusted for smoking, found elevated rates of lung cancer for miners, as shown in Table III–5. The results for miners in three of these studies (Benhamou *et al.,* 1988; Morabia *et al.,* 1992; Siemiatycki *et al.,* 1988) are given little weight, partly because of possible confounding by occupational exposure to radioactive gasses, asbestos, and silica dust. Also, Benhamou and Morabia did not verify occupational diesel exposure status for the miners. Siemiatycki performed a large number of multiple comparisons and reported that most of the miners ''were exposed to diesel exhaust for short periods of time,'' Lerchen *et al.* (1987) showed a marginally significant result for underground non-uranium miners, but cases and controls were not matched on date of birth or death, and the frequency of diesel exposure and exposure to known occupational carcinogens among these miners was not reported.

Burns and Swanson (1991)[45] reported elevated lung cancer risk for miners and especially mining machine operators, which the authors attributed to diesel exposure. Potential confounding by other carcinogens associated with mining make the results inconclusive, but the statistically significant odds ratio of 5.0 reported for mining machine operators is high enough to cause concern with respect to diesel exposures, especially in view of the significantly elevated risks reported in the same study for other diesel-exposed occupations. The authors noted that the ''occupation most likely to have high levels of continuous exposure to diesel exhaust and to experience that exposure in a confined area has the highest elevated risks: mining machine operators.''

Cohort Studies

As shown in Table III–4, MSHA identified six cohort studies reporting results for miners likely to have been exposed to dpm. An elevated risk of lung cancer was reported in five of these six studies. These results will be discussed chronologically.

Waxweiller (1973) investigated a cohort of underground and surface potash miners. The authors noted that potash ore ''is not embedded in siliceous rock'' and that the ''radon level in the air of potash mines is not significantly higher than in ambient air.'' Contrary to Dr. Valberg's review of this study, the number of lung cancer cases was reported to be slightly higher than expected, for both underground and surface miners, based on lung cancer rates in the general U.S. population (after adjustment for age, sex, race, and date of death). Although the excess was not statistically significant, the authors noted that lung cancer rates in the general population of New Mexico were about 25 percent lower than in the general U.S. population. They also noted that a higher than average percentage of the miners smoked and that this would ''tend to counterbalance'' the adjustment needed for geographic location. The authors did not, however, consider two other factors that would tend to obscure or deflate an excess risk of lung cancer, if it existed: (1) a healthy worker effect and (2) the absence of any occupational diesel exposure for a substantial percentage of the underground miners.

MSHA agrees with Dr. Valberg's conclusion that ''low statistical power and indeterminate diesel-exhaust exposure render this study inadequate for assessing the effect of diesel exhaust on lung-cancer risk in miners.'' However, given the lack of any adjustment for a healthy worker effect, and the likelihood that many of the underground miners were occupationally unexposed, MSHA views the slightly elevated risk reported in this study as consistent with other studies showing significantly greater increases in risk for exposed workers.

Boffetta *et al.* (1988) investigated mortality in a cohort of male volunteers who enrolled in a prospective study conducted by the American Cancer Society. Lung cancer mortality was analyzed in relation to self-reported diesel exhaust exposure and to employment in various occupations identified with diesel exhaust exposure, including mining. After adjusting for smoking patterns,[46] there was a statistically significant excess of 167 percent (RR = 2.67) in lung cancers among 2034 workers ever employed as miners, compared to workers never employed in occupations associated with diesel exposure. No analysis by type of mining was reported. Other findings reported from this study are discussed in the next subsection.

Although an adjustment was made for smoking patterns, the relative risk reported for mining did not control for exposures to radioactive gasses, silica dust, and asbestos. These lung carcinogens are probably present to a greater extent in mining environments than in most of the occupational environments used for comparison. Self-reported exposures to asbestos and stone dusts were taken into account in other parts of the study, but not in the calculation of excess lung cancer risks associated with specific occupations, including mining.

[45] This report is listed in Table III–5 under Swanson *et al.* (1993), which provides further analysis of the same body of data.

[46] During the public hearing on May 25, 1999, Mr. Mark Kaszniak of IMC Global incorrectly asserted that ''smoking was treated in a simplistic way in this study by using three categories: smokers, ex-smokers, and non-smokers.'' The study actually used five categories, dividing smokers into separate categories for 1–20 cigarettes per day, 21 or more cigarettes per day, and exclusively pipe and/or cigar smoking.

Several commenters reiterated two caveats expressed by the study's authors and noted in Table III–4. These are (1) that the study is susceptible to selection biases because participants volunteered and because the age-adjusted mortality rates differed between those who provided exposure information and those who did not; and (2) that all exposure information was self-reported with no quantitative measurements. Since these caveats are not specific to mining and pertain to most of the study's findings, they will be addressed when this study's overall results are described in the next subsection.

One commenter, however, (Mr. Mark Kaszniak of IMC Global) argued that selection bias due to unknown diesel exposure status played an especially important role in the RR calculated for miners. About 21 percent of all participants provided no diesel exposure information. Mr. Kaszniak noted that diesel exposure status was unknown for an even larger percentage of miners and suggested that the RR calculated for miners was, therefore, inflated. He presented the following argument:

> In the miner category, this [unknown diesel exposure status] accounted for 44.2% of the study participants, higher than any other occupation studied. This is important as this group experienced a higher mortality for all causes as well as lung cancer than the analyzed remainder of the cohort. If these persons had been included in the ''no exposure to diesel exhaust group,'' their inclusion would have lowered any risk estimates from diesel exposure because of their higher lung cancer rates. [IMC Global post-hearing comments]

This argument, which was endorsed by MARG, was apparently based on a misunderstanding of how the comparison groups used to generate the RR for mining were defined.[47] Actually, persons with unknown diesel exposure status were included among the miners, but excluded from the reference population. Including sometime miners with unknown diesel exposure status in the ''miners'' category would tend to mask or reduce any strong association that might exist between highly exposed miners and an increased risk of lung cancer. Excluding persons with unknown exposure status from the reference population had an opposing effect, since they happened to experience a higher rate of lung cancer than cohort members who said they were unexposed. Therefore, removing ''unknowns'' from the ''miner'' group and adding them to the reference group could conceivably shift the calculated RR for miners in either direction. However, the RR reported for persons with unknown diesel exposure status, compared to unexposed persons, was 1.4 (ibid., p. 412)—which is smaller than the 2.67 reported for miners. Therefore, it appears more likely that the RR for mining was deflated than inflated on account of persons with unknown exposure status.

Although confounders and selection effects may have contributed to the 2.67 RR reported for mining, MSHA believes this result was high enough to support a dpm effect, especially since elevated lung cancer rates were also reported for the three other occupations associated with diesel exhaust exposure. Dr. Borak stated without justification that ''[the] association between dpm and lung cancer was confounded by age, smoking, and other occupational exposures * * *.'' He ignored the well-documented adjustments for age and smoking. Although it does not provide strong or direct evidence that dpm exposure was responsible for any of the increased risk of lung cancer observed among miners, the RR for miners is consistent with evidence provided by the rest of the study results.

Ahlman *et al.* (1991) studied cohorts of 597 surface miners and 338 surface workers employed at two sulfide ore mines using diesel powered front-end loaders and haulage equipment. Both of these mines (one copper and one zinc) were regularly monitored for alpha energy concentrations (*i.e.*, due to radon progeny), which were at or below the Finish limit of 0.3 WL throughout the study period. The ore in both mines contained arsenic only as a trace element (less than 0.005 percent). Lung cancer rates in the two cohorts were compared to rates for males in the same province of Finland. Age-adjusted excess mortality was reported for both lung cancer and cardiovascular disease among the underground miners, but not among the surface workers. None of the underground miners who developed lung cancer had been occupationally exposed to asbestos, metal work, paper pulp, or organic dusts. Based on the alpha energy concentration measurements made for the two mines, the authors calculated that not all of the excess lung cancer for the underground miners was attributable to radon exposure. Based on a questionnaire, the authors found similar underground and surface age-specific smoking habits and alcohol consumption and determined that ''smoking alone cannot explain the difference in lung cancer mortality between the [underground] miners and surface workers.'' Due to the small size of the cohort, the excess lung cancer mortality for the underground miners was not statistically significant. However, the authors concluded that the portion of excess lung cancer not attributable to radon exposure could be explained by the combined effects of diesel exhaust and silica exposure. Three of the ten lung cancers reported for underground miners were experienced by conductors of diesel-powered ore trains.

Christie *et al.* (1994, 1995) studied mortality in a cohort of 23,630 male Australian (New South Wales, NSW) coal mine workers who entered the industry after 1972. Although the majority of these workers were underground miners, most of whom were presumably exposed to diesel emissions, the cohort included office workers and surface (''open cut'') miners. The cohort was followed up through 1992. After adjusting for age, death rates were lower than those in the general male population for all major causes except accidents. This included the mortality rate for all cancers as a group (Christie *et al.*, 1995, Table 1). Lower-than-normal incidence rates were also reported for cancers as a group and for lung cancer specifically (Christie *et al.*, 1994, Table 10).

The investigators noted that the workers included in the cohort were all subject to pre-employment physical examinations. They concluded that ''it is likely that the well known 'healthy worker' effect * * * was operating'' and that, instead of comparing to a general population, ''a more appropriate comparison group is Australian petroleum industry workers.'' (Christie *et al.*, 1995) In contrast to the comparison with the population of NSW, the all-cause standardized mortality ratio (SMR) for the cohort of coal miners was greater than for petroleum workers by a factor of over 20 percent—*i.e.*, 0.76 vs. 0.63 (ibid., p. 20). However, the investigators did not

[47] During the public hearing on May 25, 1999, Mr. Kaszniak stated his belief that, for miners, the ''relative risk calculation excluded that 44% of folks who did not respond to the questionnaire with regards to diesel exposure.'' Contrary to Mr. Kaszniak's belief, however, the ''miners'' on which the 2.67 RR was based included all 2034 cohort members who had ever been a miner, regardless of whether they had provided diesel exposure information (see Boffetta *et al.*, 1988, p. 409).

Furthermore, the 44.2-percent nonrespondent figure is not pertinent to potential selection bias in the RR calculation reported for miners. The group of 2034 ''sometime'' miners used in that calculation was 65 percent larger than the group of 1233 ''mainly'' miners to which the 44-percent nonrespondent rate applies. The reference group used for comparison in the calculation consisted of all cohort members ''with occupation different from those listed [*i.e.*, railroad workers, truck drivers, heavy equipment operators, and miners] and not exposed [to diesel exhaust].'' The overall nonrespondent rate for occupations in the reference group was about 21 percent (calculated by MSHA from Table VII of Boffetta *et al.*, 1988).

compare the cohort to petroleum workers specifically with respect to lung cancer or other causes of death. Nor did they adjust for a healthy worker effect or make any attempt to compare mortality or lung cancer rates among workers with varying degrees of diesel exposure within the cohort.

Despite the elevated SMR relative to petroleum workers, several commenters cited this study as evidence that exposure to diesel emissions was not causally associated with an increased risk of lung cancer (or with adverse health effects associated with fine particulates). These commenters apparently ignored the investigators' explanation that the low SMRs they reported were likely due to a healthy worker effect. Furthermore, since the cohort exhibited lower-than-normal mortality rates due to heart disease and non-cancerous respiratory disease, as well as to cancer, there may well have been less tobacco smoking in the cohort than in the general population. Therefore, it is reasonably likely that the age-adjusted lung cancer rate would have been elevated, if it had been adjusted for smoking and for a healthy worker effect based on mortality from causes other than accidents or respiratory disease. In addition, the cohort SMR for accidents (other than motor vehicle accidents) was significantly above that of the general population. Since the coal miners experienced an elevated rate of accidental death, they had a lower-than-normal chance to die from other causes or to develop lung cancer. The investigators made no attempt to adjust for the competing, elevated risk of death due to occupational accidents.

Given the lack of any adjustment for smoking, healthy worker effect, or the competing risk of accidental death, the utility of this study in evaluating health consequences of Dpm exposure is severely limited by its lack of any internal comparisons or comparisons to a comparable group of unexposed workers. Furthermore, even if such adjustments or comparisons were made, several other attributes of this study limit its usefulness for evaluating whether exposure to diesel emissions is associated with an increased risk of lung cancer. First, the study was designed in such a way as to allow inadequate latency for a substantial portion of the cohort. Although the cohort was followed up only through 1992, it includes workers who entered the workforce at the end of 1992. Therefore, there is no minimum duration of occupational exposure for members of the cohort. Approximately 30 percent of the cohort was employed in the industry for less than 10 years, and the maximum duration of employment and latency combined was 20 years. Second, average age for members of the cohort was only 40 to 50 years (Christie *et al.*, p. 7), and the rate of lung cancer was based on only 29 cases. The investigators acknowledged that ''it is a relatively young cohort'' and that ''this means a small number of cancers available for analysis, because cancer is more common with advancing age * * *.'' They further noted that ''* * * the number of cancers available for analysis is increasing very rapidly. As a consequence, every year that passes makes the cancer experience of the cohort more meaningful in statistical terms.'' (ibid., p. 27) Third, miners's work history was not tracked in detail, beyond identifying the first mine in which a worker was employed. Some of these workers may have been employed, for various lengths of time, in both underground and surface operations at very different levels of diesel exposure. Without detailed work histories, it is not possible to construct even semi-quantitative measures of diesel exposure for making internal comparisons within the cohort.

One commenter (MARG) claimed that this (NSW) study ''* * * reflects the latest and best scientific evidence, current technology, and the current health of miners'' and that it ''is not rational to predicate regulations for the year 2000 and beyond upon older scientific studies * * *.'' For the reasons stated above, MSHA believes, to the contrary, that the NSW study contributes little or no information on the potential health effects of long-term dpm exposures and that whatever information it does contribute does not extend to effects, such as cancer, expected in later life.

Furthermore, three even more recent studies are available that MSHA regards as far more informative for the purposes of the present risk assessment. Unlike the NSW study, these directly address dpm exposure and the risk of lung cancer. Two of these studies (Johnston *et al.*, 1997; Säverin *et al.*, 1999), both incorporating a quantitative dpm exposure assessment, were carried out specifically on mining cohorts and will be discussed next. The third (Brüske-Hohlfeld *et al.*, 1999) is a case-control study not restricted to miners and will be discussed in the following subsection. In accordance with MARG's emphasis on the timeliness of scientific studies, MSHA places considerable weight on the fact that all three—the most recent epidemiologic studies available—reported an association between diesel exposure and an increased risk of lung cancer.

Johnston *et al.* (1997) studied a cohort of 18,166 coal miners employed in ten British coal mines over a 30-year period. Six of these coal mines used diesel locomotives, and the other four were used for comparison. Historical NO_X and respirable dust concentration measurements were available, having routinely been collected for monitoring purposes. Two separate approaches were taken to estimate dpm exposures, leading to two different sets of estimates. The first approach was based on NO_X measurements, combined with estimated ratios between dpm and NO_X. The second approach was based on complex calculations involving measurements of total respirable dust, ash content, and the ratio of quartz to dust for diesel locomotive drivers compared to the ratio for face workers (ibid., Figure 4.1 and pp. 25–46). These calculations were used to estimate dpm exposure concentrations for the drivers, and the estimates were then combined with traveling times and dispersion rates to form estimates of dpm concentration levels for other occupational groups. In four of the six dieselized mines, the NO_X-based and dust-based estimates of dpm were in generally good agreement, and they were combined to form time-independent estimates of shift average dpm concentration for individual seams and occupational groups within each mine. In the fifth mine, the PFR measurements were judged unreliable for reasons extensively discussed in the report, so the NO_X-based estimates were used. There was no NO_X exposure data for the sixth mine, so they used dust-based estimates of dpm exposure.

Final estimates of shift-average dpm concentrations ranged from 44 $\mu g/m^3$ to 370 $\mu g/m^3$ for locomotive drivers and from 1.6 $\mu g/m^3$ to 40 $\mu g/m^3$ for non-drivers at various mines and work locations (ibid., Tables 8.3 and 8.6, respectively). These were combined with detailed work histories, obtained from employment records, to provide an individual estimate of cumulative dpm exposure for each miner in the cohort. Although most cohort members (including non-drivers) had estimated cumulative exposures less than 1 g-hr/m^3, some members had cumulative exposures that ranged as high as 11.6 g-hr/m^3 (ibid., Figure 9.1 and Table 9.1).

A statistical analysis (time-dependent proportional hazards regression) was performed to examine the relationship between lung cancer risk and each miner's estimated cumulative dpm exposure (unlagged and lagged by 15 years), attained age, smoking habit,

mine, and cohort entry date. Smoking habit was represented by non-smoker, ex-smoker, and smoker categories, along with the average number of cigarettes smoked per day for the smokers. Pipe tobacco consumption was expressed by an equivalent number of cigarettes per day.

In their written comments, MARG and the NMA both mischaracterized the results of this study, apparently confusing it with a preliminary analysis of the same cohort. The preliminary analysis (one part of what Johnston *et al.* refer to as the ''wider mortality study'') was summarized in Section 1.2 (pp. 3–5) of the 105-page report at issue, which may account for the confusion by MARG and the NMA.[48]

Contrary to the MARG and NMA characterization, Johnston *et al.* found a positive, quantitative relationship between cumulative dpm exposure (lagged by 15 years) and an excess risk of lung cancer, after controlling for age, smoking habit, and cohort entry date. For each incremental g-hr/m^3 of cumulative occupational dpm exposure, the relative risk of lung cancer was estimated to increase by a factor of 22.7 percent. Adjusting for mine-to-mine differences that may account for a portion of the elevated risk reduced the estimated RR factor to 15.6 percent. Therefore, with the mine-specific adjustment, the estimated RR was 1.156 per g-hr/m^3 of cumulative dpm exposure. It follows that, based on the mine-adjusted model, the estimated RR for a specified cumulative exposure is 1.156 raised to a power equal to that exposure. For example, RR = $(1.156)^{3.84}$ = 1.74 for a cumulative dpm exposure of 3.84 g-hr/m^3, and RR = $(1.156)^{7.68}$ = 3.04 for a cumulative dpm exposure of 7.68 g-hr/m^3.[49] Estimates of RR based on the mine-unadjusted model would substitute 1.227 for 1.156 in these calculations.

Two limitations of this study weaken the evidence it presents of an increasing exposure-response relationship. First, although the exposure assessment is quantitative and carefully done, it is indirect and depends heavily on assumptions linking surrogate measurements to dpm exposure levels. The authors, however, analyzed sources of inaccuracy in the exposure assessment and concluded that ''the similarity between the estimated * * * [dpm] exposure concentrations derived by the two different methods give some degree of confidence in the accuracy of the final values * * *.'' (ibid., pp.71–75) Second, the highest estimated cumulative dpm exposures were clustered at a single coal mine, where the SMR was elevated relative to the regional norm. Therefore, as the authors pointed out, this one mine greatly influences the results and is a possible confounder in the study. The investigators also noted that this mine was ''* * * found to have generally the higher exposures to respirable quartz and low level radiation.'' Nevertheless, MSHA regards it likely that the relatively high dpm exposures at this mine were responsible for at least some of the excess mortality. There is no apparent way, however, to ascertain just how much of the excess mortality (including lung cancer) at this coal mine should be attributed to high occupational dpm exposures and how much to confounding factors distinguishing it (and the employees working there) from other mines in the study.

The RR estimates based on the mine-unadjusted model assume that the excess lung cancer observed in the cohort is entirely attributable to dpm exposures, smoking habits, and age distribution. If some of the excess lung cancer is attributed to other differences between mines, then the dpm effect is estimated by the lower RR based on the mine-adjusted model.

For purposes of comparison with the findings of Säverin *et al.* (1999), it will be useful to calculate the RR for a cumulative dpm exposure of 11.7 g-hr/m^3 (*i.e.*, the approximate equivalent of 4.9 mg-yr/m^3 TC).[50] At this exposure level, the mine-unadjusted model produces an estimated RR = $(1.227)^{11.7}$ = 11, and the mine-adjusted model produces an estimated RR = $(1.156)^{11.7}$ = 5.5.

Säverin *et al.* (1999) studied a cohort of male potash miners in Germany who had worked underground for at least one year after 1969, when the mines involved began converting to diesel powered vehicles and loading equipment. Members of the cohort were selected based on company medical records, which also provided bi-annual information on work location for each miner and, routinely after 1982, the miner's smoking habits. After excluding miners whose workplace histories could not be reconstructed from the medical records (5.5 percent) and miners lost to follow-up (1.9 percent), 5,536 miners remained in the cohort. Within this full cohort, the authors defined a sub-cohort consisting of 3,258 miners who had ''worked underground for at least ten years, held one single job during at least 80% of their underground time, and held not more than three underground jobs in total.''

The authors divided workplaces into high, medium, and low diesel exposure categories, respectively corresponding to production, maintenance, and workshop areas of the mine. Each of these three categories was assigned a representative respirable TC concentration, based on an average of measurements made in 1992. These averages were 390 μg/m^3 for production, 230 μg/m^3 for maintenance, and 120 μg/m^3 for workshop. Some commenters expressed concern about using average exposures from 1992 to represent exposure throughout the study. The authors justified using these measurement averages to represent exposure levels throughout the study period because ''the mining technology and the type of machinery used did not change substantially after 1970.'' This assumption was based on interviews with local engineers and industrial hygienists.

Thirty-one percent of the cohort consented to be interviewed, and information from these interviews was used to validate the work history and smoking data reconstructed from the medical records. The TC concentration assigned to each work location was combined with each miner's individual work history to form an estimate of cumulative exposure for each member of the cohort. Mean duration of exposure was 15 years. As of the end of follow-up in 1994, average age was 49 years, average time since first exposure was 19 years, and average cumulative exposure was 2.70 mg-y/m^3.

[48] Since MARG and the NMA both stressed the importance of a quantitative exposure assessment, it is puzzling that they focused on a crude SMR from the preliminary analysis and ignored the quantitative results from the subsequent analysis. Johnston et al. noted that SMRs from the preliminary analysis were consistent ''with other studies of occupational cohorts where a healthy worker effect is apparent.'' But even the preliminary analysis explored a possible surrogate exposure-response relationship, rather than simply relying on SMRs. Unlike the analysis by Johnston et al., the preliminary analysis used travel time as a surrogate measure of dpm exposure and made no attempt to further quantify dpm exposure concentrations. (ibid., p. 5)

[49] Assuming an average dpm concentration of 200 μg/m^3 and 1920 work hours per year, 3.84 g-hr/m^3 and 7.68 g-hr/m^3 correspond to 10 and 20 years of occupational exposure, respectively.

[50] This value represents 20 years of cumulative exposure for the most highly exposed category of workers in the cohort studied by Säverin et al.

As explained elsewhere in this preamble, TC constitutes approximately 80 percent of total dpm. Therefore, the TC value of 4.9 mg-yr/m^3 presented by Säverin *et al.* must first be divided by 0.8 to produce a corresponding dpm value of 6.12 mg-yr/m^3. To convert this result to the units used by Johnston *et al.*, it is then multiplied by 1920 work hours per year and divided by 1000 mg/g to yield 11.7 g-hr/m^3. This is nearly identical to the maximum cumulative dpm exposure estimated for locomotive drivers in the study by Johnston *et al.* (See Johnston *et al., op cit.*, Table 9.1.)

The authors performed an analysis (within each TC exposure category) of smoking patterns compared with cumulative TC exposure. They also analyzed smoking misclassification as estimated by comparing information from the interviews with medical records. From these analyses, the authors determined that the cohort was homogeneous with respect to smoking and that a smoking adjustment was neither necessary nor desirable for internal comparisons. However, they did not entirely rule out the possibility that smoking effects may have biased the results to some extent. On the other hand, the authors concluded that asbestos exposure was minor and restricted to jobs in the workshop category, with negligible effects. The miners were not occupationally exposed to radon progeny, as documented by routine measurement records.

As compared to the general male population of East Germany, the cohort SMR for all causes combined was less than 0.6 at a 95-percent confidence level. The authors interpreted this as demonstrating a healthy worker effect, noting that ''underground workers are heavily selected for health and sturdiness, making any surface control group incomparable.'' Accordingly, they performed internal comparisons within the cohort of underground miners. The RR reported for lung cancer among miners in the high-exposure production category, compared to those in the low-exposure workshop category, was 2.17. The corresponding RR was not elevated for other cancers or for diseases of the circulatory system.

Two statistical methods were used to investigate the relationship between lung cancer RR and each miner's age and cumulative TC exposure: Poisson regression and time-dependent proportional hazards regression. These two statistical methods were applied to both the full cohort and the subcohort, yielding four different estimates characterizing the exposure-response relationship. Although a high confidence level was not achieved, all four of these results indicated that the RR increased with increasing cumulative TC exposure. For each incremental mg-yr/m^3 of occupational TC exposure, the relative risk of lung cancer was estimated to increase by the following multiplicative factor: [51]

Method	RR per mg-yr/m^3	
	Full cohort	Subcohort
Poisson	1.030	1.139
Proportional Hazards	1.112	1.225

Based on these estimates, the RR for a specified cumulative TC exposure (X) can be calculated by raising the tabled value to a power equal to X. For example, using the proportional hazards analysis of the subcohort, the RR for X = 3.5 mg-yr/m^3 is $(1.225)^{3.5} = 2.03$.[52]

The authors calculated the RR expected for a cumulative TC exposure of 4.9 mg-yr/m3, which corresponds to 20 years of occupational exposure for miners in the production category of the cohort. These miners were exposed for five hours per 8-hour shift at an average TC concentration of 390 µg/m.^{3} The resulting RR values were reported as follows:

Method	RR for 4.9 mg-yr/m^3	
	Full cohort	Subcohort
Poisson	1.16	1.89
Proportional Hazards	1.68	2.70

This study has two important limitations that weaken the evidence it presents of a positive correlation between cumulative TC exposure and the risk of lung cancer. These are (1) potential confounding due to tobacco smoking and (2) a significant probability (i.e., greater than 10 percent) that a correlation of the magnitude found could have arisen simply by chance, given that it were based on a relatively small number of lung cancer cases.

Although data on smoking habits were compiled from medical records for approximately 80 percent of the cohort, these data were not incorporated into the statistical regression models. The authors justified their exclusion of smoking from these models by showing that the likelihood of smoking was essentially unrelated to the cumulative TC exposure for cohort members. Based on the portion of the cohort that was interviewed, they also determined that the average number of cigarettes smoked per day was the same for smokers in the high and low TC exposure categories (production and workshop, respectively). However, these same interviews led them to question the accuracy of the smoking data that had been compiled from medical records. Despite the cohort's apparent homogeneity with respect to smoking, the authors noted that smoking was potentially such a strong confounder that ''even small inaccuracies in smoking data could cause effects comparable in size to the weak carcinogenic effect of diesel exhaust.'' Therefore, they excluded the smoking data from the analysis and stated they could not entirely rule out the possibility of a smoking bias. MSHA agrees with the authors of this report and the HEI Expert Panel (op cit.) that even a high degree of cohort homogeneity does not rule out the possibility of a spurious correlation due to residual smoking effects. Nevertheless, because of the cohort's homogeneity, the authors concluded that ''the results are unlikely to be substantially biased by confounding,'' and MSHA accepts this conclusion.

The second limitation of this study is related to the fact that the results are based on a total of only 38 cases of lung cancer for the full cohort and 21 cases for the subcohort. In their description of

[51] MSHA determined these values by calculating the antilog, to the base e, of each corresponding estimate of α reported by Säverin et al. (op cit.) in their Tables III and IV. The cumulative exposure unit of mg-yr/m^3 refers to the average TC concentration experienced over a year's worth of 8-hour shifts.

[52] This is the estimated risk relative not to miners in the workshop category but to a theoretical age-adjusted baseline risk for cohort members accumulating zero occupational TC exposure.

this study at the May 27, 1999, public hearing, NIOSH noted that the ''lack of [statistical] significance may be a result of the study having a small cohort (approximately 5,500 workers), a limited time from first exposure (average of 19 years), and a young population (average age of 49 years at the end of follow-up).'' More cases of lung cancer may be expected to occur within the cohort as its members grow older. The authors of the study addressed statistical significance as follows:

* * * the small number of lung cancer cases produced wide confidence intervals for all measures of effect and substantially limited the study power. We intend to extend the follow-up period in order to improve the statistical precision of the exposure-response relationship. [Säverin et al., op cit.]

Some commenters stated that due to these limitations, data from the Säverin et al. study should not be the basis of this rule. On the other hand, NIOSH commented that ''[d]espite the limitations discussed * * * the findings from the Säverin et al. (1999) study should be used as an alternative source of data for quantifying the possible lung cancer risks associated with Dpm exposures.'' As stated earlier, MSHA is not relying on any single study but, instead, basing its evaluation on the weight of evidence from all available data.

(iii) Best Available Epidemiologic Evidence. Based on the evaluation criteria described earlier, and after considering all the public comment that was submitted, MSHA has identified four cohort studies (including two from U.S.) and four case-control studies (including three from U.S.) that provide the best currently available epidemiologic evidence relating dpm exposure to an increased risk of lung cancer. Three of the 11 studies involving miners fall into this select group. MSHA considers the statistical significance of the combined evidence far more important than confidence levels for individual studies. Therefore, in choosing the eight most informative studies, MSHA placed less weight on statistical significance than on the other criteria. The basis for MSHA's selection of these eight studies is summarized as follows:

Study	Statistical Significance (at 95% Conf.)	Comparison groups	Exposure assessment	Controls on potential confounding
Boffetta et al. 1988 (cohort).	Yes	Internal Comparison	Job history and self-reported duration of occupational diesel exposure.	Adjustments for age, smoking, and, in some analyses, for occupational exposures to asbestos, coal & stone dusts, coal tar & pitch, and gasoline exhaust.
Boffetta et al. 1990 (case-control).	No	Matched within hospital on smoking, age, year of interview.	Job history and self-reported duration of occupational diesel exposure.	Adjustments for age, smoking habit and intensity, asbestos exposure, race, and education.
Brüske-Hohlfeld et al. 1999 (case-control).	Yes	Matched on sex, age, and region of residence of residence.	Total duration of occupational diesel exposure based on detailed job history.	Adjustments for current and past smoking patterns, cumulative amount smoked (packyears), and asbestos exposure.
Garshick et al. 1987 (case-control).	Yes	Matched within cohort on dates of birth and death.	Semi-quantitative, based on job history and tenure combined with exposure status established later for each job.	Adjustments for lifetime smoking and asbestos exposure.
Garshick et al. 1988, 1991 (cohort).	Yes	Internal Comparison	Semi-quantitative, based on job history and tenure combined with exposure status established later for each job.	Subjects with likely or possible asbestos exposure excluded from cohort. Cigarette smoking determined to be uncorrelated with diesel exposure within cohort.
Johnston et al. 1997 (cohort).	No (marginal)	Internal Comparison	Quantitative, based on surrogate exposure measurements and detailed employment records.	Adjustments for age, smoking habit & intensity, mine site, and cohort entry date.
Säverin et al. 1999 (cohort).	No	Internal Comparison	Quantitative, based on TC exposure measurements and detailed employment records.	Adjustment for age. Cigarette smoking determined to be uncorrelated with cumulative TC exposure within cohort.
Steenland et al. 1990, 1992, 1998 (case-control).	Yes	Matached within cohort on date of death within 2 years.	Semi-quantitative, based on job history and subsequent EC measurements.	Adjustments for age, smoking, and asbestos exposure. Dietary covariates were tested and found not to confound the analysis.

Six entirely negative studies were identified earlier in this risk assessment. Several commenters objected to MSHA's treatment of the negative studies, indicating that they had been discounted without sufficient justification. To put this in proper perspective, the six negative studies should be compared to those MSHA has identified as the best available epidemiologic evidence, with respect to the same evaluation criteria. (It should be noted that the statistical significance of a negative study is best represented by its power.) In accordance with those criteria, MSHA discounts the evidentiary significance of these six studies for the following reasons:

Study	Power	Comparison groups	Exposure assessment	Controls on potential confounding
Bender et al. 1989 (cohort)	Relative small cohort (N=4849).	External comparison; No adjustment for healthy worker effect.	Job only: highway maintenance workers.	Disparate comparison groups with no smoking adjustment.

Study	Power	Comparison groups	Exposure assessment	Controls on potential confounding
Christie et al. 1996 (cohort)	Inadequate latency allowance.	External comparison; No adjustment for healthy worker effect.	Industry only: combined all underground and surface workers at coal mines.	Disparate comparison groups with no smoking adjustment.
DeCoufle et al. 1977 (case-control).	Inadequate latency allowance.	Cases not matched with controls.	Job only: (1) Combined bus, taxi, and truck drivers; (2) locomotive engineers.	Age differences not taken into account.
Edling et al. 1987 (cohort)	Small cohort (N=694)	External comparison; No adjustment for healthy worker effect.	Job only: bus workers	Disparate comparison groups with no smoking adjustment.
Kaplan 1959 (cohort)	Inadequate latency allowance.	External comparison; No adjustment for healthy worker effect.	Jobs classified by diesel exposure. No attempt to differentiate between diesel and coal-fired locomotives.	Disparate comparison groups with no smoking adjustment.
Waller 1981 (cohort)	Acceptable	External comparison; No adjustment for healthy worker effect; Selection bias due to excluding retirees from cohort.	Job only: bus workers	Disparate coparison groups with no smoking adjustment.

Other studies proposed as counter-evidence by some commenters will be addressed in the next subsection of this risk assessment.

The eight studies MSHA identified as representing the best available epidemiologic evidence all reported an elevated risk of lung cancer associated with diesel exposure. The results from these studies will now be reviewed, along with MSHA's response to public comments as appropriate.

Boffetta et al., 1988

The structure of this cohort study was summarized in the preceding subsection of this risk assessment. The following table contains the main results. The relative risks listed for duration of exposure were calculated with reference to all members of the cohort reporting no diesel exposure, regardless of occupation, and adjusted for age, smoking pattern, and other occupational exposures (asbestos, coal and stone dusts, coal tar and pitch, and gasoline exhausts). The relative risks listed for occupations were calculated for cohort members that ever worked in the occupation, compared to cohort members never working in any of the four occupations listed and reporting no diesel exposure. These four relative risks were adjusted for age and smoking pattern only. Smoking pattern was coded by 5 categories: never smoker; current 1–20 cigarettes per day; current 21 or more cigarettes per day; ex-smoker of cigarettes; current or past pipe and/or cigar smoker.

MAIN RESULTS FROM BOFFETTA ET AL., 1988

[RRs by duration adjusted for age, smoking, and other occupational exposures; Occupational RRs adjusted for age and smoking only]

Self-reported duration of exposure to diesel exhaust	Lung cancer RR	95-percent confidence interval
Years:		
1 to 15	1.05	0.80–1.39
16 or more	1.21	0.94–1.56
Occupation:		
Truck Drivers	1.24	0.93–1.66
Railroad Workers ..	1.59	0.94–2.69
Heavy Equipment Operators	2.60	1.12–6.06
Miners	2.67	1.63–4.37

In addition to comments (addressed earlier) on the RR for miners in this study, IMC Global submitted several comments pertaining to the RR calculated for persons who explicitly stated that they had been occupationally exposed to diesel emissions. This RR was 1.18 for persons reporting any exposure (regardless of duration) compared to all subjects reporting no exposure. MSHA considers the most important issue raised by IMC Global to be that 20.6 percent of all cohort members did not answer the question about occupational diesel exhaust exposure during their lifetimes, and these subjects experienced a higher age-adjusted mortality rate than the others. As the authors of this study acknowledged, this ''could introduce a substantial bias in the estimate of the association.'' (Boffetta et al., 1988, p. 412).

To show that the impact of this bias could indeed be substantial, the authors of the study addressed one extreme possibility, in which all ''unknowns'' were actually unexposed. Under this scenario, excluding the ''unknowns'' would have biased the calculated RR upward by a sufficient amount to explain the entire 18-percent excess in RR. This would not, however, explain the higher RR for persons reporting more than 16 years exposure, compared to the RR for persons reporting 1 to 15 years. Moreover, the authors did not discuss the opposite extreme: if all or most of the ''unknowns'' who experienced lung cancer were actually exposed, then excluding them would have biased the calculated RR downward. There is little basis for favoring one of these extremes over the other.

Another objection to this study raised by IMC Global was:

> All exposure information in the study was self-reported and not validated. The authors of the study have no quantitative data or measurements of actual diesel exhaust exposures.

MSHA agrees with IMC Global and other commenters that a lack of quantitative exposure measurements limits the strength of the evidence this study presents. MSHA believes, however, that the evidence presented is nevertheless substantial. The possibility of random classification errors due to self-reporting of exposures does not explain why persons reporting 16 or more years of exposure would experience a higher relative risk of lung cancer than persons reporting 1 to 15 years of exposure. This difference is not statistically significant, but random exposure misclassification would tend to make the effects of exposure less

conspicuous. Nor can self-reporting explain why an elevated risk of lung cancer would be observed for four occupations commonly associated with diesel exposure.

Furthermore, the study's authors did perform a rough check on the accuracy of the cohort's exposure information. First, they confirmed that, after controlling for age, smoking, and other occupational exposures, a statistically significant relationship was found between excess lung cancer and the cohort's self-reported exposures to asbestos. Second they found no such association for self-reported exposure to pesticides and herbicides, which they considered unrelated to lung cancer (ibid., pp. 410–411).

IMC Global also commented that the ''* * * study may suffer from volunteer bias in that the cohort was healthier and less likely to be exposed to important risk factors, such as smoking or alcohol.'' They noted that this possibility ''is supported by the U.S. EPA in their draft Health Assessment Document for Diesel Emissions.''

The study's authors noted that enrollment in the cohort was nonrandom and that participants tended to be healthier and less exposed to various risk factors than the general population. These differences, however, would tend to reduce any relative risk for the cohort calculated in comparison to the external, general population. The authors pointed out that external comparisons were, therefore, inappropriate; but ''the internal comparisons upon which the foregoing analyses are based are not affected strongly by selection biases.'' (ibid.)

Although the 1999 EPA draft notes potential volunteer bias, it concludes: ''Given the fact that all diesel exhaust exposure occupations * * * showed elevated lung cancer risk, this study is suggestive of a causal association.''[53] (EPA, 1999, p. 7–13) No objection to this conclusion was raised in the most recent CASAC review of the EPA draft (CASAC, 2000).

Boffetta et al., 1990

This case-control study was based on 2,584 male hospital patients with histologically confirmed lung cancer, matched with 5099 male patients with no tobacco-related diseases. Cases and controls were matched within each of 18 hospitals by age (within two years) and year of interview. Information on each patient, including medical and smoking history, occupation, and alcohol and coffee consumption, was obtained at the time of diagnosis in the hospital, using a structured questionnaire. For smokers, smoking data included the number of cigarettes per day. Prior to 1985, only the patient's usual job was recorded. In 1985, the questionnaire was expanded to include up to five other jobs and the length of time worked in each job. After 1985, information was also obtained on dietary habits, vitamin consumption, and exposure to 45 groups of chemicals, including diesel exhaust.

The authors categorized all occupations into three groups, representing low, possible, and probable diesel exhaust exposure. The ''low exposure'' group was used as the reference category for calculating odds ratios for the ''possible'' and ''probable'' job groups. These occupational comparisons were based on the full cohort of patients, enrolled both before and after 1985. A total of 35 cases and 49 controls (all enrolled after the questionnaire was expanded in 1985) reported a history of diesel exposure. The reference category for self-reported diesel exposure consisted of a corresponding subset of 442 cases and 897 controls reporting no diesel exposure on the expanded questionnaire. The authors made three comparisons to rule out bias due to self-reporting of exposure: (1) No difference was found between the average number of jobs reported by cases and controls; (2) the association between self-reported asbestos exposure was in agreement with previously published estimates; and (3) no association was found for two exposures (pesticides and fuel pumping) considered unrelated to lung cancer (ibid., p. 584).

Stöber and Abel (1996) identified this study as being ''of eminent importance owing to the care taken in including the most influential confounding factors and analyses of dose-effect relationships.'' The main findings are presented in the following table. All of these results were obtained using logistic regression, factoring in the estimated effects of age, race, years of education, number of cigarettes per day, and asbestos exposure (yes or no). An elevated risk of lung cancer was reported for workers with more than 30 years of either self-reported or ''probable'' diesel exposure. The authors repeated the occupational analysis using ''ever'' rather than ''usual'' employment in jobs classified as ''probable'' exposure, with ''remarkably similar'' results (ibid., p. 584).

MAIN RESULTS FROM BOFFETTA ET AL., 1990

[Adjusted for age, race, education, smoking, and asbestos exposure]

Self-reported duration of exposure to diesel exhaust	Lung cancer odds ratio	95-percent confidence interval
Years:		
1 to 15	0.90	0.40–1.99
16 to 30	1.04	0.44–2.48
31 or more	2.39	0.87–6.57
Likelihood of Exposure:		
19 jobs with ''possible'' exposure	0.92	0.76–1.10
13 jobs with ''probable'' exposure	0.95	0.78–1.16
1 to 15 years in ''probable'' jobs	0.52	0.15–1.86
16 to 30 years in ''probable'' jobs	0.70	0.34–1.44
31 or more years in ''probable'' jobs	1.49	0.72–3.11

[53] In his review of this study for the NMA, Dr. Peter Valberg stated: ''This last sentence reveals EPA's bias; the RRs for truck drivers and railroad workers were not statistically elevated.'' Contrary to Dr. Valberg's statement, the RRs were greater than 1.0 and, therefore, were ''statistically elevated.'' Although the elevation for these two occupations was not statistically significant at a 95-percent confidence level, the EPA made no claim that it was. Under a null hypothesis of no real association, the probability should be ½ that the RR would exceed 1.0 for an occupation associated with diesel exposure. Therefore, under the null hypothesis, the probability that the RR would exceed 1.0 for all four such occupations is $(1/2)^4 = 0.06$. This corresponds to a 94-percent confidence level for rejecting the null hypothesis.

The study's authors noted that most U.S. trucks did not have diesel engines until the late 1950s or early 1960s and that many smaller trucks are still powered by gasoline engines. Therefore, they performed a separate analysis of truck drivers cross-classified by self-reported diesel exposure ''to compare presumptive diesel truck drivers with nondiesel drivers.'' After adjusting for smoking, the resulting OR for diesel drivers was 1.25, with a 95-percent confidence interval of 0.85 to 2.76 (*ibid.,* p. 585).

Brüske-Hohlfeld et al., 1999

This was a pooled analysis of two case-control studies on lung cancer in Germany. The data pool consisted of 3,498 male cases with histologically or cytologically confirmed lung cancer and 3,541 male controls randomly drawn from the general population. Cases and controls were matched for age and region of residence. For the pooled analysis, information on demographic characteristics, smoking, and detailed job and job-task history was collected by personal interviews with the cases and controls, using a standardized questionnaire.

Over their occupational lifetimes, cases and controls were employed in an average of 2.9 and 2.7 different jobs, respectively. Jobs considered to have had potential exposure to diesel exhaust were divided into four groups: Professional drivers (including trucks, buses, and taxis), other ''traffic-related'' jobs (including switchmen and operators of diesel locomotives or diesel forklift trucks), full-time drivers of farm tractors, and heavy equipment operators. Within these four groups, each episode of work in a particular job was classified as being exposed or not exposed to diesel exhaust, based on the written description of job tasks obtained during the interview. This exposure assessment was done without knowledge of the subject's case or control status. Each subject's lifetime duration of occupational exposure was compiled using only the jobs determined to have been diesel-exposed. There were 264 cases and 138 controls who accumulated diesel exposure exceeding 20 years, with 116 cases and 64 controls accumulating more than 30 years of occupational exposure.

For each case and control, detailed smoking histories from the questionnaire were used to establish smoking habit, including consumption of other tobacco products, cumulative smoking exposure (expressed as packyears), and years since quitting smoking. Cumulative asbestos exposure (expressed as the number of exposed working days) was assessed based on 17 job-specific questionnaires that supplemented the main questionnaire.

The main findings of this study, all adjusted for cumulative smoking and asbestos exposure, are presented in the following table. Although the odds ratio for West German professional drivers was a statistically significant 1.44, as shown, the odds ratio for East German professional drivers was not elevated. As a possible explanation, the authors noted that after 1960, the number of vehicles (cars, busses, and trucks) with diesel engines per unit area was about five times higher in West Germany than in East Germany. Also, the higher OR shown for professional drivers first exposed after 1955, compared to earlier years of first exposure, may have resulted from the higher density of diesel traffic in later years.

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Main results from Brüske-Hohlfeld et al., 1999

(controlled for age; adjusted for smoking and asbestos exposure)

Occupational Exposure to Diesel Exhaust	Lung Cancer Odds Ratio	95-Percent Confidence Interval
Any During Lifetime	1.43	1.23 - 1.67
West German Professional Drivers	*1.44*	*1.18 - 1.76*
First exposed before 1946	1.32	0.68 - 2.07
First exposed 1946 - 1955	1.49	0.96 - 1.88
First exposed after 1955	1.56	1.21 - 2.03
"Traffic-Related" Jobs other than Driving	*1.53*	*1.04-2.24*
4 to 10 years	1.18	0.6 - 2.4†
11 to 20 years	2.49	1.1 - 5.6†
More than 20 years	2.88	1.1 - 7.2†
Full-Time Drivers of Farm Tractors	*1.29*	*0.78 - 2.14*
11 to 20 years	1.51	0.4 - 3.8‡
21 to 30 years	3.67	1.0 - 13‡
More than 30 years	6.81	1.1 - 40‡
Heavy Equipment Operators	*2.31*	*1.44 - 3.70*
More than 20 years	4.30	statistically significant (interval not reported)

† Confidence limits estimated from Fig. 1 of Brüske-Hohlfeld et al. (1999).

‡ Confidence limits estimated from Fig. 2 of Brüske-Hohlfeld et al. (1999).

BILLING CODE 4510–43–C

As the authors noted, a strength of this study is the good statistical power resulting from having a significant number of workers exposed to diesel emissions for more than 30 years. Another strength is the statistical treatment of potential confounders, using quantitative measures of cumulative smoking and asbestos exposures.

Although they did not rely solely on job title, and differentiated between diesel-exposed and unexposed work periods, the authors identified limitations in the assessment of diesel exposure, ''under these circumstances leading to an odds ratio that is biased towards one and an underestimation of the true [relative] risk of lung cancer.'' A more quantitative assessment of diesel exposure would tend to remove this bias, thereby further elevating the relative risks. Therefore, the authors concluded that their study ''showed a statistically significant increase in lung cancer risk for workers occupationally exposed to [diesel exhaust] in Germany with the exception of professional drivers in East Germany.'' Garshick et al., 1987

This case-control study was based on 1,256 primary lung cancer deaths and 2,385 controls whose cause of death was not cancer, suicide, accident, or unknown. Cases and controls were drawn from records of the U.S. Railroad Retirement Board (RRB) and matched within 2.5 years of birth date and 31 days of death date. Selected jobs, with and without regular diesel exposure, were identified by a review of job titles and duties and classified as ''exposed'' or ''unexposed'' to diesel exhaust. For

39 jobs, this exposure classification was confirmed by personal sampling of current respirable dust concentrations, adjusted for cigarette smoke, at four different railroads. Jobs for which no personal sampling was available were classified based on similarities in location and activity to sampled jobs.

A detailed work history for each case and control was obtained from an annual report filed with the RRB. This was combined with the exposure classification for each job to estimate the lifetime total diesel exposure (expressed as ''diesel-years'') for each subject. Years spent not working for a railroad, or for which a job was not recorded, were considered to be unexposed. This amounted to 2.4% of the total worker-years from 1959 to death or retirement.

Because of the transition from steam to diesel locomotives in the 1950s, occupational lifetime exposures were accumulated beginning in 1959. Since many of the older workers retired not long after 1959 and received little or no diesel exposure, separate analyses were carried out for subjects above and below the age of 65 years at death. The group of younger workers was considered to be less susceptible to exposure misclassification.

Detailed smoking histories, including years smoked, cigarettes per day, and years between quitting and death, were obtained from next of kin. Based on job history, each case and control was also classified as having had regular, intermittent, or no occupational asbestos exposure.

The main results of this study, adjusted for smoking and asbestos exposure, are presented in the following table for workers aged less than 65 years at the time of their death. All of these results were obtained using logistic regression, conditioned on dates of birth and death. The odds ratio presented in the shaded cell for 20 years of unlagged exposure was derived from an analysis that modeled diesel-years as a continuous variable. All of the other odds ratios in the table were derived from analyses that modeled cumulative exposure categorically, using workers with less than five diesel-years of exposure as the reference group. Statistically significant elevations of lung cancer risk were reported for the younger workers with at least 20 diesel-years of exposure or at least 15 years accumulated five years prior to death. No elevated risk of lung cancer was observed for the older workers, who were 65 or more years old at the time of their death. The authors attributed this to the fact, mentioned above, that many of these older workers retired shortly after the transition to diesel-powered locomotives and, therefore, experienced little or no occupational diesel exposure. Based on the results for younger workers, they concluded that ''this study supports the hypothesis that occupational exposure to diesel exhaust increases lung cancer risk.''

MAIN RESULTS FROM GARSHICK ET AL., 1987, FOR WORKERS AGED LESS THAN 65 YEARS AT DEATH

[Controlled for dates of birth and death; adjusted for cigarette smoking and asbestos exposure]

Diesel exposure	Lung cancer odds ratio	95-percent confidence interval
No lag:		
0–4 diesel-years	1	N/A (reference group)
5–19 diesel-years	1.02	0.72–1.45
20 diesel-years (diesel exposure modeled as continuous variable)	1.41	1.06–1.88
20 or more diesel-years	1.64	1.18–2.29
Accumulated at least 5 years before death:		
0–4 diesel-years	1	N/A (reference group)
5–14 diesel-years	1.07	0.69– 1.66
15 or more diesel-years	1.43	1.06– 1.94

In its 1999 draft Health Assessment Document for Diesel Emissions, the U.S. EPA noted various limitations of this study but concluded that ''compared with previous studies [i.e., prior to 1987] * * *, [it] provides the most valid evidence that occupational diesel exhaust emission exposure increases the risk of lung cancer.'' (EPA, 1999, p. 7–33) No objection to this conclusion was raised in the most recent CASAC review of the EPA draft (CASAC, 2000).

The EMA objected to this study's determination of smoking frequency based on interviews with next of kin, stating that such determination ''generally results in an underestimate, as it has been shown that cigarette companies manufacture 60% more product than public surveys indicate are being smoked.''

A tendency to mischaracterize smoking frequency would have biased the study's reported results if the degree of under- or over-estimation varied systematically with diesel exposure. The EMA, however, submitted no evidence that the smoking under-estimate, if it existed at all, was in any way correlated with cumulative duration of diesel exposure. In the absence of such evidence, MSHA finds no reason to assume differential mis-reporting of smoking frequency.

Even more importantly, the EMA failed to distinguish between ''public surveys'' of the smokers themselves (who may be inclined to understate their habit) and interviews with next of kin. The investigators specifically addressed the accuracy of smoking data obtained from next of kin, citing two studies on the subject. Both studies reported a tendency for surrogate respondents to overestimate, rather than underestimate, cigarette consumption. The authors concluded that ''this could exaggerate the contribution of cigarette smoking to lung cancer risk if the next of kin of subjects dying of lung cancer were more likely to report smoking histories than were those of controls.'' (ibid, p.1246)

IMC Global, along with Cox (1997) objected to several methodological features of this study. MSHA's response to each of these criticisms appears immediately following a summary quotation from IMC Global's written comments:

(A) The regression models used to analyze the data assumed without justification that an excess risk at any exposure level implied an excess risk at all exposure levels.

The investigators did not extrapolate their regression models outside the range supported by the data. Furthermore, MSHA is using this study only for purposes of hazard identification at exposure levels at least as high as those experienced by workers in the study. Therefore, the possibility of a threshold effect at much lower levels is irrelevant.

(B) The regression model used did not specify that the exposure estimates were

imperfect surrogates for true exposures. As a result, the regression coefficients do not bear any necessary relationship to the effects that they try to measure.

As noted by Cox (op cit.), random measurement errors for exposures in an univariate regression model will tend to bias results in the direction of no apparent association, thereby masking or reducing any apparent effects of exposure. The crux of Cox's criticism, however, is that, for statistical analysis of the type employed in this study, random errors in a mutivariate exposure (such as an interdependent combination of smoking, asbestos, and diesel exposure) can potentially bias results in either direction. This objection fails to consider the fact that a nearly identical regression result was obtained for the effect of diesel exposure when smoking and asbestos exposure were removed from the model: OR = 1.39 instead of 1.41. Furthermore, even with a multivariate exposure, measurement errors in the exposure being evaluated typically bias the estimate of relative risk downward toward a null result. Relative risk is biased upwards only when the various exposures are interrelated in a special way. No evidence was presented that the data of this study met the special conditions necessary for upward bias or that any such bias would be large enough to be of any practical significance.

(C) The * * * analysis used regression models without presenting diagnostics to show whether the models were appropriate for the data.

MSHA agrees that regression diagnostics are a valuable tool in assuring the validity of a statistical regression analysis. There is nothing at all unusual, however, about their not having been mentioned in the published report of this study. Regression diagnostics are rarely, if ever, published in epidemiologic studies making use of regression analysis. This does not imply that such diagnostics were not considered in the course of identifying an appropriate model or checking how well the data conform to a given model's underlying assumptions. Evaluation of the validity of any statistical analysis is (or should be) part of the peer-review process prior to publication.

(D) The * * * risk models assumed that 1959 was the effective year when DE exposure started for each worker. Thus, the analysis ignored the potentially large differences in pre-1959 exposures among workers. This modeling assumption makes it impossible to interpret the results of the study with confidence.

MSHA agrees that the lack of diesel exposure information on individual workers prior to 1959 represents an important limitation of this study. This limitation, along with a lack of quantitative exposure data even after 1959, may preclude using it to determine, with reasonable confidence, the shape or slope of a quantitative exposure-response relationship. Neither of these limitations, however, invalidates the study's finding of an elevated lung cancer risk for exposed workers. MSHA is not basing any quantitative risk assessment on this study and is relying on it, in conjunction with other evidence, only for purposes of hazard identification.

(E) The risk regression models * * * assume, without apparent justification, that all exposed individuals have identical dose-response model parameters (despite the potentially large differences in their pre-1959 exposure histories). This assumption was not tested against reasonable alternatives, *e.g.,* that individuals born in different years have different susceptibilities * * *

Cases and controls were matched on date of birth to within 2.5 years, and separate analyses were carried out for the two groups of younger and older workers. Furthermore, it is not true that the investigators performed no tests of reasonable alternatives even to the assumption that younger workers shared the same model parameters. They explored and tested potential interactions between smoking intensity and diesel exposure, with negative results. The presence of such interactions would have meant that the response to diesel exposure differed among individuals, depending on their smoking intensity.

One other objection that Cox (op cit.) raised specifically in connection with this study was apparently overlooked by IMC Global. To illustrate what he considered to be an improper evaluation of statistical significance when more than one hypothesis is tested in a study, Cox noted the finding that for workers aged less than 65 years at time of death, the odds ratio for lung cancer was significantly elevated at 20 diesel-years of exposure. He then asserted that this finding was merely

* * * an instance of a whole family of statements of the form ''Workers who were A years or younger at the time of death and who were exposed to diesel exhaust for Y years had a significantly increased relative odds ratios for lung cancer. The probability of at least one false positive occurring among the multiple hypotheses in this family corresponding to different combinations of A (*e.g.,* no more than 54, 59, 64, 69, 74, 79, etc. years old at death) and durations of exposure (*e.g.,* Y = 5, 10, 15, 20, 25, etc. years) is not limited to 5% when each combination of A and Y values is tested at a p = 5% significance level. For example, if 30 different (A, Y) combinations are considered, each independently having a 5% probability of a false positive (i.e., a reported 5% significance level), then the probability of at least one false positive occurring in the study as a whole is $p = 1-(1-0.05)\ 30 = 78\%$. This p-value for the whole study is more than 15 times greater than the reported significance level of 5%.

MSHA is evaluating the cumulative weight of evidence from many studies and is not relying on the level of statistical significance attached to any single finding or study viewed in isolation. Furthermore, Cox's analysis of the statistical impact of multiple comparisons or hypothesis tests is flawed on several counts, especially with regard to this study in particular. First, the analysis relies on a highly unrealistic assumption that when several hypotheses are tested within the same study, the probabilities of false positives are statistically independent. Second, Cox fails to distinguish between those hypotheses or comparisons suggested by exploration of the data and those motivated by prior considerations. Third, Cox ignores the fact that the result in question was based on a statistical regression analysis in which diesel exposure duration was modeled as a single continuous variable. Therefore, this particular result does not depend on multiple hypothesis-testing with respect to exposure duration. Fourth, and most importantly, Cox assumes that age and exposure duration were randomly picked for testing from a pool of interchangeable possibilities and that the only thing distinguishing the combination of ''65 years of age'' and ''20 diesel-years of exposure'' from other random combinations was that it happened to yield an apparently significant result. This is clearly not the case. The investigators divided workers into only two age groups and explained that this division was based on the history of dieselization in the railroad industry—not on the results of their data analysis. Similarly, the result for 20 diesel-years of exposure was not favored over shorter exposure times simply because 20 years yielded a significant result and the shorter times did not. Lengthy exposure and latency periods are required for the expression of increased lung cancer risks, and this justifies a focus on the longest exposure periods for which sufficient data are available.

Garshick et al., 1988; Garshick, 1991

In this study, the investigators assessed the risk of lung cancer in a cohort of 55,407 white male railroad workers, aged 40 to 64 years in 1959,

who had begun railroad work between 1939 and 1949 and were employed in one of 39 jobs later surveyed for exposure. Workers whose job history indicated likely occupational exposure to asbestos were excluded. Based on the subsequent exposure survey, each of the 39 jobs represented in the cohort was classified as either exposed or unexposed to diesel emissions. The cohort was followed through 1980, and 1,694 cases of death due to lung cancer were identified.

As in the 1987 study by the same investigators, detailed railroad job histories from 1959 to date of death or retirement were obtained from RRB records and combined with the exposure classification for each job to provide the years of diesel exposure accumulated since 1959 for each worker in the cohort. Using workers classified as ''unexposed'' within the cohort to establish a baseline, time-dependent proportional hazards regression models were employed to evaluate the relative risk of lung cancer for exposed workers. Although the investigators believed they had excluded most workers with significant past asbestos exposures from the cohort, based on job codes, they considered it possible that some workers classified as hostlers or shop workers may have been included in the cohort even if occupationally exposed to asbestos. Therefore, they carried out statistical analyses with and without shop workers and hostlers included.

The main results of this study are presented in the following table. Statistically significant elevations of lung cancer risk were found regardless of whether or not shop workers and hostlers were included. The 1988 analysis adjusted for age in 1959, and the 1991 analysis adjusted, instead, for age at death or end of follow-up (i.e., end of 1980).[54] In the 1988 analysis, any work during a year counted as a diesel-year if the work was in a diesel-exposed job category, and the results from the 1991 analysis presented here are based on this same method of compiling exposure durations. Exposure durations excluded the year of death and the four prior years, thereby allowing for some latency in exposure effects. Results for the analysis excluding shop workers and hostlers were not presented in the 1991 report, but the report stated that ''similar results were obtained.'' Using either method of age adjustment, a statistically significant elevation of lung cancer risk was associated with each exposure duration category. Using ''attained age,'' however, there was no strong indication that risk increased with increasing exposure duration. The 1991 report concluded that ''there appears to be an effect of diesel exposure on lung cancer mortality'' but that ''because of weaknesses in exposure ascertainment * * *, the nature of the exposure-response relationship could not be found in this study.''

MAIN RESULTS FROM GARSHICK ET AL., 1988 AND GARSHICK, 1991

Exposure duration (diesel-years, last 5 years excluded)	Full cohort		Shopworkers & hostlers excluded	
	Relative risk	95% conf. int.	Relative risk	95% conf. int.
1–4	1.20	1.01–1.44	1.34	1.08–1.65
	1.31	1.09–1.57	N.R.	N.R.
5–9	1.24	1.06–1.44	1.33	1.12–1.58
	1.28	1.09–1.49	N.R.	N.R.
10–14	1.32	1.13–1.56	1.33	1.10–1.60
	1.19	1.002–1.41	N.R.	N.R.
15 or more	1.72	1.27–2.33	1.82	1.30–2.55
	1.40	1.03–1.90	N.R.	N.R.

Top entry within each cell is from 1988 analysis, adjusted for age in 1959. Bottom entry is from 1991 analysis, adjusted for age at death or end of follow-up (''attained age''). N.R. means ''not reported.''

Some commenters noted that removing the shop workers and hostlers from the analysis increased the relative risk estimates. Dr. Peter Valberg found this ''paradoxical,'' since workers in these categories had later been found to experience higher average levels of diesel exposure than other railroad workers.

This so-called paradox is likely to have resulted simply from exposure misclassification for a significant portion of the shop workers. The effect was explained by Garshick (1991) as follows:

> * * * shop workers who worked in the diesel repair shops shared job codes with workers in non-diesel shops where there was no diesel exhaust * * *. Apparent exposure as a shop worker based on the job code was then diluted with workers with the same job code but without true exposure, making it less likely to see an effect in the shop worker group. In addition, workers in the shop worker group of job codes tended to have less stable career paths * * * compared to the other diesel exposure categories.

So although many of the shopworkers may have been exposed to relatively high dpm concentrations, many others were among the lowest-exposed workers or were even unexposed because they spent their entire occupational lifetimes in unexposed locations. This could readily account for the increase in relative risks calculated when shop workers were excluded from the analysis.

Dr. Valberg also noted that, according to Crump (1999), mortality rates for cirrhosis of the liver and heart disease were significantly elevated for ''train riders,'' who were exposed to diesel emissions, as compared to other members of the cohort, who were less likely to be exposed. It is also the train riders who account, primarily, for the elevated risk of lung cancer associated with diesel exposure in the overall cohort. Dr. Valberg interpreted this as suggesting that ''lifestyle'' factors such as diet or smoking habits, rather than diesel exposure, were responsible for the increased risk of lung cancer observed among the diesel-exposed workers.

Dr. Valberg presented no evidence that, apart from diesel exposure, the train riders differed systematically from the other workers in their smoking habits or in other ways that would be expected to affect their risk of lung cancer. Therefore, MSHA views the suggestion of such a bias as speculative. Even if lifestyle factors associated with

[54] Also, the 1991 analysis excluded 12 members of the cohort due to discrepancies between work history and reported year of death, leaving 55,395 railroad workers included in the analysis.

train ridership were responsible for an increased risk of cirrhosis of the liver or heart disease, this would not necessarily mean that the same factors were also responsible for the increased risk of lung cancer. Still, it is hypothetically possible that systematic differences, other than diesel exposure, between train riders and other railroad workers could account for some or even all of the increased lung cancer risk. That is why MSHA does not rely on this, or any other, single study in isolation.

Some commenters, including the NMA, objected to this study on grounds that it failed to control for potentially confounding factors, principally smoking. The NMA stated that this ''has rendered its utility questionable at best.'' As explained earlier, there is more than one way in which a study can control for smoking or other potential confounders. One of the ways is to make sure that groups being compared do not differ with respect to the potential confounder. In this study, workers with likely asbestos exposure were excluded from the cohort, stability of workers within job categories was well documented, and similar results were reported when job categories subject to asbestos exposure misclassification were excluded. In their 1988 report, the investigators provided the following reasons to believe that smoking did not seriously affect their findings:

> * * * the cohort was selected to include only blue-collar workers of similar socioeconomic class, a known correlate of cigarette smoking * * *, in our case-control study [Garshick et al., 1987], when cigarette smoking was considered, there was little difference in the crude or adjusted estimates of diesel exhaust effects. Finally, in the group of 517 current railroad workers surveyed by us in 1982 * * *, we found no difference in cigarette smoking prevalence between workers with and without potential diesel exhaust exposure. [Garshick et al., 1988]

Since relative risks were based on internal comparisons, and the cohort appears to have been fairly homogeneous, MSHA regards it as unlikely that the association of lung cancer with diesel exposure in this study resulted entirely from uncontrolled asbestos or smoking effects. Nevertheless, MSHA recognizes that differential smoking patterns may have affected, in either direction, the degree of association reported in each of the exposure duration categories.

Cox (1997) re-analyzed the data of this study using exploratory, nonparametric statistical techniques. As quoted by IMC Global, Cox concluded that ''these methods show that DE [i.e., dpm] concentration has no positive causal association with lung cancer mortality risk.'' MSHA believes this quotation (taken from the abstract of Cox's article) overstates the findings of his analysis. At most, Cox confirmed the conclusion by Garshick (1991) that these data do not support a positive exposure-response relationship. Specifically, Cox determined that inter-relationships among cumulative diesel exposure, age in 1959, and retirement year make it ''impossible to prove causation by eliminating plausible rival hypotheses based on this dataset.'' (Cox, 1997; p. 826) Even if Cox's analysis were correct, it would not follow that there is no underlying causal connection between dpm exposure and lung cancer. It would merely mean that the data do not contain internal evidence implicating dpm exposure as the cause, rather than one or more of the variables with which exposure is correlated. Cox presented no evidence that any ''rival hypotheses'' were more plausible than causation by dpm exposure. Furthermore, it may simply be, as Garshick suggested, that an underlying exposure-response relationship is not evident ''because of weaknesses in exposure ascertainment.'' (Garshick, 1991, op cit.) None of this negates the fact that, after adjusting for either age in 1959 or ''attained'' age, lung cancer was significantly more prevalent among the exposed workers.

Along similar lines, many commenters pointed out that an HEI expert panel examined the data of this study (HEI, 1999) and found that it had very limited use for quantitative risk assessment (QRA). Several of these commenters mischaracterized the panel's findings. The NMA, for example, drew the following unjustified conclusion from the panel's report: ''In short, * * * the correct interpretation of the Garshick study is that any occupational increase in lung cancer among train workers was not due to diesel exposures.''

Contrary to the NMA's characterization, the HEI Expert Panel's report stated that the data are

> * * * consistent with findings of a weak association between death from lung cancer and occupational exposure to diesel exhaust. Although the secondary exposure-response analyses * * * are conflicting, the overall risk of lung cancer was elevated among diesel-exposed workers. [Ibid., p. 25]

The panel agreed with Garshick (1991) and Cox (1997) that the data of this study do not support a positive exposure-response relationship. Like Garshick and unlike Cox, however, the panel explicitly recognized that problems with the data could mask such a relationship and that this does not negate the statistically significant finding of elevated risk among exposed workers. Indeed, the panel even identified several factors, in addition to weak exposure assessment as suggested by Garshick, that could mask a positive relationship: unmeasured confounding variables such as cigarette smoking, previous occupational exposures, or other sources of pollution; a ''healthy worker survivor effect''; and differential misclassification or incomplete ascertainment of lung cancer deaths. (HEI, 1999; p. 32)

Positive exposure-response relationships based on these data were reported by the California EPA (OEHHA, 1998). MSHA recognizes that those findings were sensitive to various assumptions and that other investigators have obtained contrary results. The West Virginia Coal Association, paraphrasing Dr. Peter Valberg, concluded that although the two studies by Garshick et al. ''* * * may represent the best in the field, they fail to firmly support the proposition that lung cancer risk in workers derives from exposure to dpm.'' At least one commenter (IMC Global) apparently reached a considerably stronger conclusion that they were of no value whatsoever, and urged MSHA to ''discount their results and not consider them in this rulemaking.'' On the other hand, in response to the ANPRM, a consultant to the National Coal Association who was critical of all other studies available at the time acknowledged that these two:

> [* * * have successfully controlled for severally [sic] potentially important confounding factors * * *. Smoking represents so strong a potential confounding variable that its control must be nearly perfect if an observed association between cancer and diesel exhaust is * * * [inferred to be causal]. In this regard, two observations are relevant. First, both case-control [Garshick et al., 1987] and cohort [Garshick et al., 1988] study designs revealed consistent results. Second, an examination of smoking related causes of death other than lung cancer seemed to account for only a fraction of the association observed between diesel exposure and lung cancer. A high degree of success was apparently achieved in controlling for smoking as a potentially confounding variable. [Robert A. Michaels, RAM TRAC Corporation, submitted by National Coal Association].

To a limited extent, MSHA agrees with Dr. Valberg and the West Virginia Coal Association: these two studies—like every real-life epidemiologic study—are not ''firmly'' conclusive when viewed in isolation. Nevertheless, MSHA believes that they provide important contributions to the overall body of evidence. Whether or not they

can be used to quantify an exposure-response relationship, these studies—among the most comprehensive and carefully controlled currently available—do show statistically significant increases in the risk of lung cancer among diesel-exposed workers. Johnston et al. (1997)

Since it focused on miners, this study has already been summarized and discussed in the previous subsection of this risk assessment. The main results are presented in the following table. The tabled relative risk estimates presented for cumulative exposures greater than 1000 mg-hr/m^3 (i.e., 1 g-hr/m^3) were calculated by MSHA based on the regression coefficients reported by the authors. The conversion from mg-hr/m^3 to mg-yr/m^3 assumes 1,920 occupational exposure hours per year. Although 6.1 mg-yr/m^3 Dpm roughly equals the cumulative exposure estimated for the most highly exposed locomotive drivers in the study, the relative risk associated with this exposure level is presented primarily for purposes of comparison with findings of Saverin et al. (1999).

MAIN RESULTS FROM JOHNSTON ET AL., 1997

Cumulative dpm exposure	Mine-adjusted model (15-yr lag)		Mine-unadjusted model (15-yr lag)	
	Relative risk	95% conf. interval	Relative risk	95% conf. interval
1000 mg-hr/m^3 (= 0.521 mg-yr/m^3)	1.156	0.90–1.49	1.227	1.00–1.50.
1920 mg-hr/m^3 (= 1 mg-yr/m^3)	1.321	Not reported	1.479	Not reported
11,700 mg-hr/m^3 ($\simeq$ 6.1 mg-yr/m^3)	5.5	Not reported	11.0	Not reported

In its post-hearing comments, MARG acknowledged that this study ''found a 'weak association' between lung cancer and respiratory diesel particulate exposure'' but failed to note that the estimated relative risk increased with increasing exposure. MARG also stated that the association was ''deemed non-significant by the researchers'' and that ''no association was found among men with different exposures working in the same mines.'' Although the mine-adjusted model did not support 95-percent confidence for an increasing exposure-response relationship, the mine-unadjusted model yielded a statistically significant positive slope at this confidence level. Furthermore, since the mine-adjusted model adjusts for differences in lung cancer rates between mines, the fact that relative risk increased with increasing exposure under this model indicates (though not at a 95-percent confidence level) that the risk of lung cancer increased with exposure among men with different exposures working in the same mines.

Säverin et al. (1999)

Since this study, like the one by Johnston et al., was carried out on a cohort of miners, it too was summarized and discussed in the previous subsection of this risk assessment. The main results are presented in the following table. The relative risk estimates and confidence intervals at the mean exposure level of 2.7 mg-yr/m^3 TC (total carbon) were calculated by MSHA, based on values of α and corresponding confidence intervals presented in Tables III and IV of the published report (ibid., p. 420). The approximate equivalency between 4.9 mg-yr/m^3 TC and 6.1 mg-yr/m^3 Dpm assumes that, on average, TC comprises 80 percent of Dpm.

MAIN RESULTS FROM SAVERIN ET AL., 1999

	Relative risk	95% confidence interval
Highest compared to least exposed worker category	2.17	0.79–5.99

Cumulative total carbon exposure	Proportional hazards (Cox) Model *		Poisson mode *	
	Relative risk	95% conf. interval	Relative risk	95% conf. interval
2.7 mg-yr/m^3 TC (i.e., cohort mean)	1.33	0.67–2.64	1.08	0.59–1.99
	1.73	0.70–4.30	1.42	0.65–3.92
4.9 mg-yr/m^3 TC ($\simeq$6.1 mg-yr/m^3 dpm)	1.68	0.49–5.8	1.16	0.38–3.3
	2.70	0.52–14.1	1.89	0.46–11.9

* Top entry in each cell is based on full cohort; bottom entry is based on subcohort, which was restricted to miners who worked underground at least ten years, with at least 80 percent of employment in same job, etc.

These results are not statistically significant at the conventional 95-percent confidence level. However, the authors noted that the relative risk calculated for the subcohort was consistently higher than that calculated for the full cohort. They also considered the subcohort to have a superior exposure assessment and a better latency allowance than the full cohort. According to the authors, these factors provide ''some assurance that the observed risk elevation was not entirely due to chance since improving the exposure assessment and allowing for latency effects should, in general, enhance exposure effects.''

Steenland et al., (1990, 1992, 1998)

The basis for the analyses in this series was a case-control study comparing the risk of lung cancer for diesel-exposed and unexposed workers who had belonged to the Teamsters Union for at least twenty years (Steenland et al., 1990). Drawing from union records, 996 cases of lung cancer

were identified among more than 10,000 deaths in 1982 and 1983. For comparison to these cases, a total of 1,085 controls was selected (presumably at random) from the remaining deaths, restricted to those who died from causes other than lung cancer, bladder cancer, or motor vehicle accident. Information on work history, duration and intensity of cigarette smoking, diet, and asbestos exposure was obtained from next of kin. Detailed work histories were also obtained from pension applications on file with the Teamsters Union.

Both data sources were used to classify cases and controls according to a job category in which they had worked the longest. Based on the data obtained from next of kin, the job categories were diesel truck drivers, gasoline truck drivers, drivers of both truck types, truck mechanics, and dock workers. Based on the pension applications, the principal job categories were long-haul drivers, short-haul or city drivers, truck mechanics, and dock workers. Of the workers identified by next of kin as primarily diesel truck drivers, 90 percent were classified as long-haul drivers according to the Teamster data. The corresponding proportions were 82 percent for mechanics and 81 percent for dock workers. According to the investigators, most Teamsters had worked in only one exposed job category. However, because of the differences in job category definitions, and also because the next of kin data covered lifetimes whereas the pension applications covered only time in the Teamsters Union, the investigators found it problematic to fully evaluate the concordance between the two data sources.

In the 1990 report, separate analyses were conducted for each source of data used to compile work histories. The investigators noted that ''many trucking companies (where most study subjects worked) had completed most of the dieselization of their fleets by 1960, while independent drivers and nontrucking firms may have obtained diesel trucks later * * *'' Therefore, they specifically checked for associations between increased risk of lung cancer and occupational exposure after 1959 and, separately, after 1964. In the 1992 report, the investigators presented, for the Union's occupational categories used in the study, dpm exposure estimates based on subsequent measurements of submicrometer elemental carbon (EC) as reported by Zaebst et al. (1991). In the 1998 report, cumulative dpm exposure estimates for individual workers were compiled by combining the individual work histories obtained from the Union's records with the subsequently measured occupational exposure levels, along with an evaluation of historical changes in diesel engine emissions and patterns of diesel usage. Three alternative sets of cumulative exposure estimates were considered, based on alternative assumptions about the extent of improvement in diesel engine emissions between 1970 and 1990. A variety of statistical models and techniques were then employed to investigate the relationship between estimated cumulative dpm exposure (expressed as EC) and the risk of lung cancer. The authors pointed out that the results of these statistical analyses depended heavily on ''very broad assumptions'' used to generate the estimates of cumulative dpm exposure. While acknowledging this limitation, however, they also evaluated the sensitivity of their results to various changes in their assumptions and found these changes to have little impact on the results.

The investigators also identified and addressed several other limitations of this study as follows:

> (1) possible misclassification smoking habits by next of kin, (2) misclassification of exposure by next of kin, (3) a relatively small non-exposed group (n = 120) which by chance may have had a low lung cancer risk, and (4) lack of sufficient latency (time since first exposure) to observe a lung cancer excess. On the other hand, next-of-kin data on smoking have been shown to be reasonably accurate, non-differential misclassification of exposure * * * would only bias our findings toward * * * no association, and the trends of increased risk with increased duration of employment in certain jobs would persist even if the non-exposed group had a higher lung cancer risk. Finally, the lack of potential latency would only make any positive results more striking. (Steenland et al., 1990)

The main results from the three reports covering this study are summarized in the following table. All of the analyses were controlled for age, race, smoking (five categories), diet, and asbestos exposure as reported by next of kin. Odds ratios for the occupations listed were calculated relative to the odds of lung cancer for occupations other than truck driver (all types), mechanic, dock worker, or other potentially diesel exposed jobs (Steenland et al., 1990, Appendix A). The exposure-response analyses were carried out using logistic regression. Although the investigators performed analyses under three different assumptions for the rate of engine emissions (gm/mile) in 1970, they considered the intermediate value of 4.5 gm/mile to be their best estimate, and this is the value on which the results shown here are based. Under this assumption, cumulative occupational EC exposure for all workers in the study was estimated to range from 0.45 to 2,440 μg-yr/m^3, with a median value of 373 μg-yr/m^3. The estimates of relative risk (expressed as odds ratios) presented for EC exposures of 373 μg-yr/m^3, 1000 μg-yr/m^3, and 2450 μg-yr/m^3 were calculated by MSHA based on the regression coefficients reported by the authors for five-year lagged exposures (Steenland et al. 1998, Table II).

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Main results from Steenland et al., (1990, 1992, 1998)

Principal Occupation	Mean 1990 EC Concentration (μg/m³)	Duration of Employment	Lung Cancer Odds Ratio	95-percent Conf. Interval
Diesel truck driver	N.A.	35 or more years*	1.89	1.04 - 3.42
Short-haul driver	5.4	18 or more years after 1959	1.79	0.94 - 3.42
Long-haul driver	5.1	18 or more years after 1959	1.55	0.97 - 2.47
		13 or more years after 1964	1.64	1.05 - 2.57
Truck mechanic	26.6	18 or more years after 1959	1.50	0.59 - 3.40
Cumulative Occupational Exposure (μg-yr/m³, lagged 5 years)**			**Lung Cancer Odds Ratio**	**95-percent Conf. Interval**
EC	**TC ≈ 2•EC**	**dpm ≈ TC/0.8 ≈ 2.5•EC**		
0 - 169	0 - 338	0 - 422	1.08	0.72 - 1.63
169 - 257	338 - 514	422 - 642	1.10	0.74 - 1.65
257 - 331	514 - 662	642 - 827	1.36	0.90 - 2.04
more than 331	more than 662	more than 827	1.64	1.09 - 2.49
			Lung Cancer Odds Ratio‡	
		Logistic regression model →	**Simple Cum. Exposure**	**Log of Cum. Exposure**
373	746	932	1.16	1.41
1,000	2,000	2,500	1.48	1.66
2,450	4,900	6,100	2.59	1.93

*Although primary occupation was driving diesel trucks, employment duration includes years driving any type of truck.

**Conversions between EC, TC, and dpm assume that, on average, TC ≈ 2•EC and TC ≈ 0.8•dpm.

‡ Calculated by MSHA from regression coefficients presented by Steenland et al. (1990), Table II. Statistically significant regression coefficients reported for both models (95% Conf. level). Tabled results for Log(Cum. exposure) model have been adjusted for lifetime background exposure of 65 μg-yr/m³ assumed in regression analysis.

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Under the assumption of a 4.5 gm/mile emissions rate in 1970, the cumulative EC exposure of 2450 μg-yr/m³ (≃ 6.1 mg-yr/m³ dpm) shown in the table closely corresponds to the upper limit of the range of data on which the regression analyses were based (Steenland et al., 1998, p. 224). However, the relative risks (i.e., odds ratios) calculated for this level of occupational exposure are presented primarily for purposes of comparison with the findings of Johnston et al. (1997) and Säverin et al. (1999). At a cumulative dpm exposure of approximately 6.1 mg-yr/m³, it is evident that the Johnston models predict a far greater elevation in lung cancer risk than either the Säverin or Steenland models. A possible explanation for this is that the Johnston data included exposures of up to 30 years in duration, and the statistical models showing an exposure-response relationship allowed for a 15-year lag in exposure effects. The other two studies were based on generally shorter diesel exposures and allowed less time for latent effects. In Subsection 3.b.ii(3) of this risk assessment, the quantitative results of these three studies will be further compared with respect to

exposure levels found in underground mines.

Several commenters noted that the HEI Expert Panel (HEI, 1999) had identified uncertainties in the diesel exposure assessment as an important limitation of the exposure-response analyses by Steenland et al. (1998) and had recommended further investigation before the quantitative results of this study were accepted as conclusive. In addition, Navistar International Transportation (NITC) raised a number of objections to the methods by which diesel exposures were estimated for the period between 1949 and 1990 (NITC, 1999). In general, the thrust of these objections was that exposures to diesel engine emissions had been overestimated, while potentially relevant exposures to gasoline engine emissions had been underestimated and/or unduly discounted.[55]

As mentioned above, the investigators recognized that these analyses rely on ''broad assumptions rather than actual [concurrent] measurements,'' and they proposed that the ''results should be regarded with appropriate caution.'' While agreeing with both the investigators and the HEI Expert Panel that these results should be interpreted with appropriate caution, MSHA also agrees with the Panel ''* * * that regulatory decisions need to be made in spite of the limitations and uncertainties of the few studies with quantitative data currently available.'' (HEI, 1999, p. 39) In this context, MSHA considers it appropriate to regard the 1998 exposure-response analyses as contributing to the weight of evidence that dpm exposure increases the risk of lung cancer, even if the results are not conclusive when viewed in isolation.

Some commenters also noted that the HEI Expert Panel raised the possibility that the method for selecting controls in this study could potentially have biased the results in an unpredictable direction. Such bias could have occurred because deaths among some of the controls were likely due to diseases (such as cardiovascular disease) that shared some of the same risk factors (such as tobacco smoking) with lung cancer. The Panel presented hypothetical examples of how this might bias results in either direction. Although the possibility of such bias further demonstrates why the results of this study should be regarded with ''appropriate caution,'' it is important to distinguish between the mere possibility of a control-selection bias, evidence that such a bias actually exists in this particular study, and the further evidence required to show that such bias not only exists but is of sufficient magnitude to have produced seriously misleading results. Unlike the commenters who cited the HEI Expert Panel on this issue, the Panel itself clearly drew this distinction, stating that ''no direct evidence of such bias is apparent'' and emphasizing that ''even though these examples [presented in HEI (1999), Appendix D] could produce misleading results, it is important to note that they are only hypothetical examples. Whether or not such bias is present will require further examination.'' (HEI, 1999, pp. 37–38) As the HEI showed in its examples, such bias (if it exists) could lead to underestimating the association between lung cancer and dpm exposure, as well as to overestimating it. Therefore, in the absence of evidence that control-selection bias actually distorted the results of this study one way or the other, MSHA considers it prudent to accept the study's finding of an association at face value.

One commenter (MARG) noted that information on cigarette smoking, asbestos exposure, and diet in the trucking industry study was obtained from next of kin and stated that such information was ''likely to be unreliable.'' By increasing random variability in the data, such errors could widen the confidence intervals around an estimated odds ratio or reduce the confidence level at which a positive exposure-response relationship might be established. However, unless such errors were correlated with diesel exposure or lung cancer in such a way as to bias the results, they would not, on average, inflate the estimated degree of association between diesel exposure and an increased risk of ling cancer. The commenter provided no reason to suspect that errors with respect to these factors were in any way correlated with diesel exposure or with the development of lung cancer.

Some commenters pointed out that EC concentrations measured in 1990 for truck mechanics were higher, on average, than for truck drivers, but the mechanics, unlike the drivers, showed no evidence of increasing lung cancer risk with increasing duration of employment. NITC referred to this as a ''discrepancy'' in the data, assuming that ''cumulative exposure increases with duration of employment such that mechanics who have been employed for 18 or more years would have greater cumulative exposure than workers who have been employed for 1–11 years.'' (NITC, 1999)

Mechanics were included in the logistic regression analyses (Steenland et al., 1998) showing an increase in lung cancer risk with increasing cumulative exposure. These analyses pooled the data for all occupations by estimating exposure for each worker based on the worker's occupation and the particular years in which the worker was employed. There are at least three reasons why, for mechanics viewed as a separate group, an increase in lung cancer risk with increasing dpm exposure may not have been reflected by increasing duration of employment.

First, relatively few truck mechanics were available for analyzing the relationship between length of employment and the risk of lung cancer. Based on the union records, 50 cases and 37 controls were so classified; based on the next-of-kin data, 43 cases and 41 controls were more specifically classified as diesel truck mechanics (Steenland et al., 1990). In contrast, 609 cases and 604 controls were classified as long-haul drivers (union records). This was both the largest occupational category and the only one showing statistically significant evidence of increasing risk with increasing employment duration. The number of mechanics included in the study population may simply not have been sufficient to detect a pattern of increasing risk with increasing length of employment, even if such a pattern existed.

The second part of the explanation as to why mechanics did not exhibit a pattern similar to truck drivers could be that the data on mechanics were more subject to confounding. After noting that ''the risk for mechanics did not appear to increase consistently with duration of employment,'' Steenland et al. (1990) further noted that the mechanics may have been exposed to asbestos when working on brakes. The data used to adjust for asbestos exposure may have been inadequate to control for variability in asbestos exposure among the mechanics.

Third, as noted by NITC, the lung cancer risk for mechanics (adjusted for age, race, tobacco smoking, asbestos exposure, and diet) would be expected to increase with increasing duration of

[55] Many of the issues NITC raised in its critique of this study depend on a peculiar identification of dpm exclusively with elemental carbon. For example, NITC argued that ''more than 65 percent of the total carbon to which road drivers (and mechanics) were exposed consisted of organic (i.e., non-diesel) carbon, further suggesting that some other etiology caused or contributed to excess lung cancer mortality in these workers.'' (NITC, 1999, p. 16) Such lines of argument, which depend on identifying organic carbon as ''non-diesel,'' ignore the fact that dpm contains a large measure of organic carbon compounds (and also some sulfates), as well as elemental carbon. Any adverse health effects due to the organic carbon or sulfate constituents of dpm would nonetheless be due to dpm exposures.

employment only if the mechanics' cumulative dpm exposure corresponded to the length of their employment. None of the commenters raising this issue, however, provided any support for this assumption, which fails to consider the particular calendar years in which mechanics included in the study were employed. In compiling cumulative exposure for an individual worker, the investigators took into account historical changes in both diesel emissions and the proportion of trucks with diesel engines—so the exposure level assigned to each occupational category was not the same in each year. In general, workers included in the study neither began nor ended their employment in the same year. Consequently, workers with the same duration of employment in the same occupational category could be assigned different cumulative exposures, depending on when they were employed. Similarly, workers in the same occupational category who were assigned the same cumulative exposure may not have worked the same length of time in that occupation. Therefore, it should not be assumed that duration of employment corresponds very well to the cumulative exposure estimated for workers within any of the occupational categories. Furthermore, in the case of mechanics, there is an additional historical variable that is especially relevant to actual cumulative exposure but was not considered in formulating exposure estimates: the degree of ventilation or other means of protection within repair shops. Historical changes in shop design and work practices, as well as differences between shops, may have caused more exposure misclassification among mechanics than among long-haul or diesel truck drivers. Such misclassification would tend to further obscure any relationship between mechanics' risk of lung cancer and either duration of employment or cumulative exposure.

(iv) Counter-Evidence. Several commenters stated that, in the proposal, MSHA had dismissed or not adequately addressed epidemiology studies showing no association between lung cancer and exposures to diesel exhaust. For example, the EMA wrote:

> MSHA's discussion of the negative studies generally consists of arguments to explain why those studies should be dismissed. For example, MSHA states that, ''All of the studies showing negative or statistically insignificant positive associations . . . lacked good information about dpm exposure . . .'' or showed similar shortcomings. 63 Fed. Reg. at 17533. The statement about exposure information is only partially true, for, in fact, very few of any of the cited studies (the ''positive'' studies as well) included any exposure measurements, and none included concurrent exposures.

It should, first of all, be noted that the statement in question on dpm exposure referred to the issue of any diesel exposure—not to quantitative exposure measurements, which MSHA acknowledges are lacking in most of the available studies. In the absence of quantitative measurements, however, studies comparing workers known to have been occupationally exposed to unexposed workers are preferable to studies not containing such comparisons. Furthermore, two of the studies now available (and discussed above) utilize essentially concurrent exposure measurements, and both show a positive association (Johnston et al., 1997; Säverin *et al.,* 1999).

MSHA did not entirely ''dismiss'' the negative studies. They were included in both MSHA's tabulation (see Tables III–4 and III–5) and (if they met the inclusion criteria) in the two meta-analyses cited both here and in the proposal (Lipsett and Campleman, 1999, and Bhatia et al., 1998). As noted by the commenter, MSHA presented reasons (such as an inadequate latency allowance) for why negative studies may have failed to detect an association. Similarly MSHA gave reasons for giving less weight to some of the positive studies, such as Benhamou et al. (1988), Morabia et al. (1992), and Siemiatycki et al., 1988. Additional reasons for giving less weight to the six entirely negative studies have been tabulated above, under the heading of ''Best Available Epidemiologic Evidence.'' The most recent of these negative studies (Christie et al., 1994, 1995) is discussed in detail under the heading of ''Studies Involving Miners.''

One commenter (IMC Global) listed the following studies (all of which MSHA had considered in the proposed risk assessment) as ''examples of studies that reported negative associations between [dpm] exposure and lung cancer risk'':

- Waller (1981). This is one of the six negative studies discussed earlier. Results were likely to have been biased by excluding lung cancers occurring after retirement or resignation from employment with the London Transit Authority. Comparison was to a general population, and there was no adjustment for a healthy worker effect. Comparison groups were disparate, and there was no adjustment for possible differences in smoking frequency or intensity.
- Howe et al. (1983). Contrary to the commenter's characterization of this study, the investigators reported statistically significant elevations of lung cancer risk for workers classified as ''possibly exposed'' or ''probably exposed'' to diesel exhaust. MSHA recognizes that these results may have been confounded by asbestos and coal dust exposures.
- Wong et al. (1985). The investigators reported a statistically insignificant deficit for lung cancer in the entire cohort and a statistically significant deficit for lung cancer in the less than 5-year duration group. However, since comparisons were to a general population, these deficits may be the result of a healthy worker effect, for which there was no adjustment. Because of the latency required for development of lung cancer, the result for ''less than 5-year duration'' is far less informative than the results for longer durations of employment and greater latency allowances. Contrary to the commenter's characterization of this study, the investigators reported statistically significant elevations of lung cancer risks for ''normal'' retirees (SMR = 1.30) and for ''high exposure'' dozer operators with 15–19 years of union membership and a latency allowance of at least 20 years (SMR = 3.43).
- Edling et al. (1987). This is one of the six negative studies discussed earlier. The cohort consisted of only 694 bus workers and, therefore, lacked statistical power. Furthermore, comparison was to a general, external population with no adjustment for a healthy worker effect.
- Garshick (1988). The reason the commenter (IMC Global) gave for characterizing this study as negative was: ''That the sign of the association in this data set changes based on the models used suggests that the effect is not robust. It apparently reflects modeling assumptions more than data.'' Contrary to the commenter's characterization, however, the finding of increased lung cancer risk for workers classified as diesel-exposed did not change when different methods were used to analyze the data. What changed, depending on modeling assumptions, was the shape and direction of the exposure-response relationship among exposed workers (Cal-EPA, 1998; Stayner et al., 1998; Crump, 1999; HEI, 1999). MSHA agrees that the various exposure-response relationships that have been derived from this study are highly sensitive to data modeling assumptions. This includes assumptions about historical patterns of exposure, as well as assumptions related to technical aspects of the statistical analysis. However, as noted by the HEI Expert Panel, the study provides evidence of a

positive association between exposure and lung cancer despite the conflicting exposure-response analyses. Even though different assumptions and methods of analysis have led to different conclusions about the utility of this study for quantifying an exposure-response relationship, ''the overall risk of lung cancer was elevated among diesel-exposed workers'' (HEI, 1999, p. 25).

Another commenter (MARG) cited a number of studies (all of which had already been placed in the public record by MSHA) that, according to the commenter, ''reflect either negative health effects trends among miners or else failed to demonstrate a statistically significant positive trend correlated with dpm exposure.'' It should be noted that, as explained earlier, failure of an individual study to achieve statistical significance (i.e., a high confidence level for its results) does not necessarily prevent a study from contributing important information to a larger body of evidence. An epidemiologic study may fail to achieve statistical significance simply because it did not involve a sufficient number of subjects or because it did not allow for an adequate latency period. In addition to this general point, the following responses apply to the specific studies cited by the commenter.

• Ahlman et al. (1991). This study is discussed above, under the heading of ''Studies Involving Miners.'' MSHA agrees with the commenter that this study did not ''establish'' a relationship between diesel exposure and the excess risk of lung cancer reported among the miners involved. Contrary to the commenter's characterization, however, the evidence presented by this study does incrementally point in the direction of such a relationship. As mentioned earlier, none of the underground miners who developed lung cancer had been occupationally exposed to asbestos, metal work, paper pulp, or organic dusts. Based on measurements of the alpha energy concentration at the mines, and a comparison of smoking habits between underground and surface miners, the authors concluded that not all of the excess lung cancer for the underground miners was attributable to radon daughter exposures and/or smoking. A stronger conclusion may have been possible if the cohort had been larger.

• Ames et al. (1984). MSHA has taken account of this study, which made no attempt to evaluate cancer effects, under the heading of ''Chronic Effects other than Cancer.'' The commenter repeated MSHA's statement (in the proposed risk assessment) that the investigators had not detected any association of chronic respiratory effects with diesel exposure, but ignored MSHA's observation that the analysis had failed to consider baseline differences in lung function or symptom prevalence. Furthermore, as acknowledged by the investigators, diesel exposure levels in the study population were low.

• Ames et al. (1983). As discussed later in this risk assessment, under the heading of ''Mechanisms of Toxicity,'' this study was among nine (out of 17) that did not find evidence of a relationship between exposure to respirable coal mine dust and an increased risk of lung cancer. Unlike the Australian mines studied by Christie et al. (1995), the coal mines included in this study were not extensively dieselized, and the investigators did not relate their findings to diesel exposures.

• Ames et al. (1982). As noted earlier under the heading of ''Acute Health Effects,'' this study, which did not attempt to evaluate cancer or other chronic health effects, detected no statistically significant relationship between diesel exposure and pulmonary function. However, the authors noted that this might have been due to the low concentrations of diesel emissions involved.

• Armstrong et al. (1979). As discussed later in this risk assessment, this study was among nine (out of 17) that did not find evidence of a relationship between exposure to respirable coal mine dust and an increased risk of lung cancer. As pointed out by the commenter, comparisons were to a general population. Therefore, they were subject to a healthy worker effect for which no adjustment was made. The commenter further stated that ''diesel emissions were not found to be related to increased health risks.'' However, diesel emissions were not mentioned in the report, and the investigators did not attempt to compare lung cancer rates in exposed and unexposed miners.

• Attfield et al (1982). MSHA has taken the results of this study into account, under the heading of ''Chronic Effects other than Cancer.''

• Attfield (1979). MSHA has taken account of this study, which did not attempt to evaluate cancer effects, under the heading of ''Chronic Effects other than Cancer.'' Although the results were not conclusive at a high confidence level, miners occupationally exposed to diesel exhaust for five or more years exhibited an increase in various respiratory symptoms, as compared to miners exposed for less than five years.

• Boffetta et al. (1988). This study is discussed in two places above, under the headings ''Studies Involving Miners'' and ''Best Available Epidemiologic Evidence.'' The commenter stated that ''the study obviously does not demonstrate risks from dpm exposure.'' If the word ''demonstrate'' is taken to mean ''conclusively prove,'' then MSHA would agree that the study, viewed in isolation, does not do this. As explained in the earlier discussion, however, MSHA considers this study to contribute to the weight of evidence that dpm exposure increases the risk of lung cancer.

• Costello et al. (1974). As discussed later in this risk assessment, this study was among nine (out of 17) that did not find evidence of a relationship between exposure to respirable coal mine dust and an increased risk of lung cancer. Since comparisons were to a general population, they were subject to a healthy worker effect for which no adjustment was made. Diesel emissions were not mentioned in the report.

• Gamble and Jones (1983). MSHA has taken account of this study, which did not attempt to evaluate cancer effects, under the heading of ''Chronic Effects other than Cancer.'' The commenter did not address MSHA's observation that the method of statistical analysis used by the investigators may have masked an association of respiratory symptoms with diesel exposure.

• Glenn et al. (1983). As summarized by the commenter, this report reviewed NIOSH medical surveillance on miners exposed to dpm and found that ''* * * neither consistent nor obvious trends implicating diesel exhaust in the mining atmosphere were revealed.'' The authors noted that ''results were rather mixed,'' but also noted that ''levels of diesel exhaust contaminants were generally low,'' and that ''overall tenure in these diesel equipped mines was fairly short.'' MSHA acknowledges the commenter's emphasis on the report's 1983 conclusion: ''further research on this subject is needed.'' However, the authors also pointed out that ''all four of the chronic effects analyses revealed an excess of cough and phlegm among the diesel exposed group. In the potash, salt and trona groups, these excesses were substantial.'' The miners included in the studies summarized by this report would not have been exposed to dpm for sufficient time to exhibit a possible increase in the risk of lung cancer.

• Johnston et al. (1997). This study is discussed in two places above, under the headings ''Studies Involving Miners'' and ''Best Available Epidemiologic Evidence.'' MSHA disagrees with the commenter's

assertion that ''the study does not support a health risk from dpm.'' This was not the conclusion drawn by the authors of the study. As explained in the earlier discussion, this study, one of the few containing quantitative estimates of cumulative dpm exposures, provides evidence of increasing lung cancer risk with increasing exposure.

• Jörgenson and Svensson (1970). MSHA discussed this study, which did not attempt to evaluate cancer effects, under the heading of ''Chronic Effects other than Cancer.'' Contrary to the commenter's characterization, the investigators reported higher rates of chronic productive bronchitis, for both smokers and nonsmokers, among the underground iron ore miners exposed to diesel exhaust as compared to surface workers at the same mine.

• Kuempel (1995); Lidell (1973); Miller and Jacobsen (1985). As discussed later in this risk assessment, under the heading of ''Mechanisms of Toxicity,'' these three studies were among the nine (out of 17) that did not find evidence of a relationship between exposure to respirable coal mine dust and an increased risk of lung cancer. The extent, if any, to which workers involved in these studies were occupationally exposed to diesel emissions was not documented, and diesel emissions were not mentioned in any of these reports.

• Morfeld et al. (1997). The commenter's summary of this study distorted the investigators' conclusions. Contrary to the commenter's characterization, this is one of eight studies that showed an increased risk of lung cancer for coal miners, as discussed later in this risk assessment under the heading of ''Mechanisms of Toxicity.'' For lung cancer, the relative SMR, which adjusts for the healthy worker effect, was 1.11. (The value of 0.70 cited by the commenter was the unadjusted SMR.) The authors acknowledged that the relative SMR obtained by the ''standard analysis'' (i.e., 1.11) was not statistically significant. However, the main object of the report was to demonstrate that the ''standard analysis'' is insufficient. The investigators presented evidence that the 1.11 value was biased downward by a ''healthy-worker-survivor-effect,'' thereby masking the actual exposure effects in these workers. They found that ''all the evidence points to the conclusion that a standard analysis suffers from a severe underestimate of the exposure effect on overall mortality, cancer mortality and lung cancer mortality.'' (Morfeld et al., 1997, p. 350)

• Reger (1982). MSHA has taken account of this study, which made no attempt to evaluate cancer effects, under the heading of ''Chronic Effects other than Cancer.'' As summarized by the commenter, ''diesel-exposed miners were found to have more cough and phlegm, and lower pulmonary function,'' but the author found that ''the evidence would not allow for the rejection of the hypothesis of health equality between exposed and non-exposed miners.'' The commenter failed to note, however, that miners in the dieselized mines, had worked underground for less than 5 years on average.

• Rockette (1977). This is one of eight studies, discussed under ''Mechanisms of Toxicity,'' showing an increased risk of lung cancer for coal miners. As described by the commenter, the author reported SMRs of 1.12 for respiratory cancers and 1.40 for stomach cancer. MSHA agrees with the commenter that ''the study does not establish a dpm-related health risk,'' but notes that dpm effects were not under investigation. Diesel emissions were not mentioned in the report, and, given the study period, the miners involved may not have been occupationally exposed to diesel exhaust.

• Waxweiler (1972). MSHA's discussion of this study appears earlier in this risk assessment, under ''Studies Involving Miners.'' As noted by the commenter, the slight excess in lung cancer, relative to the general population of New Mexico, was not statistically significant. The commenter failed to note, however, that no adjustment was made for a healthy worker effect and that a substantial percentage of the underground miners were not occupationally exposed to diesel emissions.

Summation. Limitations identified in both positive and negative studies include: lack of sufficient power, inappropriate comparison groups, exposure misclassification, statistically insignificant results, and potential confounders. As explained earlier, under ''Evaluation Criteria,'' weaknesses of the first three of these types can reasonably be expected, for the most part, to artificially decrease the apparent strength of any observed association between diesel exposure and increased risk of lung cancer. Statistical insignificance and potential confounders may, in the absence of evidence to the contrary, be regarded as neutral on average. The weaknesses that have been identified in these studies are not unique to epidemiologic studies involving lung cancer and diesel exhaust. They are sources of uncertainty in virtually all epidemiologic research.

Even when there is a strong possibility that the results of a study have been affected by confounding variables, it does not follow that the effect has been to inflate rather than deflate the results or that the study cannot contribute to the weight of evidence supporting a putative association. As cogently stated by Stöber and Abel (op cit., p. 4), ''* * * associations found in epidemiologic studies can always be, at least in part, attributed to confounding.'' Therefore, an objection grounded on potential confounding can always be raised against any epidemiologic study. It is well known that this same objection was, in the past, raised against epidemiologic studies linking lung cancer and radon exposure, lung cancer and asbestos dust exposure, and even lung cancer and tobacco smoking.

Some commenters, have now proposed that virtually every existing epidemiologic study relating lung cancer to dpm exposure be summarily discredited because of susceptibility to confounding or other perceived weaknesses. Given the practical difficulties of designing and executing an epidemiologic study, this is not so much an objection to any specific study as it is an attack on applied epidemiology in general. Indeed, in their review of these studies, Stöber and Abel (1996) conclude that

> In this field * * * epidemiology faces its limits (Taubes, 1995). * * * Many of these studies were doomed to failure from the very beginning.

For important ethical reasons, however, tightly controlled lung cancer experiments cannot be performed on humans. Therefore, despite their inherent limitations, MSHA must rely on the weight of evidence from epidemiologic studies, placing greatest weight on the most carefully designed and executed studies available.

(b) Bladder Cancer

With respect to cancers other than lung cancer, MSHA's review of the literature identified only bladder cancer as a possible candidate for a causal link to dpm. Cohen and Higgins (1995) identified and reviewed 14 epidemiologic case-control studies containing information related to dpm exposure and bladder cancer. All but one of these studies found elevated risks of bladder cancer among workers in jobs frequently associated with dpm exposure. Findings were statistically significant in at least four of the studies (statistical significance was not evaluated in three).

These studies point quite consistently toward an excess risk of bladder cancer among truck or bus drivers, railroad workers, and vehicle mechanics. However, the four available cohort studies do not support a conclusion that exposure to dpm is responsible for the excess risk of bladder cancer associated with these occupations. Furthermore, most of the case-control studies did not distinguish between exposure to diesel-powered equipment and exposure to gasoline-powered equipment for workers having the same occupation. When such a distinction was drawn, there was no evidence that the prevalence of bladder cancer was higher for workers exposed to the diesel-powered equipment.

This, along with the lack of corroboration from existing cohort studies, suggests that the excessive rates of bladder cancer observed may be a consequence of factors other than dpm exposure that are also associated with these occupations. For example, truck and bus drivers are subjected to vibrations while driving and may tend to have different dietary and sleeping habits than the general population. For these reasons, MSHA does not find that convincing evidence currently exists for a causal relationship between dpm exposure and bladder cancer. MSHA received no public comments objecting to this conclusion.

ii. Studies Based on Exposures to $PM_{2.5}$ in Ambient Air. Prior to 1990, the relationship between mortality and long-term exposure to particulate matter was generally investigated by means of cross-sectional studies, but unaddressed spatial confounders and other methodological problems inherent in such studies limited their usefulness (EPA, 1996).[56] Two more recent prospective cohort studies provide better evidence of a link between excess mortality rates and exposure to fine particulate, although some of the uncertainties here are greater than with the short-term studies conducted in single communities. The two studies are the ''Six Cities'' study (Dockery et al., 1993), and the American Cancer Society (ACS) study (Pope et al., 1995).[57] The first study followed about 8,000 adults in six U.S. cities over 14 years; the second looked at survival data for half a million adults in 151 U.S. cities for 7 years. After adjusting for potential confounders, including smoking habits, the studies considered differences in mortality rates between the most polluted and least polluted cities.

Both the Six Cities study and the ACS study found a significant association between chronically higher concentrations of $PM_{2.5}$ (which includes dpm) and age-adjusted total mortality.[58] The authors of the Six Cities Study concluded that the results suggest that exposures to fine particulate air pollution ''contributes to excess mortality in certain U.S. cities.'' The ACS study, which not only controlled for smoking habits and various occupational exposures, but also, to some extent, for passive exposure to tobacco smoke, found results qualitatively consistent with those of the Six Cities Study.[59] In the ACS study, however, the estimated increase in mortality associated with a given increase in fine particulate exposure was lower, though still statistically significant. In both studies, the largest increase observed was for cardiopulmonary mortality.

Both studies also showed an increased risk of lung cancer associated with increased exposure to fine particulate. Although the lung cancer results were not statistically significant, they are consistent with reports of an increased risk of lung cancer among workers occupationally exposed to diesel emissions (discussed above).

The few studies on associations between chronic $PM_{2.5}$ exposure and morbidity in adults show effects that are difficult to separate from measures of PM_{10} and measures of acid aerosols. The available studies, however, show positive associations between particulate air pollution and adverse health effects for those with pre-existing respiratory or cardiovascular disease. This is significant for miners occupationally exposed to fine particulates such as dpm because, as mentioned earlier, there is a large body of evidence showing that respiratory diseases classified as COPD are significantly more prevalent among miners than in the general population. It also appears that PM exposure may exacerbate existing respiratory infections and asthma, increasing the risk of severe outcomes in individuals who have such conditions (EPA, 1996).

d. Mechanisms of Toxicity

Four topics will be addressed in this section of the risk assessment: (i) the agent of toxicity, (ii) clearance and deposition of dpm, (iii) effects other than cancer, and (iv) lung cancer. The section on lung cancer will include discussions of the evidence from (1) genotoxicity studies (including bioavailability of genotoxins) and (2) animal studies.

i. Agent of Toxicity. As described in Part II of this preamble, the particulate fraction of diesel exhaust is made up of aggregated soot particles, vapor phase hydrocarbons, and sulfates. Each soot particle consists of an insoluble, elemental carbon core and an adsorbed, surface coating of relatively soluble organic compounds, such as polycyclic aromatic hydrocarbons (PAHs). Many of these organic carbon compounds are suspected or known mutagens and/or carcinogens. For example, nitrated PAHs, which are present in dpm, are potent mutagens in microbial and human cell systems, and some are known to be carcinogenic to animals (IPCS, 1996, pp. 100–105).

When released into an atmosphere, the soot particles formed during combustion tend to aggregate into larger particles. The total organic and elemental carbon in these soot particles accounts for approximately 80 percent of the dpm mass. The remaining 20 percent consists mainly of sulfates, such as H_2SO_4 (sulfuric acid).

Several laboratory animal studies have been performed to ascertain whether the effects of diesel exhaust are attributable specifically to the particulate fraction. (Heinrich et al., 1986, 1995; Iwai et al., 1986; Brightwell et al., 1986). These studies compare the effects of chronic exposure to whole diesel exhaust with the effects of filtered exhaust containing no particles. The studies demonstrate that when the exhaust is sufficiently diluted to nullify the effects of gaseous irritants (NO_2 and SO_2), irritant vapors (aldehydes), CO, and other systemic toxicants, diesel particles are the prime etiologic agents of noncancer health effects. Exposure to dpm produced changes in the lung that were much more prominent than those evoked by the gaseous fraction alone. Marked differences in the effects of whole and filtered diesel exhaust were also evident from general toxicological

[56] Unlike *longitudinal studies,* which examine responses at given locations to changes in conditions over time, *cross-sectional studies* compare results from locations with different conditions at a given point in time.

[57] A third such study, the California Seventh Day Adventist study (Abbey et al., 1991), investigated only TSP, rather than fine particulate. It did not find significant excess mortality associated with chronic TSP exposures.

[58] The Six Cities study also found such relationships at elevated levels of PM_{10} and sulfates. The ACS study was designed to follow up on the fine particle results of the Six Cities Study, and also investigated sulfates separately. As explained earlier in this preamble, sulfates may be a significant constituent of dpm, depending on the type of diesel fuel used.

[59] The Six Cities study did not find a statistically significant increase in risk among non-smokers, suggesting that non-smokers might be less sensitive than smokers to adverse health effects from fine particulate exposures; however, the ACS study, with more statistical power, did find significantly increased risk even for non-smokers.

indices, such as body weight, lung weight, and pulmonary histopathology.

These studies show that, when the exhaust is sufficiently diluted, it is the particles that are primarily responsible for the toxicity observed. However, the available studies do not completely settle the question of whether the particles might act additively or synergistically with the gases in diesel exhaust. Possible additivity or interaction effects with the gaseous portion of diesel exhaust cannot be completely ruled out.

One commenter (MARG) raised an issue with regard to the agent of toxicity in diesel exhaust as follows:

> MSHA has not attempted to regulate exposure to suspected carcinogens contained in dpm, but has opted instead, in metal/nonmetal mines, to regulate total carbon (''TC'') as a surrogate for diesel exhaust, without any evidence of adverse health effects from TC exposure. * * * Nor does the mere presence of suspected carcinogens, in minute quantities, in diesel exhaust require a 95 percent reduction of total diesel exhaust [sic] in coal mines. If there are small amounts of carcinogenic substances of concern in diesel exhaust, those substances, not TC, should be regulated directly on the basis of the risks (if any) posed by those substances in the quantities actually present in underground mines. [MARG]

First, it should be noted that the ''suspected carcinogens'' in diesel exhaust to which the commenter referred are part of the organic fraction of the total carbon. Therefore, limiting the concentration of airborne total carbon attributable to dpm, or removing the soot particles from the diesel exhaust by filtration, are both ways of effectively limiting exposures to these suspected carcinogens. Second, the commenter seems to have assumed that cancer is the only adverse health effect of concern and that the only agents in dpm that could cause cancer are the ''suspected carcinogens'' in the organic fraction. This not only ignores non-cancer health effects associated with exposures to dpm and other fine particles, but also the possibility (discussed below) that, with sufficient deposition and retention, soot particles themselves could promote or otherwise increase the risk of lung cancer—either directly or by stimulating the body's natural defenses against foreign substances.

The same commenter [MARG] also stated that ''* * * airborne carbon has not been shown to be harmful at levels currently established in MSHA's dust rules. If the problem is dpm, as MSHA asserts, then it is not rationally addressed by regulating airborne carbon.'' MSHA's intent is to limit dpm exposures in M/NM mines by regulating the submicrometer carbon from diesel emissions—not any and all airborne carbon. MSHA considers its approach a rational means of limiting dpm exposures because most of the dpm consists of carbon (approximately 80 percent by weight), and because using low sulfur diesel fuel will effectively reduce the sulfates comprising most of the remaining portion. The commenter offered no practical suggestion of a more direct, effective, and rational way of limiting airborne dpm concentrations in M/NM mines. Furthermore, direct evidence exists that the risk of lung cancer increases with increasing cumulative occupational exposure to dpm as measured by total carbon (Säverin *et al.,* 1999, discussed earlier in this risk assessment).

ii. Deposition, Clearance, and Retention. As suggested by Figure II–1 of this preamble, most of the aggregated particles making up dpm are no larger than one micrometer in diameter. Particles this small are able to penetrate into the deepest regions of the lungs, called *alveoli.* In the alveoli, the particles can mix with and be dispersed by a substance called *surfactant,* which is secreted by cells lining the alveolar surfaces.

The literature on deposition of fine particles in the respiratory tract was reviewed in Green and Watson (1995) and U.S. EPA (1996). The mechanisms responsible for the broad range of potential particle-related health effects varies depending on the site of deposition. Once deposited, the particles may be cleared from the lung, translocated into the interstitium, sequestered in the lymph nodes, metabolized, or be otherwise chemically or physically changed by various mechanisms. Clearance of dpm from the alveoli is important in the long-term effects of the particles on cells, since it may be more than two orders of magnitude slower than mucociliary clearance (IPCS, 1996).

IARC (1989) and IPCS (1996) reviewed factors affecting the deposition and clearance of dpm in the respiratory tracts of experimental animals. Inhaled PAHs adhering to the carbon core of dpm are cleared from the lung at a significantly slower rate than unattached PAHs. Furthermore, there is evidence that inhalation of whole dpm may increase the retention of subsequently inhaled PAHs. IARC (op cit.) suggested that this can happen when newly introduced PAHs bind to dpm particles that have been retained in the lung.

The evidence points to significant differences in deposition and clearance for different animal species (IPCS, 1996). Under equivalent exposure regimens, hamsters exhibited lower levels of retained dpm in their lungs than rats or mice and consequently less pulmonary function impairment and pulmonary pathology. These differences may result from a lower intake rate of dpm, lower deposition rate and/or more rapid clearance rate, or lung tissue that is less susceptible to the cytotoxicity of dpm. Observations of a decreased respiration in hamsters when exposed by inhalation favor lower intake and deposition rates.

Retardation of lung clearance, called ''overload'' is not specific to dpm and may be caused by inhaling, at a sufficiently high rate, dpm in combination with other respirable particles, such as mineral dusts typical of mining environments. The effect is characterized by (1) an overwhelming of normal clearance processes, (2) disproportionately high retention and loading of the lung with particles, compared to what occurs at lower particle inhalation rates, (3) various pathological responses; generally including chronic inflammation, epithelial hyperplasia and metaplasia, and pulmonary fibrosis; and sometimes including lung tumors.

In the proposed risk assessment, MSHA requested additional information, not already covered in the sources cited above, on fine particle deposition in the respiratory tract, especially as it might pertain to lung loading in miners exposed to a combination of diesel particulate and other dusts. In response to this request, NIOSH submitted a study that investigated rat lung responses to chronic inhalation of a combination of coal dust and diesel exhaust, compared to coal dust or dpm alone (Castranova et al., 1985). Although this report did not directly address deposition or clearance, the investigators reported that another phase of the study had shown that ''particulate clearance, as determined by particulate accumulation in the lung, is inhibited after two years of exposure to diesel exhaust but is not inhibited by exposure to coal dust.''

iii. Effects other than Cancer. A number of controlled animal studies have been undertaken to ascertain the toxic effects of exposure to diesel exhaust and its components. Watson and Green (1995) reviewed approximately 50 reports describing noncancerous effects in animals resulting from the inhalation of diesel exhaust. While most of the studies were conducted with rats or hamsters, some information was also available from studies conducted using cats, guinea pigs, and monkeys. The authors also

correlated reported effects with different descriptors of dose, including both gravimetric and non-gravimetric (*e.g.,* particle surface area or volume) measures. From their review of these studies, Watson and Green concluded that:

(a) Animals exposed to diesel exhaust exhibit a number of noncancerous pulmonary effects, including chronic inflammation, epithelial cell hyperplasia, metaplasia, alterations in connective tissue, pulmonary fibrosis, and compromised pulmonary function.

(b) Cumulative weekly exposure to diesel exhaust of 70 to 80 mg• hr/m^3 or greater are associated with the presence of chronic inflammation, epithelial cell proliferation, and depressed alveolar clearance in chronically exposed rats.

(c) The extrapolation of responses in animals to noncancer endpoints in humans is uncertain. Rats were the most sensitive animal species studied.

Subsequent to the review by Watson and Green, there have been a number of animal studies on allergic immune responses to dpm. Takano et al. (1997) investigated the effects of dpm injected into mice through an intratracheal tube and found manifestations of allergic asthma, including enhanced antigen-induced airway inflammation, increased local expression of cytokine proteins, and increased production of antigen-specific immunoglobulins. The authors concluded that the study demonstrated dpm's enhancing effects on allergic asthma and that the results suggest that dpm is ''implicated in the increasing prevalence of allergic asthma in recent years.'' Similarly, Ichinose et al. (1997a) found that five different strains of mice injected intratracheally with dpm exhibited manifestations of allergic asthma, as expressed by enhanced airway inflammation, which were correlated with an increased production of antigen-specific immunoglobulin due to the dpm. The authors concluded that dpm enhances manifestations of allergic airway inflammation and that ''* * * the cause of individual differences in humans at the onset of allergic asthma may be related to differences in antigen-induced immune responses * * *.''

The mechanisms that may lead to adverse health effects in humans from inhaling fine particulates are not fully understood, but potential mechanisms that have been hypothesized for non-cancerous outcomes are summarized in Table III–6. A comprehensive review of the toxicity literature is provided in U.S. EPA (1996).

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Table III-6. — Hypothesized mechanisms of particulate toxicity†

Response	Description
Increased Airflow Obstruction	PM exposure may aggravate existing respiratory symptoms which feature airway obstruction. PM-induced airway narrowing or airway obstruction from increased mucous secretion may increase abnormal ventilation/perfusion ratios in the lung and create hypoxia. Hypoxia may lead to cardiac arrhythmias and other cardiac electrophysiologic responses that in turn may lead to ventricular fibrillation and ultimately cardiac arrest. For those experiencing airflow obstruction, increased airflow into non-obstructed areas of the lung may lead to increased particle deposition and subsequent deleterious effects on remaining lung tissue, further exacerbating existing disease processes. More frequent and severe symptoms may be present or more rapid loss of function.
Impaired Clearance	PM exposure may impair clearance by promoting hypersecretion of mucus which in turn results in plugging of airways. Alterations in clearance may also extend the time that particles or potentially harmful biogenic aerosols reside in the tracheobronchial region of the lung. Consequently alterations in clearance from either disturbance of the mucociliary escalator or of macrophage function may increase susceptibility to infection, produce an inflammatory response, or amplify the response to increased burdens of PM. Acid aerosols impair mucociliary clearance.
Altered Host Defense	Responses to an immunological challenge (e.g., infection), may enhance the subsequent response to inhalation of nonspecific material (e.g., PM). PM exposure may also act directly on macrophage function which may not only affect clearance of particles but also increase susceptibility and severity of infection by altering their immunological function. Therefore, depression or over-activation of the immune system, caused by exposure to PM, may be involved in the pathogenesis of lung disease. Decreased respiratory defense may result in increased risk of mortality from pneumonia and increased morbidity (e.g., infection).

Cardiovascular Perturbation	Pulmonary responses to PM exposure may include hypoxia, bronchoconstriction, apnea, impaired diffusion, and production of inflammatory mediators that can contribute to cardiovascular perturbation. Inhaled particles could act at the level of the pulmonary vasculature by increasing pulmonary vascular resistance and further increase ventilation/perfusion abnormalities and hypoxia. Generalized hypoxia could result in pulmonary hypertension and interstitial edema that would impose further workload on the heart. In addition, mediators released during an inflammatory response could cause release of factors in the clotting cascade that may lead to increased risk of thrombus formation in the vascular system. Finally, direct stimulation by PM of respiratory receptors found throughout the respiratory tract may have direct cardiovascular effects (e.g., bradycardia, hypertension, arrhythmia, apnea and cardiac arrest).
Epithelial Lining Changes	PM or its pathophysiological reaction products may act at the alveolar capillary membrane by increasing the diffusion distances across the respiratory membrane (by increasing its thickness) and causing abnormal ventilation/perfusion ratios. Inflammation caused by PM may increase "leakiness" in pulmonary capillaries leading eventually to increased fluid transudation and possibly to interstitial edema in susceptible individuals. PM induced changes in the surfactant layer leading to increased surface tension would have the same effect.
Inflammatory Response	Diseases which increase susceptibility to PM toxicity involve inflammatory response (e.g., asthma, COPD, and infection). PM may induce or enhance inflammatory responses in the lung which may lead to increased permeability, diffusion abnormality, or increased risk of thrombus formation in vascular system. Inflammation from PM exposure may also decrease phagocytosis by alveolar macrophages and therefore reduce particle clearance. (See discussions above for other inflammatory effects from PM exposure.)

† This table was derived from information in EPA (1996) 11:179-185; 13:67-72; and Appendix D of EPA staff report.

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Deposition of particulates in the human respiratory tract may initiate events leading to increased airflow obstruction, impaired clearance, impaired host defenses, or increased epithelial permeability. Airflow obstruction can result from laryngeal constriction or bronchoconstriction secondary to stimulation of receptors in extrathoracic or intrathoracic airways. In addition to reflex airway narrowing, reflex or local stimulation of mucus secretion can lead to mucus hypersecretion and, eventually, to mucus plugging in small airways.

Pulmonary changes that contribute to cardiovascular responses include a variety of mechanisms that can lead to hypoxemia, including bronchoconstriction, apnea, impaired diffusion, and production of inflammatory mediators. Hypoxia can lead to cardiac arrhythmias and other cardiac electrophysiologic responses that, in turn, may lead to ventricular fibrillation and ultimately cardiac arrest. Furthermore, many respiratory receptors have direct cardiovascular effects. For example, stimulation of C-fibers leads to bradycardia and hypertension, and stimulation of laryngeal receptors can result in hypertension, cardiac arrhythmia, bradycardia, apnea, and even cardiac arrest. Nasal receptor or pulmonary J-receptor stimulation can lead to vagally-mediated bradycardia and hypertension (Widdicombe, 1988).

Some commenters mistakenly attributed the sensory irritant effects of diesel exhaust entirely to its gaseous components. The mechanism by which constituents of dpm can cause sensory irritations in humans is much better understood than the mechanisms for other adverse health effects due to fine particulates. In essence, sensory irritants are ''scrubbed'' from air entering the upper respiratory tract, thereby preventing a portion from penetrating more deeply into the lower respiratory tract. However, the sensory irritants stimulate trigeminal nerve endings, which are located very close to the oro-nasal mucosa and also to the watery surfaces of the eye (cornea). This produces a burning, painful sensation. The intensity of the sensory irritant response is related to the irritant concentration and duration of exposure. Differences in relative potency are observed with different sensory irritants. Acrolein and formaldehyde are examples of highly potent sensory irritants which, along with others having low molecular weights (acids, aldehydes), are often found in the organic fraction of dpm (Nauss et al., 1995). They may be adsorbed onto the carbon-based core or released in a vapor phase. Thus, mixtures of sensory irritants in dpm may impinge upon the eyes and respiratory tract of miners and produce adverse health effects.

It is also important to note that mixtures of sensory irritants in dpm may produce responses that are not predicted solely on the basis of the individual chemical constituents. Instead, these irritants may interact at receptor sites to produce additive, synergistic, or antagonistic effects. For example, because of synergism, dpm containing a mixture of sensory irritants at relatively low concentrations may produce intense sensory responses (*i.e.,* responses far above those expected for the individual irritants). Therefore, the irritant effects of whole dpm cannot properly be evaluated by simply adding together the known effects of its individual components.

As part of its public comments on the proposed preamble, NIOSH submitted a study (Hahon et al., 1985) on the effects of diesel emissions on mice infected with influenza virus. The object of this study was to determine if exposure to diesel emissions (either alone or in combination with coal dust) could affect resistance to pulmonary infections. The investigators exposed groups of mice to either coal dust, diesel emissions, a combination of both, or filtered air (control group) for various durations, after which they were infected with influenza. Although not reflected by excess mortality, the severity of influenza infection was found to be more pronounced in mice previously exposed to diesel emissions than in control animals. The effect was not intensified by inhalation of coal dust in combination with those emissions.

In addition to possible acute toxicity of particles in the respiratory tract, chronic exposure to particles that deposit in the lung may induce inflammation. Inflammatory responses can lead to increased permeability and possibly diffusion abnormality. Furthermore, mediators released during an inflammatory response could cause release of factors in the clotting cascade that may lead to an increased risk of thrombus formation in the vascular system (Seaton, 1995). Persistent inflammation, or repeated cycles of acute lung injury and healing, can induce chronic lung injury. Retention of the particles may be associated with the initiation and/or progression of COPD.

Takenaka et al. (1995) investigated mechanisms by which dpm may act to cause allergenic effects in human cell cultures. The investigators reported that application of organic dpm extracts over a period of 10 to 14 days increased IgE production from the cells by a factor of up to 360 percent. They concluded that enhanced IgE production in the human airway resulting from the organic fraction of dpm may be an important factor in the increasing incidence of allergic airway disease. Similarly, Tsien et al. (1997) investigated the effects of the organic fraction of dpm on IgE production in human cell cultures and found that application of the organic extract doubled IgE production after three days in cells already producing IgE.

Sagai et al. (1996) investigated the potential role of dpm-induced oxygen radicals in causing pulmonary injuries. Repeated intratracheal instillation of dpm in mice caused marked infiltration of inflammatory cells, proliferation of goblet cells, increased mucus secretion, respiratory resistance, and airway constriction. The results indicated that oxygen radicals, induced by intratracheally instilled dpm, can cause responses characteristic of bronchial asthma.

Lovik et al. (1997) investigated inflammatory and systemic IgE responses to dpm, alone and in combination with the model allergen ovalbumin (OA), in mice. To determine whether it was the elemental carbon core or substances in the organic fraction of dpm that were responsible for observed allergenic effects, they compared the effects of whole dpm with those of carbon black (CB) particles of comparable size and specific surface area. Although the effects were slightly greater for dpm, both dpm and CB were found to cause significant, synergistic increases in allergenic responses to the OA, as expressed by inflammatory responses of the local lymph node and OA-specific IgE production. The investigators concluded that both dpm and CB synergistically enhance and prolong inflammatory responses in the lymph nodes that drain the site of allergen deposition. They further concluded that the elemental carbon core contributes substantially to the adjuvant activity of dpm.

Diaz-Sanchez et al. (1994, 1996, 1997) conducted a series of experiments on human subjects to investigate the effects of dpm on allergic inflammation as measured by IgE production. The studies by Takenaka et al. (op cit.) and Tsien et al. (op cit.) were also part of this series but were based on human cell cultures rather than live human volunteers. A principal objective of these experiments was to investigate the pathways and mechanisms by which dpm induces allergic inflammation. The investigators found that the organic fraction of dpm can enhance IgE production, but that the major

polyaromatic hydrocarbon in this fraction (phenanthrene) can enhance IgE without causing inflammation. On the other hand, when human volunteers were sprayed intranasally with carbon particles lacking the organic compounds, the investigators found a large influx of cells in the nasal mucosa but no increase in IgE. These results suggest that while the organic portion of dpm is not necessary for causing irritation and local inflammation, it is the organic compounds that act on the immune system to promote an allergic response.

Salvi et al. (1999) investigated the impact of diesel exhaust on human airways and peripheral blood by exposing healthy volunteers to diesel exhaust at a concentration of 300 $\mu g/m^3$ for one hour with intermittent exercise. Following exposure, they found significant evidence of acute inflammatory responses in airway lavage and also in the peripheral blood. Some commenters expressed a belief that the gaseous, rather than particulate, components of diesel exhaust caused these effects. The investigators noted that the inflammatory responses observed could not be attributed to NO_2 in the diesel exhaust because previous studies they had conducted, using a similar experimental protocol, had revealed no such responses in the airway tissues of volunteers exposed to a higher concentration of NO_2, for a longer duration, in the absence of dpm. They concluded that ''[i]t therefore seems more likely that the particulate component of DE is responsible.''

iv. *Lung Cancer.* (1) *Genotoxicity Studies.* Many studies have shown that diesel soot, or its organic component, can increase the likelihood of genetic mutations during the biological process of cell division and replication. A survey of the applicable scientific literature is provided in Shirnamé-Moré (1995). What makes this body of research relevant to the risk of lung cancer is that mutations in critical genes can sometimes initiate, promote, or advance a process of carcinogenesis.

The determination of genotoxicity has frequently been made by treating diesel soot with organic solvents such as dichloromethane and dimethyl sulfoxide. The solvent removes the organic compounds from the carbon core. After the solvent evaporates, the mutagenic potential of the extracted organic material is tested by applying it to bacterial, mammalian, or human cells propagated in a laboratory culture. In general, the results of these studies have shown that various components of the organic material can induce mutations and chromosomal aberrations.

One commenter (MARG) pointed out that ''even assuming diesel exhaust contains particular genotoxic substances, the bioavailability of these genotoxins has been questioned.'' As acknowledged in the proposed risk assessment, a critical issue is whether whole diesel particulate is mutagenic when dispersed by substances present in the lung. Since the laboratory procedure for extracting organic material with solvents bears little resemblance to the physiological environment of the lung, it is important to establish whether dpm as a whole is genotoxic, without solvent extraction. Early research indicated that this was not the case and, therefore, that the active genotoxic materials adhering to the carbon core of diesel particles might not be biologically damaging or even available to cells in the lung (Brooks *et al.*, 1980; King *et al.*, 1981; Siak *et al.*, 1981). A number of more recent research papers, however, have shown that dpm, without solvent extraction, can cause DNA damage when the soot is dispersed in the pulmonary surfactant that coats the surface of the alveoli (Wallace *et al.*, 1987; Keane *et al.*, 1991; Gu *et al.*, 1991; Gu *et al.*, 1992). From these studies, NIOSH concluded in 1992 that:

> * * * the solvent extract of diesel soot and the surfactant dispersion of diesel soot particles were found to be active in procaryotic cell and eukaryotic cell *in vitro* genotoxicity assays. The cited data indicate that respired diesel soot particles on the surface of the lung alveoli and respiratory bronchioles can be dispersed in the surfactant-rich aqueous phase lining the surfaces, and that genotoxic material associated with such dispersed soot particles is biologically available and genotoxically active. Therefore, this research demonstrates the biological availability of active genotoxic materials without organic solvent interaction. [Cover letter to NIOSH response to ANPRM, 1992].

If this conclusion is correct, it follows that dpm itself, and not only its organic extract, can cause genetic mutations when dispersed by a substance present in the lung.

One commenter (IMC Global) noted that Wallace *et al.* (1987) used aged dpm samples from scrapings inside an exhaust pipe and contended that this was not a realistic representation of dpm. The commenter further argued that the two studies cited by Gu *et al.* involved ''direct application of an unusually high concentration gradient'' that does not replicate normal conditions of dpm exposure.

MSHA agrees with this commenter's general point that conditions set up in such experiments do not duplicate actual exposure conditions. However, as a follow-up to the Wallace study, Keane *et al.* (op. cit.) demonstrated similar results with both exhaust pipe soot and particles obtained directly from an exhaust stream. With regard to the two Gu studies, MSHA recognizes that any well-controlled experiment serves only a limited purpose. Despite their limitations, however, these experiments provided valuable information. They avoided solvent extraction. By showing that solvent extraction is not a necessary condition of dpm mutagenicity, these studies provided incremental support to the hypothesis of bioavailability under more realistic conditions. This possibility was subsequently tested by a variety of other experiments, including experiments on live animals and humans.

For example, Sagai *et al.* (1993) showed that whole dpm produced active oxygen radicals in the trachea of live mice, but that dpm stripped of organic compounds did not. Whole dpm caused significant damage to the lungs and also high mortality at low doses. According to the investigators, most of the toxicity observed appeared to be due to the oxygen radicals, which can also have genotoxic effects. Subsequently, Ichinose *et al.* (1997b) examined the relationship between tumor response and the formation of oxygen radicals in the lungs of mice injected with dpm. The mice were treated with sufficiently high doses of dpm to produce tumors after 12 months. As in the earlier study, the investigators found that the dpm generated oxygen radicals, even in the absence of biologically activating systems (such as macrophages), and that these oxygen radicals were implicated in the lung toxicity of the dpm. The authors concluded that ''oxidative DNA damage induced by the repeated DEP [*i.e.*, dpm] treatment could be an important factor in enhancing the mutation rate leading to lung cancer.''

The formation of DNA adducts is an important indicator of genotoxicity and potential carcinogenicity. Adduct formation occurs when molecules, such as those in dpm, attach to the cellular DNA. These adducts can negatively affect DNA transcription and/or cellular duplication. If DNA adducts are not repaired, then a mutation or chromosomal aberration can occur during normal mitosis (*i.e.*, cell replication) eventually leading to cancer cell formation. IPCS (1996) contains a survey of animal experiments showing DNA adduct induction in the lungs of experimental animals exposed to diesel

exhaust.[60] MSHA recognizes that such studies provide limited information regarding the bioavailability of organics, since positive results may well have been related to factors associated with lung particle overload. However, the bioavailability of genotoxic dpm components is also supported by human studies showing genotoxic effects of exposure to whole dpm. DNA adduct formation and/or mutations in blood cells following exposure to dpm, especially at levels insufficient to induce lung overload, can be presumed to result from organics diffusing into the blood.

Hemminki *et al.* (1994) found that DNA adducts were significantly elevated in lymphocytes of nonsmoking bus maintenance and truck terminal workers, as compared to a control group of hospital mechanics, with the highest adduct levels found among garage and forklift workers. Hou *et al.* (1995) reported significantly elevated levels of DNA adducts in lymphocytes of non-smoking diesel bus maintenance workers compared to a control group of unexposed workers. Similarly, Nielsen *et al.* (1996) found that DNA adducts were significantly increased in the blood and urine of bus garage workers and mechanics exposed to dpm as compared to a control group.

One commenter (IMC Global) acknowledged that ''the studies conducted by Hemminiki [Hemminiki et al., 1994] showed elevations in lymphocyte DNA adducts in garage workers, bus maintenance workers and diesel forklift drivers'' but argued that ''these elevations were at the borderline of statistical significance.'' Although results at a higher level of confidence would have been more persuasive, this does not negate the value of the evidence as it stands. Furthermore, statistical significance in an individual study becomes less of an issue when, as in this case, the results are corroborated by other studies.

IMC Global also acknowledged that the Nielsen study found significant differences in DNA adduct formation between diesel-exposed workers and controls but argued that ''the real source of genotoxins was unclear, and other sources of exposure, such as skin contact with lubricating oils could not be excluded.'' As is generally the case with studies involving human subjects, this study did not completely control for potential confounders. For this reason, MSHA considers it important that several human studies—not all subject to confounding by the same variables—found elevated adduct levels in diesel-exposed workers.

IMC Global cited another human study (Qu *et al.*, 1997) as casting doubt on the genotoxic effects of diesel exposure, even though this study (conducted on Australian coal miners) reported significant increases in DNA adducts immediately after a period of intense diesel exposure during a longwall move. As noted by the commenter, adduct levels of exposed miners and drivers were, prior to the longwall move, approximately 50% higher than for the unexposed control group; but differences by exposure category were not statistically significant. A more informative part of the study, however, consisted of comparing adducts in the same workers before and after a longwall move, which involved ''intensive use of heavy equipment, diesel powered in these mines, over a 2–3 week period.'' MSHA emphasizes that the comparison was made on the same workers, because doing so largely controlled for potentially confounding variables, such as smoking habits, that may be a factor when making comparisons between different persons. After the period of ''intensive'' exposure, statistically significant increases were observed in both total and individual adducts. Contrary to the commenter's characterization of this study, the investigators stated that their analysis ''provides results in which the authors have a high level of confidence.'' They concluded that ''given the * * * apparent increase in adducts during a period of intense DEE [*i.e.*, diesel exhaust emissions] exposures it would be prudent to pay particular attention to keeping exposures as low as possible, especially during LWCO [*i.e.*, 'longwall change out'] operations.'' Although the commenter submitted this study as counter-evidence, it actually provides significant, positive evidence that high dpm exposures in a mining environment can produce genotoxic effects.

The West Virginia Coal Association submitted an analysis by Dr. Peter Valberg, purporting to show that ''* * * the quantity of particle-bound mutagens that could potentially contact lung cells under human exposure scenarios is very small.'' According to Dr. Valberg's calculations, the dose of organic mutagens deposited in the lungs of a worker occupationally exposed (40 hours per week) to 500 μg/m^3 of dpm would be equivalent in potency to smoking about one cigarette per month.[61] Dr. Valberg indicated that a person smoking at this level would generally be classified a nonsmoker, but he made no attempt to quantify the carcinogenic effects. Nor did he compare this exposure level with levels of exposures to environmental tobacco smoke that have been linked to lung cancer.

Since the commenter did not provide details of Dr. Valberg's calculation, MSHA was unable to verify its accuracy or evaluate the plausibility of key assumptions. However, even if the equivalence is approximately correct, using it to discount the possibility that dpm increases the risk of lung cancer relies on several questionable assumptions. Although their precise role in the analysis is unclear because it was not presented in detail, these assumptions apparently include:

(1) That there is a good correlation between genotoxicity dose-response and carcinogenicity dose-response. Although genotoxicity data can be very useful for identifying a carcinogenic hazard, carcinogenesis is a highly complex process that may involve the interaction of many mutagenic, physiological, and biochemical responses. Therefore, the shape and slope of a carcinogenic dose-response relationship cannot be readily predicted from a genotoxic dose-response relationship.

(2) That only the organic fraction of dpm contributes to carcinogenesis. This contradicts the findings reported by Ichinose *et al.* (1997b) and does not take into account the contribution that inflammation and active oxygen radicals induced by the inorganic carbon core of dpm may have in promoting lung cancers. Multiple routes of carcinogenesis may operate in human lungs—some requiring only the various organic mutagens in dpm and others involving induction of free radicals by the elemental carbon core, either alone or in combination with the organics.

(3) That the only mutagens in dpm are those that have been identified as mutagenic to bacteria and that the

[60] Some of these studies will be discussed in the next subsection of this risk assessment.

[61] The only details provided for this calculation pertained to adjusting 8-hour occupational exposures. Dr. Valberg adjusted the 500 μg/m^3 concentration for an 8-hour occupational exposure to a supposedly equivalent 24-hour continuous concentration of 92 μg/m^3. This adjustment ignored differences in breathing rates between periods of sleep, leisure activities, and heavy work. Even under the unrealistic assumption of homogeneous breathing rates, the calculation appears to be erroneous, since (500 μg/m^3) × (40 hours/week) is nearly 30 percent greater than (92 μg/m^3) × (168 hours/week). Also, Dr. Valberg stated that the calculation assumed a deposition fraction of 20 percent for dpm but did not state what deposition fraction was being assumed for the particles in cigarette smoke.

mutagenic constituents of dpm have all been identified. One of the most potent of all known mutagens (3-nitrobenzanthrone) was only recently isolated and identified in dpm (Enya *et al.*, 1997).

(4) That the mutagenic components of dpm have the same combined potency as those in cigarette smoke. This ignores the relative potency and amounts of the various mutagenic constituents. If the calculation did not take into account the relative amounts and potencies of all the individual mutagens in dpm and cigarette smoke, then it oversimplified the task of making such a comparison.

In sum, unlike the experimental findings of dpm genotoxicity discussed above, the analysis by Dr. Valberg is not based on empirical evidence from dpm experiments, and it appears to rely heavily on questionable assumptions. Moreover, the contention that active components of dpm are not available in sufficient quantities to cause significant mutagenic damage in humans appears to be directly contradicted by the empirical evidence of elevated DNA adduct levels in exposed workers (Hemminki *et al.*, 1994; Hou *et al.*, 1995; Nielsen *et al.*, 1996; Qu *et al.*, 1997).

(2) *Animal Inhalation Studies.* When dpm is inhaled, a number of adverse effects that may contribute to carcinogenesis are discernable by microscopic and biochemical analysis. For a comprehensive review of these effects, see Watson and Green (1995). In brief, these effects begin with phagocytosis, which is essentially an attack on the diesel particles by cells called alveolar macrophages. The macrophages engulf and ingest the diesel particles, subjecting them to detoxifying enzymes. Although this is a normal physiological response to the inhalation of foreign substances, the process can produce various chemical byproducts injurious to normal cells. In attacking the diesel particles, the activated macrophages release chemical agents that attract neutrophils (a type of white blood cell that destroys microorganisms) and additional alveolar macrophages. As the lung burden of diesel particles increases, aggregations of particle-laden macrophages form in alveoli adjacent to terminal bronchioles, the number of Type II cells lining particle-laden alveoli increases, and particles lodge within alveolar and peribronchial tissues and associated lymph nodes. The neutrophils and macrophages release mediators of inflammation and oxygen radicals, which have been implicated in causing various forms of chromosomal damage, genetic mutations, and malignant transformation of cells (Weitzman and Gordon, 1990). Eventually, the particle-laden macrophages are functionally altered, resulting in decreased viability and impaired phagocytosis and clearance of particles. This series of events may result in pulmonary inflammatory, fibrotic, or emphysematous lesions that can ultimately develop into cancerous tumors.

IARC (1989), Mauderly (1992), Busby and Newberne (1995), IPCS (1996), Cal-EPA (1998), and US EPA (1999) reviewed the scientific literature relating to excess lung cancers observed among laboratory animals chronically exposed to filtered and unfiltered diesel exhaust. The experimental data demonstrate that chronic exposure to whole diesel exhaust increases the risk of lung cancer in rats and that dpm is the causative agent. This carcinogenic effect has been confirmed in two strains of rats and in at least five laboratories. Experimental results for animal species other than the rat, however, are either inconclusive or, in the case of Syrian hamsters, suggestive of no carcinogenic effect. In two of three mouse studies reviewed by IARC (1989), lung tumor formation (including adenocarcinomas) was increased in the exposed animals as compared to concurrent controls; in the third study, the total incidence of lung tumors was not elevated compared to historical controls. Two more recent mouse studies (Heinrich et al., 1995; Mauderly et al., 1996) have both reported no statistically significant increase in lung cancer rates among exposed mice, as compared to contemporaneous controls. Monkeys exposed to diesel exhaust for two years did not develop lung tumors, but the short duration of exposure was judged inadequate for evaluating carcinogenicity in primates.

Bond et al. (1990a) investigated differences in peripheral lung DNA adduct formation among rats, hamsters, mice, and monkeys exposed to dpm at a concentration of 8100 $\mu g/m^3$ for 12 weeks. Mice and hamsters showed no increase of DNA adducts in their peripheral lung tissue, whereas rats and monkeys showed a 60 to 80-percent increase. The increased prevalence of lung DNA adducts in monkeys suggests that, with respect to DNA adduct formation, the human lungs' response to dpm inhalation may more closely resemble that of rats than that of hamsters or mice.

The conflicting carcinogenic effects of chronic dpm inhalation reported in studies of rats, mice, and hamsters may be due to non-equivalent delivered doses or to differences in response among species. Indeed, monkey lungs have been reported to respond quite differently than rat lungs to both diesel exhaust and coal dust (Nikula, 1997). Therefore, the results from rat experiments do not, by themselves, establish that there is any excess risk due to dpm exposure for humans. However, the human epidemiologic and genotoxicity (DNA adduct) data indicate that humans comprise a species that, like rats, do suffer a carcinogenic response to dpm exposure. This would be consistent with the observation, mentioned above, that lung DNA adduct formation is increased among exposed rats but not among exposed hamsters or mice. Therefore, although MSHA recognizes that there are important differences between rats and humans (as there are also between rats and hamsters or mice), MSHA considers the rat studies relevant to an evaluation of human health risks.

Reactions similar to those observed in rats inhaling dpm have also been observed in rats inhaling fine particles with no organic component (Mauderly et al., 1994; Heinrich et al., 1994, 1995; Nikula et al., 1995). Rats exposed to titanium dioxide (TiO_2) or pure carbon (''carbon black'') particles, which are not considered to be genotoxic, exhibited similar pathological responses and developed lung cancers at about the same rate as rats exposed to whole diesel exhaust. Carbon black particles were used in these experiments because they are physically similar to the inorganic carbon core of dpm but have negligible amounts of organic compounds adsorbed to their surface. Therefore, at least in some species, it appears that the lung cancer toxicity of dpm may result largely from a biochemical response to the core particle itself rather than from specific, genotoxic effects of the adsorbed organic compounds.[62]

One commenter stated that, in the proposed risk assessment, MSHA had neglected three additional studies suggesting that lung cancer risks in animals inhaling diesel exhaust are unrelated to genotoxic mechanisms. One of these studies (Mauderly et al., 1996) did not pertain to questions of

[62] NIOSH commented as follows: ''Data cited by MSHA in support of this statement are not comparable. Rats were exposed to dpm at 4 mg/m^3 for 2 years (Mauderly et al. 1987; Brightwell et al. 1989), in contrast to rats exposed to TiO_2 at 250 mg/m^3 for two years [reference to article (Lee et al. 1985) not cited by MSHA]. It is not apparent that the overload mechanism that is proposed to be responsible for tumors in the TiO_2 exposed rats could also have been responsible for the tumors seen in the dpm exposed rats at 62-fold lower exposure concentrations.'' In the reports cited by MSHA, levels of TiO_2 and/or carbon black were commensurate with dpm levels.

genotoxicity but has been cited in the discussion of mouse studies above. The other two studies (Randerath et al., 1995 and Belinsky et al., 1995) were conducted as part of the cancer bioassay described in the 1994 article by Mauderly et al. (cited in the preceding paragraph). In the Randerath study, the investigators found that no DNA adducts specific to either diesel exhaust or carbon black were induced in the lungs of rats exposed to the corresponding substance. However, after three months of exposure, the total level of DNA adducts and the levels of some individual adducts were significantly higher in the diesel-exposed rats than in the controls. In contrast, multiple DNA adducts thought to be specific to diesel exhaust formed in the skin and lungs of mice treated topically with organic dpm extract. These results are consistent with the findings of Mauderly et al. (1994, op cit.). They imply that although the organic compounds of diesel exhaust are capable of damaging cellular DNA, they did not inflict such damage under the conditions of the inhalation experiment performed. The report noted that these results do not rule out the possibility of DNA damage by inhaled organics in ''other species or * * * [in] exposure situations in which the concentrations of diesel exhaust particles are much lower.'' In the Belinsky study, the investigators measured mutations in selected genes in the tumors of those rats that had developed lung cancer. This study did not succeed in elucidating the mechanisms by which dpm and carbon black cause lung tumors in rats. The authors concluded that ''until some of the genes involved in the carcinogenicity of diesel exhaust and carbon black are identified, a role for the organic compounds in tumor development cannot be excluded.''

The carbon-black and TiO_2 studies discussed above indicate that lung cancers in rats exposed to dpm may be induced by a mechanism that does not require the bioavailability of genotoxic organic compounds adsorbed on the elemental carbon particles. Some researchers have interpreted these studies as also suggesting that (1) the carcinogenic mechanism in rats depends on massive overloading of the lung and (2) that this may provide a mechanism of carcinogenesis involving a threshold effect specific to rats, which has not been observed in other rodents or in humans (Oberdörster, 1994; Watson and Valberg, 1996). Some commenters on the ANPRM cited the lack of a link between lung cancer and coal dust or carbon black exposure as evidence that carbon particles, by themselves, are not carcinogenic in humans. Coal mine dust, however, consists almost entirely of particles larger than those forming the carbon core of dpm or used in the carbon black and TiO_2 rat studies. Furthermore, although there have been nine studies reporting no excess risk of lung cancer among coal miners (Liddell, 1973; Costello et al., 1974; Armstrong et al., 1979; Rooke et al., 1979; Ames et al., 1983; Atuhaire et al., 1985; Miller and Jacobsen, 1985; Kuempel et al., 1995; Christie et al., 1995), eight studies have reported an elevated risk of lung cancer for those exposed to coal dust (Enterline, 1972; Rockette, 1977; Howe et al., 1983; Correa et al., 1984; Levin et al., 1988; Morabia et al., 1992; Swanson et al., 1993; Morfeld et al., 1997). The positive results in five of these studies (Enterline, 1972; Rockette, 1977; Howe et al., 1983; Morabia et al., 1992; Swanson et al., 1993) were statistically significant. Morabia et al. (op cit.) reported increased risk associated with duration of exposure, after adjusting for cigarette smoking, asbestos exposure, and geographic area. Furthermore, excess lung cancers have been reported among carbon black production workers (Hodgson and Jones, 1985; Siemiatycki, 1991; Parent et al., 1996). After a comprehensive evaluation of the available scientific evidence, the World Health Organization's International Agency for Research on Cancer concluded: ''Carbon black is possibly carcinogenic to humans (Group 2B).'' (IARC, 1996).

The carbon black and TiO_2 animal studies cited above do not prove there is a threshold below which dpm exposure poses no risk of causing lung cancer in humans. They also do not prove that dpm exposure has no incremental, genotoxic effects. Even if the genotoxic organic compounds in dpm were biologically unavailable and played no role in human carcinogenesis, this would not rule out the possibility of a genotoxic route to lung cancer (even for rats) due to the presence of the particles themselves. For example, as a byproduct of the biochemical response to the presence of particles in the alveoli, free oxidant radicals may be released as macrophages attempt to digest the particles. There is evidence that dpm can both induce production of reactive oxygen agents and also depress the activity of naturally occurring antioxidant enzymes (Mori, 1996; Ichinose et al., 1997; Sagai et al., 1993). Oxidants can induce carcinogenesis either by reacting directly with DNA, or by stimulating cell replication, or both (Weitzman and Gordon, 1990). Salvi et al. (1999) reported acute inflammatory responses in the airways of human exposed to dpm for one hour at a concentration of 300 $\mu g/m^3$. Such inflammation is associated with the production of free radicals and could provide routes to lung cancer with even when normal lung clearance is occurring. It could also give rise to a ''quasi-threshold,'' or surge in response, corresponding to the exposure level at which the normal clearance rate becomes overwhelmed (lung overload).

Oxidant activity is not the only mechanism by which dpm could exert carcinogenic effects in the absence of mutagenic activity by its organic fraction. In its commentary on the Randerath study discussed above, the HEI's Health Review Committee suggested that dpm could both cause genetic damage by inducing free oxygen radicals and also enhance cell division by inducing cytokines or growth hormones:

> It is possible that diesel exhaust exerts its carcinogenic effects through a mechanism that does not involve direct genotoxicity (that is, formation of DNA adducts) but involves proliferative responses such as chronic inflammation and hyperplasia arising from high concentrations of particles deposited in the lungs of the exposed rats. * * * Phagocytes (macrophages and neutrophils) released during inflammatory reactions ''produce reactive oxygen species that can damage DNA. * * * Particles (with or without adsorbed PAHs) may thus induce oxidative DNA damage via oxygen free radicals. * * * Alternatively, activated phagocytes may release cytokines or growth factors that are known to increase cell division. Increased cell division has been implicated in cancer causation. * * * Thus, in addition to oxidative DNA damage, increased cell proliferation may be an important mechanism by which diesel exhaust and other insoluble particles induce pulmonary carcinogenesis in the rat. [Randerath et al., 1995, p. 55]

Even if lung overload were the primary or sole route by which dpm induced lung cancer, this would not mean that the high dpm concentrations observed in some mines are without hazard. It is noteworthy, moreover, that dpm exposure levels recorded in some mines have been almost as high as laboratory exposures administered to rats showing a clearly positive response. Intermittent, occupational exposure levels greater than about 500 $\mu g/m^3$ dpm may overwhelm the human lung clearance mechanism (Nauss et al., 1995). Therefore, concentrations at the even higher levels currently observed in some mines could be expected to cause overload in some humans, possibly inducing lung cancer by a mechanism

similar to what occurs in rats. In addition, a proportion of exposed individuals can always be expected to be more susceptible than normal to clearance impairments and lung overload. Inhalation at even moderate levels may significantly impair clearance, especially in susceptible individuals. Exposures to cigarette smoke and respirable mineral dusts may further depress clearance mechanisms and reduce the threshold for overload. Consequently, even at dpm concentrations far lower than 500 μg/m³ dpm, impaired clearance due to dpm inhalation may provide an important route to lung cancer in humans, especially if they are also inhaling cigarette smoke and other fine dusts simultaneously. (Hattis and Silver, 1992, Figures 9, 10, 11).

Furthermore, as suggested above, lung overload is not necessarily the only route to carcinogenesis in humans. Therefore, dpm concentrations too low to cause overload still may present a hazard. In humans exposed over a working lifetime to doses insufficient to cause overload, carcinogenic mechanisms unrelated to overload may operate, as indicated by the human epidemiologic studies and the data on human DNA adducts cited in the preceding subsection of this risk assessment. It is possible that overload provides the dominant route to lung cancer at high concentrations of fine particulate, while other mechanisms emerge as more relevant for humans under lower-level exposure conditions.

The NMA noted that, in 1998, the US EPA's Clean Air Scientific Advisory Committee (CASAC) concluded that there is ''no evidence that the organic fraction of soot played a role in rat tumorigenesis at any exposure level, and considerable evidence that it did not.'' According to the NMA, this showed ''* * * it is the rat data—not the hamster data—that lacks relevance for human health assessment.''

It must first be noted that, in MSHA's view, all of the experimental animal data on health effects has relevance for human health risk assessment—whether the evidence is positive or negative and even if the positive results cannot be used to quantify human risk. The finding that different mammalian species exhibit important differences in response is itself relevant for human risk assessment. Second, the passage quoted from CASAC pertains to the route for tumorigenesis in rats and does not discuss whether this does or does not have relevance to humans exposed at high levels. The context for the CASAC deliberations was ambient exposure conditions in the general environment, rather than the higher occupational exposures that might impair clearance rates in susceptible individuals. Third, the comment assumes that only a finding of tumorigenesis attributable to the organic portion of dpm would elucidate mechanisms of potential health effects in humans. This ignores the possibility that a mechanism promoting tumors, but not involving the organics, could operate in both rats and humans. Induction of free oxygen radicals is an example. Fourth, although there may be little or no evidence that organics contributed to rat tumorigenesis in the studies performed, there is evidence that the organics contributed to increases in DNA adduct formation. This kind of activity could have tumorigenic consequences in humans who may be exposed for periods far longer than a rat's 3-year lifetime and who, as a consequence, have more time to accumulate genetic damage from a variety of sources.

Bond et al. (1990b) and Wolff et al. (1990) investigated adduct formation in rats exposed to various concentrations of either dpm or carbon black for 12 weeks. At the highest concentration (10 mg/m³), DNA adduct levels in the lung were increased by exposure to either dpm or carbon black; but levels in the rats exposed to dpm were approximately 30 percent higher. Gallagher et al. (1994) exposed different groups of rats to diesel exhaust, carbon black, or TiO_2 and detected no significant difference in DNA adduct levels in the lung. However, the level of one type of adduct, thought to be derived from a PAH, was elevated in the dpm-exposed rats but not found in the control group or in rats exposed to carbon black or TiO_2.

These studies indicate that the inorganic carbon core of dpm is not the only possible agent of genetic damage in rats inhaling dpm. After a review of these and other studies involving DNA adducts, IPCS (1996) concluded that ''Taken together, the studies of DNA adducts suggest that some organic chemicals in diesel exhaust can form DNA adducts in lung tissue and may play a role in the carcinogenic effects. * * *however, DNA adducts alone cannot explain the carcinogenicity of diesel exhaust, and other factors, such as chronic inflammation and cell proliferation, are also important.''

Nauss et al. (1995, pp. 35–38) judged that the results observed in the carbon black and TiO_2 inhalation studies on rats do not preclude the possibility that the organic component of dpm has important genotoxic effects in humans. More generally, they also do not prove that lung overload is necessary for dpm-induced lung cancer. Because of the relatively high doses administered in some of the rat studies, it is conceivable that an overload phenomenon masked or even inhibited other potential cancer mechanisms. At dpm concentrations insufficient to impair clearance, carcinogenesis may have followed other routes, some possibly involving the organic compounds. At these lower concentrations, or among rats for which overload did not occur, tumor rates for dpm, carbon black, and TiO_2 may all have been too low to make statistically meaningful comparisons.

The NMA argued that ''MSHA's contention that lung overload might ''mask'' tumor production by lower doses of dpm has been convincingly rebutted by recognized experts in the field,'' but provided no convincing explanation of why such masking could not occur. The NMA went on to say:

> The [CASAC] Panel viewed the premises that: a) a small tumor response at low exposure was overlooked due to statistical power; and b) soot-associated organic mutagens had a greater effect at low than at high exposure levels to be without foundation. In the absence of supporting evidence, the Panel did not view derivation of a quantitative estimate of human lung cancer risk from the low-level rat data as appropriate.

MSHA is not attempting to ''derive a quantitative estimate of human lung cancer risk from the low-level rat data.''

Dr. Peter Valberg, writing for the West Virginia Coal Association, provided the following argument for discounting the possibility of other carcinogenic mechanisms being masked by overload in the rat studies:

> Some regulatory agencies express concern about the mutagens bound to dpm. They hypothesize that, at high exposure levels, genotoxic mechanisms are overwhelmed (masked) by particle-overload conditions. However, they argue that at low-exposure concentrations, these organic compounds could represent a lung cancer risk. Tumor induction by mutagenic compounds would be characterized by a linear dose-response and should be detectable, given enough exposed rats. By using a ''meta-analysis'' type of approach and combining data from eight long-term rat inhalation studies, the lung tumor response can be analyzed. When all dpm-exposed rats from lifetime-exposure studies are combined, a threshold of response (noted above) occurs at approximately 600 μg/m³ continuous lifetime exposure (approximately 2,500 μg/m³ of occupational exposure). Additional statistical analysis of only those rats exposed to low concentrations of dpm confirms the absence of a tumorigenic effect below that threshold. Thus, even data in rats (the most sensitive laboratory species) do not support the hypothesis that particle-bound organics cause tumors.

MSHA finds that this analysis relies on several questionable and unsupported assumptions and that, for the following reasons, the possibility remains that organic compounds in inhaled dpm may, under the right exposure conditions, contribute to its carcinogenic effects:

(1) The absence of evidence for an organic carbon effect is not equivalent to evidence of the absence of such an effect. Dr. Valberg did not demonstrate that enough rats were exposed, at levels insufficient to cause overload, to ensure detection of a 30- to 40-percent increase in the risk of lung cancer. Also, the normal lifespan of a rat whose lung is not overloaded with particles may, because of the lower concentrations involved, provide insufficient time for the organic compounds to express carcinogenic effects. Furthermore, low bioavailability of the organics could further reduce the likelihood that a carcinogenic sequence of mutations would occur within a rat's relatively short lifespan (i.e., at particle concentrations too low to cause overload).

(2) If the primary mechanism for carcinogenesis requires a reduced clearance rate (due to overload), then acute exposures are important, and it may not be appropriate to represent equivalent hazards by spreading an 8-hour occupational exposures over a 24-hour period. For example, eight hours at 600 $\mu g/m^3$ would have different implications for lung clearance than 24 hours at 200 $\mu g/m^3$.

(3) Granting that the rat data cannot be used to extrapolate risk for humans, these data should also not be used to rule out mechanisms of carcinogenesis that may operate in humans but not in rats. Clearance, for example, may operate differently in humans than in rats, and there may be a gradual rather than abrupt change in human overload conditions with increasing exposure. Also, at least some of the organic compounds in dpm may be more biologically available to the human lung than to that of the rat.

(4) For experimental purposes, laboratory rats are deliberately bred to be homogeneous. This is done, in part, to deliberately minimize differences in response between individuals. Therefore, individual differences in the threshold for lung overload would tend to be masked in experiments on laboratory rats. It is likely that human populations would exhibit, to a far greater extent than laboratory rats, a range of susceptibilities to lung overload. Also some humans, unlike the laboratory rats in these experiments, place additional burdens on their lung clearance by smoking.

One commenter (MARG) concluded that ''[t]here is * * * no basis for extrapolating the rat results to human beings; the animal studies, taken together, do not justify MSHA's proposals.''

MSHA is neither extrapolating the rat results to make quantitative risk estimates for humans nor using them, in isolation, as a justification for these regulations. MSHA does regard it as significant, however, that the evidence for an increased risk of lung cancer due to chronic dpm inhalation comes from both human and animal studies. MSHA agrees that the quantitative results observed for rats in existing studies should not be extrapolated to humans. Nevertheless, the fact that high dpm exposures for two or three years can induce lung cancer in rats enhances the epidemiologic evidence that much longer exposures to miners, at concentrations of the same order of magnitude, could also induce lung cancers.

3. Characterization of Risk

After reviewing the evidence of adverse health effects associated with exposure to dpm, MSHA evaluated that evidence to ascertain whether exposure levels currently existing in mines warrant regulatory action pursuant to the Mine Act. The criteria for this evaluation are established by the Mine Act and related court decisions. Section 101(a)(6)(A) provides that:

> The Secretary, in promulgating mandatory standards dealing with toxic materials or harmful physical agents under this subsection, shall set standards which most adequately assure on the basis of the best available evidence that no miner will suffer material impairment of health or functional capacity even if such miner has regular exposure to the hazards dealt with by such standard for the period of his working life.

Based on court interpretations of similar language under the Occupational Safety and Health Act, there are three questions that need to be addressed: (a) Whether health effects associated with dpm exposure constitute a ''material impairment'' to miner health or functional capacity; (b) whether exposed miners are at significant excess risk of incurring any of these material impairments; and (c) whether the rule will substantially reduce such risks.

Some commenters argued that the link between dpm exposure and material health impairments is questionable, and that MSHA should wait until additional scientific evidence becomes available before concluding that there are health risks due to such exposure warranting regulatory action. For example, MARG asserted that ''[c]ontrary to the suggestions in the [proposed] preamble, a link between dpm exposure and serious illness has never been established by reliable scientific evidence.'' [63] MARG continued as follows:

> Precisely because the scientific evidence * * * is inconclusive at best, NIOSH and NCI are now conducting a * * * [study] to determine whether diesel exhaust is linked to illness, and if so, at what level of exposure. * * * MARG is also funding an independent parallel study.
>
> * * * Until data from the NIOSH/NCI study, and the parallel MARG study, are available, the answers to these important questions will not be known. Without credible answers to these and other questions, MSHA's regulatory proposals * * * are premature * * *.''

For reasons explained below, MSHA does not agree that the collective weight of scientific evidence is ''inconclusive at best.'' Furthermore, the criteria for evaluating the health effects evidence do not require scientific certainty. As noted by Justice Stevens in an important case on risk involving the Occupational Safety and Health Administration, the need to evaluate risk does not mean an agency is placed into a ''mathematical straitjacket.'' [*Industrial Union Department, AFL–CIO* v. *American Petroleum Institute,* 448 U.S. 607, 100 S.Ct. 2844 (1980), hereinafter designated the ''Benzene'' case]. The Court recognized that regulation may be necessary even when scientific knowledge is not complete; and—

> so long as they are supported by a body of reputable scientific thought, the Agency is free to use conservative assumptions in interpreting the data * * * risking error on the side of overprotection rather than underprotection. [Id. at 656].

[63] MARG supported this assertion by claiming that ''[t]he EPA reports which MSHA references in its preamble were found 'not scientifically adequate for making regulatory decisions concerning the use of diesel-powered engines' by EPA's Clean Air Scientific Advisory Committee. [reference to CASAC (1998)]'' Contrary to MARG's claim, CASAC (1998) did not review any of the 20 EPA documents MSHA cited in the proposed preamble. Instead, the document reviewed by CASAC (1998) was an unpublished draft of a health risk assessment on diesel exhaust (EPA, 1998), to which MSHA made no reference. Since MSHA has not relied in any way on this 1998 draft document, its ''scientific adequacy'' is entirely irrelevant to this rulemaking.

In response to the 1998 CASAC review, EPA modified its draft risk assessment (EPA, 1999), and CASAC subsequently reviewed the 1999 draft (CASAC, 2000). CASAC found the revised draft much improved over the previous version and agreed that even environmental exposure to diesel emissions is likely to increase the risk of lung cancer (CASAC, 2000). CASAC endorsed this conclusion for dpm concentrations in ambient air, which are lower, by a factor of more than 100, than the levels observed in some mines (see Fig. III–4).

Moreover, the statutory criteria for evaluating health effects do not require MSHA to wait for incontrovertible evidence. In fact, MSHA is required to set standards based on the ''best *available* evidence'' (emphasis added).

a. Material Impairments to Miners' Health or Functional Capacity

MSHA recognizes that there is considerable disagreement, among knowledgeable parties, in the interpretation of the overall body of scientific research and medical evidence related to human health effects of dpm exposures. One commenter for example, interpreted the collective evidence as follows:

> * * * the best available scientific evidence shows that diesel particulate exposure is associated with serious material impairment of health. * * * there is *clear* evidence that diesel particulate exposure can cause lung cancer (as well as other serious non-malignant diseases) among workers in a variety of occupational settings. While no body of scientific evidence is ever completely definitive, the evidence regarding diesel particulate is particularly strong * * *. [Michael Silverstein, MD, State of Washington Dept. of Labor and Industries]

Other commenters, including several national and regional organizations representing the mining industry, sharply disagreed with this interpretation. For example, one commenter stated that ''[i]n our opinion, the best available evidence does not provide substantial or credible support for the proposal.'' Several commenters argued that evidence from within the mining industry itself was especially weak.[64] A representative of one mining company that had been using diesel equipment for many years commented: ''[t]o date, the medical history of our employees does not indicate a single case of lung cancer, chronic illness, or material impairment of health due to exposure to diesel exhaust. This appears to be the established norm throughout the U.S. coal mining industry.'' This commenter, however, submitted no evidence comparing the rate of lung cancer or other material impairment among exposed miners to the rate for unexposed miners (or comparable workers) of similar age, smoking habits, and geographic location.

With due consideration to all oral and written testimony, comments, and evidence submitted during the rulemaking proceedings, MSHA conducted a review of the scientific literature cited in Part III.2. Based on the combined weight of the best available evidence, MSHA has concluded that underground miners exposed to current levels of dpm are at excess risk of incurring the following three kinds of material impairment: (i) Sensory irritations and respiratory symptoms (including allergenic responses); (ii) premature death from cardiovascular, cardiopulmonary, or respiratory causes; and (iii) lung cancer. The next three subsections will respectively explain MSHA's basis for linking these effects with dpm exposure.

i. Sensory Irritations and Respiratory Symptoms (including allergenic responses). Kahn et al. (1988), Battigelli (1965), Gamble et al. (1987a), and Rudell et al. (1996) identified a number of debilitating acute responses to diesel exhaust exposure. These responses included irritation of the eyes, nose and throat; headaches, nausea, and vomiting; chest tightness and wheeze. These symptoms were also reported by miners at the 1995 workshops and the public hearings held on these proceedings in 1998. In addition, Ulfvarson et al. (1987, 1990) reported evidence of reduced lung function in workers exposed to dpm for a single shift. The latter study supports attributing a portion of the reduction to the dpm in diesel exhaust. After reviewing this body of literature, Morgan et al. (1997) concluded ''it is apparent that exposure to diesel fumes in sufficient concentrations may lead to [transient] eye and nasal irritation'' and ''a transient decline of ventilatory capacity has been noted following such exposures.''

One commenter (Nevada Mining Association) acknowledged there was evidence that miners exposed to diesel exhaust experienced, as a possible consequence of their exposure, ''acute, short-term or 'transitory' irritation, such as watering eyes, in susceptible individuals * * *''; but asserted that ''[a]ddressing any such transient irritant effects does not require the Agency's sweeping, stringent PEL approach [in M/NM mines].''

Although there is evidence that such symptoms subside within one to three days of no occupational exposure, a miner who must be exposed to dpm day after day in order to earn a living may not have time to recover from such effects. Hence, the opportunity for a so-called ''reversible'' health effect to reverse itself may not be present for many miners. Furthermore, effects such as stinging, itching and burning of the eyes, tearing, wheezing, and other types of sensory irritation can cause severe discomfort and can, in some cases, be seriously disabling. Also, workers experiencing sufficiently severe sensory irritations can be incapacitated or distracted as a result of their symptoms, thereby endangering themselves and other workers and increasing the risk of accidents. For these reasons, MSHA considers such irritations to constitute ''material impairments'' of health or functional capacity within the meaning of the Act, regardless of whether or not they are reversible. Further discussion of why MSHA believes reversible effects can constitute material impairments can be found above, in Subsection 2.a.2 of this risk assessment.

The best available evidence also points to more severe respiratory consequences of exposure to dpm. Significant statistical associations have been detected between acute environmental exposures to fine particulates and debilitating respiratory impairments in adults, as measured by lost work days, hospital admissions, and emergency room visits (see Table III–3). Short-term exposures to fine particulates, or to particulate air pollution in general, have been associated with significant increases in the risk of hospitalization for both pneumonia and COPD (EPA, 1996).

The risk of severe respiratory effects is exemplified by specific cases of persistent asthma linked to diesel exposure (Wade and Newman, 1993). Glenn et al. (1983) summarized results of NIOSH health evaluations among coal, salt, trona, and potash miners and reported that ''all four of the chronic effects analyses revealed an excess of cough and phlegm among the diesel exposed group.'' There is persuasive evidence for a causal connection between dpm exposure and increased manifestations of allergic asthma and other allergic respiratory diseases, coming from recent experiments on animals and human cells (Takenaka et al., 1995; Lovik et al., 1997; Takano et al., 1997; Ichinose et al., 1997a). Based on controlled experiments on healthy human volunteers, Diaz-Sanchez et al. (1994, 1996, 1997), Peterson and Saxon (1996), and Salvi et al. (1999) reported significant increases in various markers of allergic response resulting from exposure to dpm.

Peterson and Saxon (1996) reviewed the scientific literature on the relationship between PAHs and other products of fossil fuel combustion found

[64] At the public hearing on May 11, 1999, a commenter representing MARG suggested there is evidence that miners exposed to dpm experience adverse health effects at lower-than-normal rates. According to this commenter, ''[s]ignificantly, the human studies conducted in the mining industry reveal a negative propensity for diesel particulate matter-related health effects.'' These studies drew comparisons against an external reference population and failed to adjust for the ''healthy worker effect.'' (See MSHA's discussion of this effect, especially as manifested in the study by Christie et al., 1995, in Subsection 2.c.i(2)(a) of this risk assessment.)

in dpm and trends in allergic respiratory disease. They found that the prevalences of allergic rhinitis (''hay fever'') and allergic asthma have significantly increased with the historical increase in fossil fuel combustion and that laboratory data support the hypothesis that certain organic compounds found in dpm ''* * * are an important factor in the long-term increases in the prevalence in allergic airway disease.'' Similarly, much of the research on allergenic responses to dpm was reviewed by Diaz-Sanchez (1997), who concluded that dpm pollution in the ambient environment ''may play an important role in the increased incidence of allergic airway disease.'' Morgan et al. (1997) noted that dpm ''* * * may be partly responsible for some of the exacerbations of asthma'' and that ''* * * it would be wise to err on the side of caution.'' Such health outcomes are clearly ''material impairments'' of health or functional capacity within the meaning of the Act.

ii. Premature Death from Cardiovascular, Cardiopulmonary, or Respiratory Causes. The evidence from air pollution studies identifies death, largely from cardiovascular, cardiopulmonary, or respiratory causes, as an endpoint significantly associated with acute exposures to fine particulates ($PM_{2.5}$—see Table III–3). The weight of epidemiologic evidence indicates that short-term ambient exposure to particulate air pollution contributes to an increased risk of daily mortality (EPA, 1996). Time-series analyses strongly suggest a positive effect on daily mortality across the entire range of ambient particulate pollution levels. Relative risk estimates for daily mortality in relation to daily ambient particulate concentration are consistently positive and statistically significant across a variety of statistical modeling approaches and methods of adjustment for effects of relevant covariates such as season, weather, and co-pollutants. The mortality effects of acute exposures appear to be primarily attributable to combustion-related particles in $PM_{2.5}$ (such as dpm) and are especially pronounced for death due to pneumonia, COPD, and IHD (Schwartz et al., 1996). After thoroughly reviewing this body of evidence, the U.S. Environmental Protection Agency (EPA) concluded:

> It is extremely unlikely that study designs not yet employed, covariates not yet identified, or statistical techniques not yet developed could wholly negate the large and consistent body of epidemiologic evidence * * *. [EPA, 1996]

There is also substantial evidence of a relationship between chronic exposure to fine particulates ($PM_{2.5}$) and an excess (age-adjusted) risk of mortality, especially from cardiopulmonary diseases. The Six Cities and ACS studies of ambient air particulates both found a significant association between chronic exposure to fine particles and excess mortality. In some of the areas studied, $PM_{2.5}$ is composed primarily of dpm; and significant mortality and morbidity effects were also noted in those areas. In both studies, after adjusting for smoking habits, a statistically significant excess risk of cardiopulmonary mortality was found in the city with the highest average concentration of $PM_{2.5}$ as compared to the city with the lowest. Both studies also found excess deaths due to lung cancer in the cities with the higher average level of $PM_{2.5}$, but these results were not statistically significant (EPA, 1996). The EPA concluded that—

> * * * the chronic exposure studies, taken together, suggest there may be increases in mortality in disease categories that are consistent with long-term exposure to airborne particles and that at least some fraction of these deaths reflect cumulative PM impacts above and beyond those exerted by acute exposure events * * * There tends to be an increasing correlation of long-term mortality with PM indicators as they become more reflective of fine particle levels. [EPA, 1996]

Whether associated with acute or chronic exposures, the excess risk of death that has been linked to pollution of the air with fine particles like dpm is clearly a ''material impairment'' of health or functional capacity within the meaning of the Act.

In a review, submitted by MARG, of MSHA's proposed risk assessment, Dr. Jonathan Borak asserted that ''MSHA appears to regard all particulates smaller than 2.5 $\mu g/m^3$ as equivalent.'' He argued that ''dpm and other ultra-fine particulates represents only a small proportion of ambient particulate samples,'' that ''chronic cough, chronic phlegm, and chronic wheezing reflect mainly tracheobronchial effects,'' and that tracheobronchial deposition is highly dependent on particle size distribution.

No part of Dr. Borak's argument is directly relevant to MSHA's identification of the risk of death from cardiovascular, cardiopulmonary, or respiratory causes faced by miners exposed to high concentrations of dpm. First, MSHA does not regard all fine particulates as equivalent. However, dpm is a major constituent of $PM_{2.5}$ in many of the locations where increased mortality has been linked to $PM_{2.5}$ levels. MSHA regards dpm as presenting a risk by virtue of its comprising a type of $PM_{2.5}$. Second, the studies MSHA used to support the existence of this risk specifically implicate fine particles (i.e., $PM_{2.5}$), so the percentage of dpm in ''total suspended particulate emissions'' (which includes particles even larger than PM_{10}) is not relevant. Third, the chronic respiratory symptoms listed by Dr. Borak are not among the material impairments that MSHA has identified from the $PM_{2.5}$ studies. Much of the evidence pertaining to excess mortality is based on acute—not chronic—ambient exposures of relatively high intensity. In the preceding subsection of this risk assessment, MSHA identified various respiratory symptoms, including allergenic responses, but the evidence for these comes largely from studies on diesel emissions.

As discussed in Section 2.a.iii of this risk assessment, many miners smoke tobacco, and miners experience COPD at a significantly higher rate than the general population. This places many miners in two of the groups that EPA (1996) identified as being at greatest risk of premature mortality due to particulate exposures.

iii. Lung Cancer. It is clear that lung cancer constitutes a ''material impairment'' of health or functional capacity within the meaning of the Act. Therefore, the issue to be addressed in this section is whether there is sufficient evidence (i.e., enough to warrant regulatory action) that occupational exposure to dpm causes the risk of lung cancer to increase.

In the proposed risk assessment, MSHA noted that various national and international institutions and governmental agencies had already classified diesel exhaust or particulate as a probable human carcinogen. Considerable weight was also placed on two comprehensive meta-analyses of the epidemiologic literature, which had both found that the combined evidence supported a causal link. MSHA also acknowledged, however, that some reviewers of the evidence disagreed with MSHA's conclusion that, collectively, it strongly supports a causal connection. As examples of the opposing viewpoint, MSHA cited Stöber and Abel (1996), Watson and Valberg (1996), Cox (1997), Morgan et al. (1997), and Silverman (1998). As stated in the proposed risk assessment, MSHA considered the opinions of these reviewers and agreed that no individual study was perfect: even the strongest of the studies had limitations when viewed in isolation. MSHA nevertheless concluded (in the proposal) that the best available epidemiologic studies, supported by experimental data

showing toxicity, collectively provide strong evidence that chronic dpm exposure (at occupational levels) actually does increase the risk of lung cancer in humans.

Although miners and labor representatives generally agreed with MSHA's interpretation of the collective evidence, many commenters representing the mining industry strongly objected to MSHA's conclusion. Some of these commenters also expressed dissatisfaction with MSHA's treatment, in the proposed risk assessment, of opposing interpretations of the collective evidence—saying that MSHA had dismissed these opposing views without sufficient explanation. Some commenters also submitted new critiques of the existing evidence and of the meta-analyses on which MSHA had relied. These commenters also emphasized the importance of two reports (CASAC, 1998 and HEI, 1999) that both became available after MSHA completed its proposed risk assessment.

MSHA has re-evaluated the scientific evidence relating lung cancer to diesel emissions in light of the comments, suggestions, and detailed critiques submitted during these proceedings. Although MSHA has not changed its conclusion that occupational dpm exposure increases the risk of lung cancer, MSHA believes that the public comments were extremely helpful in identifying areas of MSHA's discussion of lung cancer needing clarification, amplification, and/or additional supportive evidence.

Accordingly MSHA has re-organized this section of the risk assessment into five subsections. The first of these provides MSHA's summary of the collective epidemiologic evidence. Second is a description of results and conclusions from the only two existing peer-reviewed and published statistical meta-analyses of the epidemiologic studies: Bhatia et al. (1998) and Lipsett and Campleman (1999). The third subsection contains a discussion of potential systematic biases that might tend to shift all study results in the same direction. The fourth evaluates the overall weight of evidence for causality, considering not only the collective epidemiologic evidence but also the results of toxicity experiments. Within each of these first four subsections, MSHA will respond to the relevant issues and criticisms raised by commenters in these proceedings, as well as by other outside reviewers. The final subsection will describe general conclusions reached by other reviewers of this evidence, and present some responses by MSHA about opposing interpretations of the collective evidence.

(1) Summary of Collective Epidemiologic Evidence. As mentioned in Section III.2.c.i(2)(a) and listed in Tables III–4 and III–5, MSHA reviewed a total of 47 epidemiologic studies involving lung cancer and diesel exposure. Some degree of association between occupational dpm exposure and an excess rate of lung cancer was reported in 41 of these studies: 22 of the 27 cohort studies and 19 of the 20 case-control studies. Section III.2.c.1(2)(a) explains MSHA's criteria for evaluating these studies, summarizes those on which MSHA places greatest weight, and explains why MSHA places little weight on the six studies reporting no increased risk of lung cancer for exposed workers. It also contains summaries of the studies involving miners, addresses criticisms of individual studies by commenters and reviewers, and discusses studies that, according to some commenters, suggest that dpm exposure does not increase the risk of lung cancer.

Here, as in the earlier, proposed version of the risk assessment, MSHA was careful to note and consider limitations of the individual studies. Several commenters interpreted this as demonstrating a corresponding weakness in the overall body of epidemiologic evidence. For example, one commenter [Energy West] observed that ''* * * by its own admission in the preamble * * * most of the evidence in [the epidemiologic] studies is relatively weak'' and argued that MSHA's conclusion was, therefore, unjustified.

It should first be noted that the three most recent epidemiologic studies became available too late for inclusion in the risk assessment as originally written. These three (Johnston et al., 1997; Säverin et al., 1999; Brüske-Hohlfeld, 1999) rank among the strongest eight studies available (see Section III.2.c.1(2)(a)) and do not have the same limitations identified in many of the other studies. Even so, MSHA recognizes that no single one of the existing epidemiologic studies, viewed in isolation, provides conclusive evidence of a causal connection between dpm exposure and an elevated risk of lung cancer in humans. Consistency and coherency of results, however, do provide such evidence. An appropriate analogy for the collective epidemiologic evidence is a braided steel cable, which is far stronger than any of the individual strands of wire making it up. Even the thinnest strands can contribute to the strength of the cable.

(a) Consistency of Epidemiologic Results

Although no epidemiologic study is flawless, studies of both cohort and case-control design have quite consistently shown that chronic exposure to diesel exhaust, in a variety of occupational circumstances, is associated with an increased risk of lung cancer. Furthermore, as explained earlier in this risk assessment, limitations such as small sample size, short latency, and (usually) exposure misclassification reduce the power of a study. These limitations make it more difficult to detect a relationship even when one exists. Therefore, the sheer number of studies showing a positive association readily distinguishes those studies criticized by Taubes (1995), where weak evidence is available from only a single study. With only rare exceptions, involving too few workers and/or observation periods too short to have a good chance of detecting excess cancer risk, the human studies have shown a greater risk of lung cancer among exposed workers than among comparable unexposed workers.

Moreover, the fact that 41 out of 47 studies showed an excess risk of lung cancer for exposed workers may itself be a significant result, even if the evidence in most of those 41 studies is relatively weak. Getting ''heads'' on a single flip of a coin, or two ''heads'' out of three flips, does not provide strong evidence that there is anything special about the coin. However, getting 41 ''heads'' in 47 flips would normally lead one to suspect that the coin was weighted in favor of heads. Similarly, results reported in the epidemiologic literature lead one to suspect that the underlying relationship between diesel exposure and an increased risk of lung cancer is indeed positive.

More formally, as MSHA pointed out in the earlier version of this risk assessment, the high proportion of positive studies is statistically significant according to the 2-tailed sign test. Under the ''null hypothesis'' that there is no systematic bias in one direction or the other, and assuming that the studies are independent, the probability of 41 or more out of 47 studies being either positive or negative is less than one per ten million. Therefore, the sign test rejects, at a very high confidence level, the null hypothesis that each study is equally likely to be positive or negative. This means that the collective results, showing increased risk for exposed workers, are statistically significant at a very high confidence level—regardless

of the statistical significance of any individual study.

MSHA received no comments directly disputing its attribution of statistical significance to the collective epidemiologic evidence based the sign test. However, several commenters objected to the concept that a number of inconclusive studies can, when viewed collectively, provide stronger evidence than the studies considered in isolation. For example, the Engine Manufacturers Association (EMA) asserted that—

> [j]ust because a number of studies reach the same conclusion does not make the collective sum of those studies stronger or more conclusive, particularly where the associations are admittedly weak and scientific difficulties exist in each. [EMA]

Similarly, IMC Global stated that

> * * * IMC Global does not consider cancer studies with a relative risk of less than 2.0 as showing evidence of a casual relationship between dpm exposure and lung cancer. * * * Thus while MSHA states [in the proposed risk assessment; now updated to 41 out of 47] that 38 of 43 epidemiologic studies show some degree of association between occupational dpm exposures and lung cancer and considers that fact significant, IMC Global does not. [IMC Global]

Although MSHA agrees that even statistically significant consistency of epidemiologic results is not sufficient to establish causality, MSHA believes that consistency is an important part of establishing that a suspected association is causal.[65] Many of the commenters objecting to MSHA's emphasis on the collective evidence failed to distinguish the strength of evidence in each individual study from the strength of evidence in total.

Furthermore, weak evidence (from just one study) should not be confused with a weak effect. As Dr. James Weeks pointed out at the public hearing on Nov. 19, 1998, a 40-percent increase in lung cancer is a strong effect, even if it may be difficult to detect in an epidemiologic study.

Explicable differences, or heterogeneity, in the magnitudes of relative risk reported from different studies should not be confused with inconsistency of evidence. For example, as described by Silverman (1998), one of the available meta-analyses (Bhatia et al., 1998) ''examined the primary sources of heterogeneity among studies and found that a main source of heterogeneity is the variation in diesel exhaust exposure across different occupational groups.'' Figures III–5 and III–6, taken from Cohen and Higgins (1995), respectively show relative risks reported for the two occupations on which the most studies are available: railroad workers and truck drivers.

Each of these two charts compares results from studies that adjusted for smoking to results from studies that did not make such an adjustment. For each study, the point plotted is the estimated relative risk or odds ratio, and the horizontal line surrounding it represents a 95-percent confidence interval. If the left endpoint of a confidence interval exceeds 1.0, then the corresponding result is statistically significant at a 95-percent confidence level.

The two charts show that the risk of lung cancer has consistently been elevated for exposed workers and that the results are not significantly different within each occupational category. Differences in the magnitude and statistical significance of results within occupation are not surprising, since the groups studied differed in size, average exposure intensity and duration, and the time allotted for latent effects.

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[65] With respect to the IMC Global's blanket rejection of studies showing a relative risk less than 2.0, please see also the related discussions in Subsection 2.c.i(2)(a) above, under the heading of ''Potential Confounders,'' and in Subsection 3.a.iii(3) below, entitled ''Potential Systemic Biases.''

Figure III-5

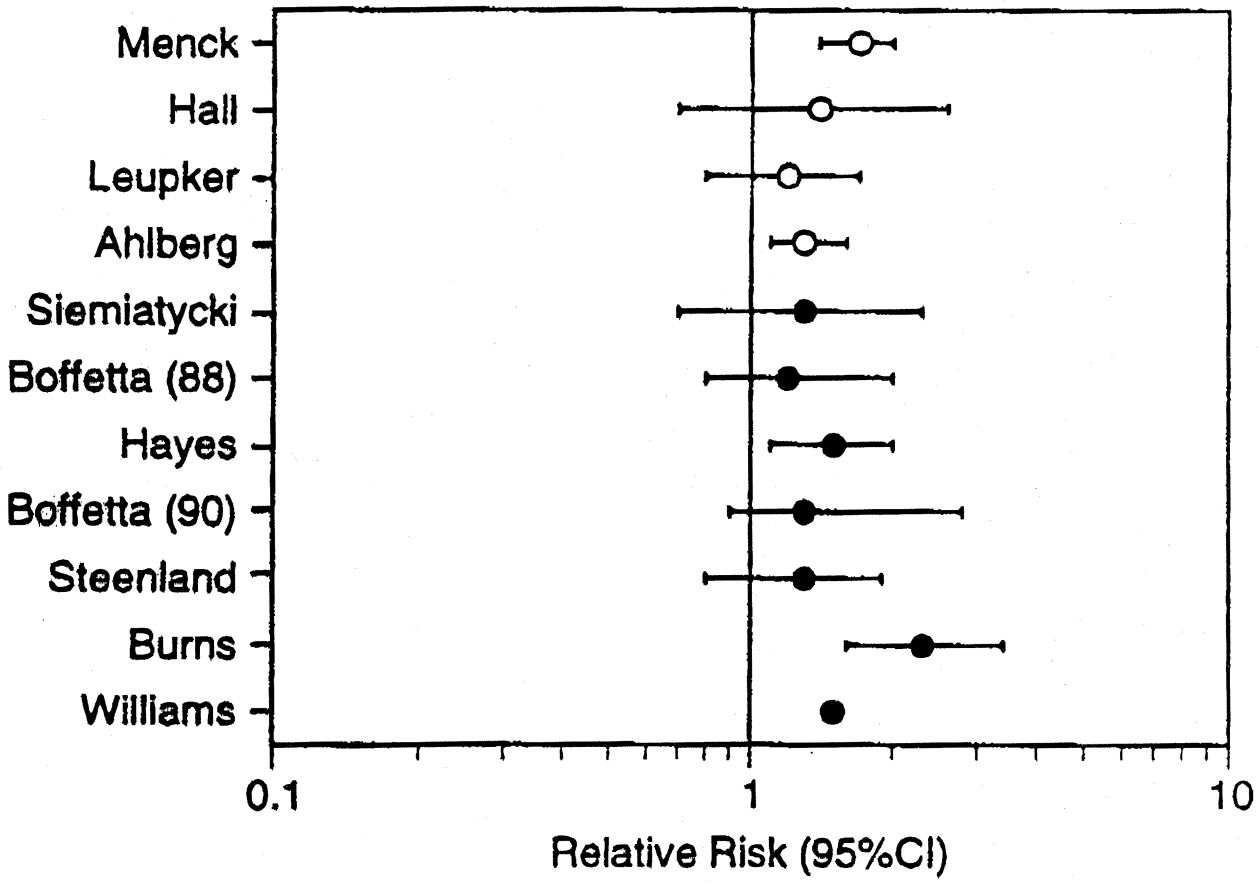

Figure . Lung cancer and exposure to diesel exhaust in truck drivers. ● = RR adjusted for cigarette smoking; O = RR not adjusted for cigarette smoking. For the study by Williams, CIs were not reported and could not be calculated. For the Steenland study, the data were gathered from union reports of long-haul truckers; for the Boffetta (1988) study, the data were self-reported by diesel truck drivers; and for the Siemiatycki study, they were self-reported by heavy-duty truck drivers (personal communication).

Figure III–6

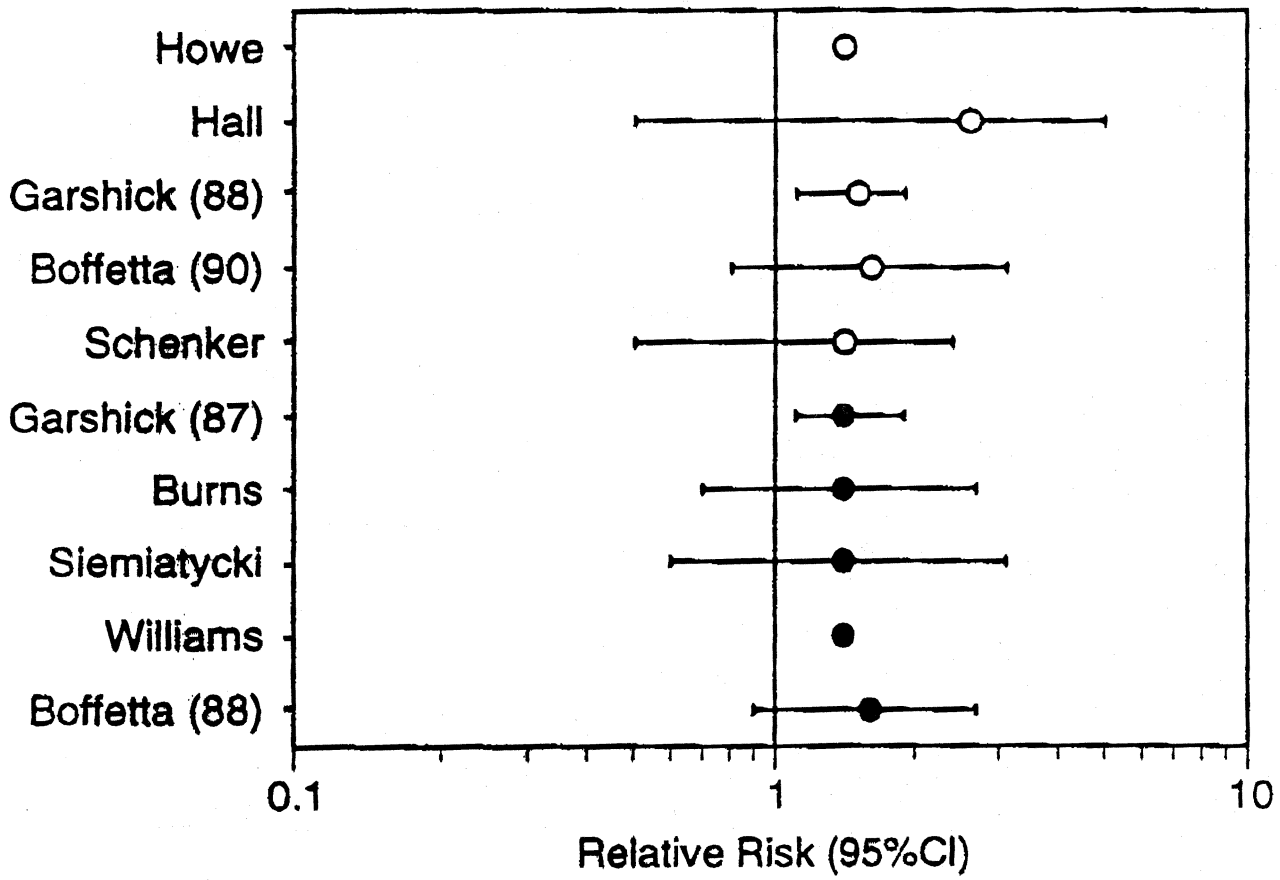

Figure Lung cancer and exposure to diesel exhaust in railroad workers. ● = RR adjusted for cigarette smoking; O = RR not adjusted for cigarette smoking. For the two studies by Howe and Williams, CIs were not reported and could not be calculated.

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As documented in Subsection 2.c.i(2)(a) of this risk assessment, all of the studies showing negative associations were either based on relatively short observation or follow-up periods, lacked good information about dpm exposure, involved low duration or intensity of dpm exposure, or, because of inadequate sample size or latency allowance, lacked the power to detect effects of the magnitude found in the ''positive'' studies. Boffetta et al. (1988, p. 404) noted that, in addition, studies failing to show a statistically significant association—

> * * * often had low power to detect any association, had insufficient latency periods, or compared incidence or mortality rates among workers to national rates only, resulting in possible biases caused by the ''healthy worker effect.''

Some commenters noted that limitations such as insufficient duration of exposure, inadequate latency allowance, small worker populations, exposure misclassification, and comparison to external populations with no adjustment for a healthy worker effect may explain why not all of the studies showed a statistically significant association between dpm exposure and an increased prevalence of lung cancer. According to these commenters, if an epidemiologic study shows a statistically significant result, this often occurs in spite of methodological weaknesses rather than because of them. MSHA agrees that limitations such as those listed make it more difficult to obtain a statistically significant result when a real relationship exists.

(b) Best Available Epidemiologic Evidence

As explained above, it is statistically significant that 41 of the 47 available epidemiologic studies reported an elevated risk of lung cancer for workers exposed to dpm. MSHA finds it even more informative, however, to examine the collective results of the eight studies identified in Section III.2.c.i(2)(a) as providing the best currently available epidemiologic evidence. These studies, selected using the criteria described earlier, are: Boffetta et al. (1988), Boffetta et al. (1990), Brüske-Hohlfeld et al. (1999), Garshick et al. (1987), Garshick et al. (1988, 1991), Johnston et al. (1997), Steenland et al. (90, 92, 98), and Säverin *et al.,* (1999). All eight of these studies reported an increased risk of lung cancer for workers with the longest diesel exposures and for those most likely to have been exposed, compared to unexposed workers. Tables showing the results from each of these studies are provided in Section III.2.c.1(2)(a).

The sign test of statistical significance can also be applied to the collective results of these eight studies. If there were no underlying association between exposure to diesel exhaust and an increased risk of lung cancer, or anything else systematically favoring a positive result, then there should be equal probabilities (equal to one-half) that any one of these eight studies would turn out positive or negative. Therefore, under the null hypothesis that positive and negative results are equally likely, the probability that all eight studies would show either a positive or a negative association is $(0.5)^8 = 0.0039$, or 0.39 percent. This shows that the collective results of the eight studies comprising the best available epidemiologic evidence are statistically significant at a confidence level exceeding 99 percent (i.e., $100 - 2 \times 0.39$).

When the risk of disease or death increases in response to higher cumulative exposures, this is described by a ''positive'' exposure-response relationship. Like consistency of results, the existence of a positive exposure-response relationship is important in establishing that the exposures in question actually cause an increase in risk. Among the eight studies MSHA has identified as comprising the best available epidemiologic evidence, there are five that provide evidence of increasing lung cancer risk with increasing cumulative exposure: Boffetta, et al. (1990), Brüske-Hohlfeld et al. (1999), Johnston et al. (1997), Säverin et al. (1999), and Steenland et al. (1990, 1992, 1998). The results supporting such a relationship are provided in the table accompanying discussion of each of these studies in Section III.2.c.i(2)(a).

Although some have interpreted the results from the two studies by Garshick et al. as also providing evidence of a positive exposure-response relationship (*e.g.,* Cal–EPA, 1998), this interpretation is highly sensitive to the statistical models and techniques used to analyze the data (HEI, 1999; Crump 1999). Therefore, for purposes of this risk assessment, MSHA is not relying on Garshick et al. (1987) or Garshick et. al (1988, 1991) to demonstrate the existence of a positive exposure-response relationship. MSHA used the study for purposes of hazard identification only. The Garshick studies contributed to the weight of evidence favoring a causal interpretation, since they show statistically significant excesses in lung cancer risk for the exposed workers.

The relative importance of the five studies identified in demonstrating the existence of a positive exposure-response relationship varies with the quality of exposure assessment. Boffetta *et al.* (1990) and Brüske-Hohlfeld *et al.* (1999) were able to show such a relationship based on the estimated duration of occupational exposure for exposed workers, but quantitative measures of exposure intensity (*i.e.*, dpm concentration) were unavailable. Although duration of exposure is frequently used as a surrogate of cumulative exposure, it is clearly preferable, as many commenters pointed out, to base estimates of cumulative exposure and exposure-response analyses on quantitative measurements of exposure levels combined with detailed work histories. Positive exposure-response relationships based on such data were reported in all three studies: Johnston *et al.* (1997), Steenland *et al.* (1998), and Säverin *et al.* (1999).

(c) Studies With Quantitative or Semiquantitative Exposure Assessments

Several commenters stressed the fact that most of the available epidemiologic studies contained little or no quantitative information on diesel exposures and that those studies containing such information (such as Steenland *et al.*, 1998) generated it using questionable assumptions. Some commenters also faulted MSHA for insufficiently addressing this issue. For example, one commenter stated:

> * * * the Agency fails to highlight the lack of acceptable (or any) exposure measurements concurrent with the 43 epidemiology studies cited in the Proposed Rule. * * * the lack of concurrent exposure data is a significant deficiency of the epidemiology studies at issue and is a major factor that prevents application of those epidemiology results to risk assessment. [EMA]

MSHA agrees that the nature and quality of exposure information should be an important consideration in evaluating the strength of epidemiologic evidence. That is why MSHA included exposure assessment as one of the criteria used to evaluate and rank studies in Section 2.c.1(2)(a) of this risk assessment. Two of the most recent studies, both conducted specifically on miners, utilize concurrent, quantitative exposure data and are included among the eight in MSHA's selection of best available epidemiologic evidence (Johnston *et al.*, 1997 and Säverin *et al.*, 1999). As a practical matter, however, epidemiologic studies rarely have concurrent exposure measurements; and, therefore, the commenter's line of

reasoning would exclude nearly all of the available studies from this risk assessment—including all six of the negative studies. Since Section 101(a)(6) of the Mine Act requires MSHA to consider the ''best available evidence'' (emphasis added), MSHA has not excluded studies with less-than-ideal exposure assessments, but, instead, has taken the quality of exposure assessment into account when evaluating them. This approach is also consistent with the recognition by the HEI Expert Panel on Diesel Emissions and Lung Cancer that ''regulatory decisions need to be made in spite of the limitations and uncertainties of the few studies with quantitative data currently available'' (HEI, 1999; p.39).

The degree of quantification, however, is not the only relevant consideration in evaluating studies with respect to exposure assessment. MSHA also considered the likely effects of potential exposure misclassification. As expressed by another commenter:

> * * * [S]tudies that * * * have poor measures of exposure to diesel exhaust have problems in classification and will have weaker results. In the absence of information that misclassification is systematic or differential, in which case study results would be biased towards either positive or no-effect level, it is reasonable to assume that misclassification is random or nondifferentiated. If so, * * * study results are biased towards a risk ratio of 1.0, a ratio showing no association between diesel exhaust exposure and the occurrence of lung cancer. [Dr. James Weeks, representing UMWA]

In her review of Bhatia *et al.* (1998), Silverman (1998) proposed that ''[o]ne approach to assess the impact of misclassification would be to exclude studies without quantitative or semiquantitative exposure data.'' According to Dr. Silverman, this would leave only four studies among those considered by Dr. Bhatia: Garshick *et al.* (1988), Gustavsson *et al.* (1990), Steenland *et al.* (1992), and Emmelin *et al.* (1993).[66] All four of these studies showed higher rates of lung cancer for the workers estimated to have received the greatest cumulative exposure, as compared to workers who had accumulated little or no diesel exposure. Statistically significant results were reported in three of these four studies. Furthermore, the two more recent studies utilizing fully quantitative exposure assessments (Johnston *et al.*, 1997; Säverin *et al.*, 1999) were not evaluated or otherwise considered in the articles by Drs. Bhatia and Silverman. Like the other four studies, these too reported elevated rates of lung cancer for workers with the highest cumulative exposures. Specific results from all six of these studies are presented in Tables III–4 and III–5.

Once again, the sign test of statistical significance can be applied to the collective results of the four studies identified by Dr. Silverman plus the two more recent studies with quantitative exposure assessments. As before, under the null hypothesis of no underlying effect, the probability would equal one-half that any one of these six studies would turn out positive or negative. The probability that all six studies would show either a positive or a negative association would, under the null hypothesis, be $(0.5)^6 = 0.0156$, or 1.56 percent. This shows that the collective results of these six studies, showing an elevated risk of lung cancer for workers estimated to have the greatest cumulative exposure, are statistically significant at a confidence level exceeding 96 percent (i.e., $100 - 2 \times 1.56$).

As explained in the previous subsection, three studies showing evidence of increased risk with increasing exposure based on quantitative or semi-quantitative exposure assessments are included in MSHA's selection of best available epidemiologic evidence: Johnston et al. (1997), Steenland et al. (1998), and Säverin et al. (1999). Not only do these studies provide consistent evidence of elevated lung cancer risk for exposed workers, they also each provide evidence of a positive exposure-response relationship—thereby significantly strengthening the case for causality.

(d) Studies Involving Miners

Eleven studies involving miners are summarized and discussed in Section 2.c.i(2)(a) of this risk assessment. Commenters' observations and criticisms pertaining to the individual studies in this group are also addressed in that section. Three of these studies are among the eight in MSHA's selection of best available epidemiologic evidence: (Boffetta et al., 1988; Johnston et al., 1997; Säverin et al., 1999). All three of these studies provide evidence of an increased risk of lung cancer for exposed miners. Although MSHA places less weight on the remaining eight studies, seven of them show some evidence of an excess lung cancer risk among the miners involved. The remaining study (Christie et al., 1995) reported a greater all-cause SMR for the coal miners involved than for a comparable population of petroleum workers but did not compare the miners to a comparable group of workers with respect to lung cancer.

The NMA submitted a review of six of these studies by Dr. Peter Valberg, who concluded that ''[t]hese articles do not implicate diesel exhaust, per se, as strongly associated with lung cancer in miners * * * The reviewed studies do not form a consistent and cohesive picture implicating diesel exhaust as a major risk factor for miners.'' Similarly, Dr. Jonathan Borak reviewed six of the studies on behalf of MARG and concluded:

> [T]he strongest conclusion that can be drawn from these six studies is that the miners in those studies had an increased risk of lung cancer. These studies cannot relate such increased [risk] to any particular industrial exposure, lifestyle or combination of such factors.

Apparently, neither Dr. Valberg nor Dr. Borak disputed MSHA's observation that the miners involved in the studies they reviewed exhibited, overall, an excess risk of lung cancer. It is possible that any excess risk found in epidemiologic studies may be due to extraneous unknown or uncontrolled risk factors (i.e., confounding variables). However, neither Drs. Valberg or Borak, nor the NMA or MARG, offered evidence, beyond a catalog of speculative possibilities, that the excess lung cancer risk for these miners was due to anything other than dpm exposure.

Nevertheless, MSHA agrees that the studies reviewed by Drs. Valberg and Borak do not, by themselves, conclusively implicate dpm exposure as the causal agent. Miners are frequently exposed to other occupational hazards associated with lung cancer, such as radon progeny, and it is not always possible to distinguish effects due to dpm exposure from effects due to these other occupational hazards. This is part of the reason why MSHA did not restrict its consideration of evidence to epidemiologic studies involving miners. What implicates exposure to diesel exhaust is the fact that diesel-exposed workers in a variety of different occupations, under a variety of different working conditions (including different types of mines), and in a variety of different geographical areas consistently exhibit an increased risk of lung cancer.

Drs. Valberg and Borak did not review the two studies that utilize quantitative dpm exposure assessments: Johnston et al. (1997) and Säverin et al. (1999). In recently received comments Dr. Valberg, writing for the NMA brought up four issues on the Säverin et al. 1999. These issues were potential exposure misclassification, potential flaws in the sampling method, potential smoker

[66] Emmelin *et al.* (1993) was considered but excluded from the meta-analysis by Bhatia *et al.* (1998) for reasons explained by the authors.

misclassification, and insufficient latency. Two of these issues have already been extensively discussed in section 2.c.i.2.a.ii and therefore will not be repeated here. Dr. Valberg suggested that the potential flaw in the sampling method would tend to over-estimate exposure and that there was insufficient latency. If, in fact, both of these issues are relevant, they would act to UNDERESTIMATE the lung cancer risk in this cohort instead of OVERESTIMATE it. MSHA regards these, along with Boffetta et al. (1988), Burns and Swanson (1991),[67] and Lerchen et al. (1987) to be the most informative of the available studies involving miners. Results on miners from these five studies are briefly summarized in the following table, with additional details provided in Section 2.c.1(2)(a) and Tables III–4 and III–5 of this risk assessment. The cumulative exposures at which relative risks from the Johnston and Säverin studies are presented are equivalent, assuming that TC constitutes 80 percent of total dpm. The cumulative dpm exposure of 6.1 mg-yr/m^3 is the multiplicative product of exposure duration and dpm concentration for the most highly exposed workers in each of these two studies.

[67] Listed in Table III–5 under Swanson et al., 1993.

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Results from best available studies involving miners.

Study	Mine Type	Exposure Assessment	Smoking Adjustm't	Result
Boffetta et al. (1988)	various	Occupational history	yes	RR = 2.67 for miners, compared to workers never employed in diesel -exposed occupations.†
Burns and Swanson (1991)	unknown	Occupational history	yes	OR = 5.03 for mining machinery operators.†
Johnston et al. (1997)	UG coal	Occupational history & indirect dpm measurements	yes	For cumulative dpm exposure = 6.12 mg-yr/m^3 : RR = 5.5 using mine-adjusted statistical model; RR= 11.0 using mine-unadjusted statistical model.
Lerchen et al. (1987)	various	Occupational history	yes	OR = 2.1 for underground non-uranium mining.
Säverin et al. (1999)	UG potash	Occupational history & TC measurements	smoking uncorrelated with TC within cohort	RR = 2.17 for most highly exposed group, compared to least exposed group. For cumulative TC exposure = 4.9 mg-yr/m^3 : RR = 1.16 to 2.70 depending on statistical model.

†Statistically significant at a 95-percent confidence level.

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Although MSHA places less weight on the studies by Burns and Swanson and by Lerchen than on the other three, it is significant that the five best available studies involving miners all support an increased risk of lung cancer attributable to dpm exposure.

(2) Meta-Analyses

MSHA recognizes that simply tabulating epidemiologic studies as positive or negative can sometimes be misleading. There are generally a variety of outcomes that could render a study positive or negative, some studies contain different analyses of related data sets, some studies involve multiple comparisons of various subgroups, and the studies differ widely in the reliability of their results. Therefore, MSHA is not limiting its assessment of the epidemiologic evidence to such a tabulation or relying only on the sign test described above. MSHA has also considered the results of two statistical meta-analyses covering most of the available studies (Lipsett and Campleman, 1999; Bhatia *et al.*, 1998). These meta-analyses weighted and pooled independent results from those studies meeting certain inclusion requirements to form overall estimates of relative risk for exposed workers based on the combined body of data. In addition to forming pooled estimates of the effect of diesel exposure, both meta-analyses analyzed sources of heterogeneity in the individual results and investigated but rejected publication bias as an explanation for the generally positive results reported. Both meta-analyses derived a statistically significant increase of 30 to 40 percent in the risk of lung cancer, attributable to occupational dpm exposure.

Lipsett and Campleman (1999) systematically analyzed and combined results from most of the studies summarized in Tables III–4 and III–5. Forty-seven studies published between 1957 and 1995 were identified for initial consideration. Some studies were excluded from the pooled analysis because they did not allow for a period of at least 10 years for the development of clinically detectable lung cancer. Others were excluded because of bias resulting from incomplete ascertainment of lung cancer cases in cohort studies or because they examined the same cohort population as another study. One study was excluded because standard errors could not be calculated from the data presented. The remaining 30 studies, contributing a total of 39 separate estimates of exposure effect (for distinct occupational groups within studies), were analyzed using a random-effects analysis of variance (ANOVA) model.

Potential effects of publication bias (*i.e.*, the likelihood that papers with positive results may be more likely to be published than those with negative results) were investigated by plotting the logarithm of relative risk estimated from each study against its estimated precision, as expressed by the inverse of its standard error. According to the authors, the resulting ''funnel plot'' was generally consistent with the absence of significant publication bias, although there were relatively few small-scale, statistically insignificant studies. The investigators performed a further check of potential publication bias by comparing results of the included studies with the only relevant unpublished report that became available to them during the course of their analysis. Smoking-adjusted relative risks for several diesel-exposed occupations in the unpublished study were, according to the investigators, consistent with those found in the studies included in the meta-analysis.

Each of the 39 separate estimates of exposure effect was weighted by a factor proportional to its estimated precision. Sources of heterogeneity in results were investigated by subset analysis—using categorical variables to characterize each study's design, target population (general or industry-specific), occupational group, source of control or reference population, latency, duration of exposure, method of ascertaining occupation, location (North America or Europe), covariate adjustments (age, smoking, and/or asbestos exposure), and absence or presence of a clear healthy worker effect (as manifested by lower than expected all-cause mortality in the occupational population under study).

Sensitivity analyses were conducted to evaluate the sensitivity of results to inclusion criteria and to various assumptions used in the analysis. This included (1) substitution of excluded ''redundant'' studies of the same cohort population for the included studies and (2) exclusion of studies involving questionable exposure to dpm. An influence analysis was also conducted to examine the effect of dropping one study at a time, to determine if any individual study had a disproportionate effect on results of the ANOVA.

The pooled relative risk from all 39 exposure effects (estimated from 30 studies) was RR = 1.33, with a 95-percent confidence interval (CI) extending from 1.21 to 1.46. For the subgroup of 13 smoking-adjusted exposure effects (nine studies) from populations ''most likely to have had substantial exposure'' to dpm, the pooled effect was RR = 1.47, with a CI from 1.29 to 1.67. Based on the all of the various analyses they conducted, the authors concluded:

> Although substantial heterogeneity existed in the initial pooled analysis, stratification on several factors substantially reduced heterogeneity, producing subsets of studies with increased relative risk estimates that persisted through various influence and sensitivity analyses. * * *
>
> In studies that adjusted for confounding by cigarette smoking, not only did the positive association between diesel exhaust exposure and lung cancer persist but the pooled risk estimate showed a modest increase, with little evidence of heterogeneity.
>
> * * * [T]his meta-analysis provides quantitative evidence consistent with several prior reviews, which have concluded that the epidemiologic evidence supports a causal relationship between occupational exposure to diesel exhaust and lung cancer. [Lipsett and Campleman, 1999]

The other meta-analysis was conducted by Bhatia *et al.* (1998) on epidemiologic studies published in peer-reviewed journals between 1957 and 1993. In this analysis, studies were excluded if actual work with diesel equipment ''could not be confirmed or reliably inferred'' or if an inadequate latency period was allowed for cancer to develop, as indicated by less than 10 years from time of first exposure to end of follow-up. Studies of miners were also excluded, because of potential exposure to radon and silica. Likewise, studies were excluded if they exhibited selection bias or examined the same cohort population as a study published later. A total of 29 independent results on exposure effects from 23 published studies were identified as meeting the inclusion criteria.

To address potential publication bias, the investigators identified several unpublished studies on truck drivers and noted that elevated risks for exposed workers observed in these studies were similar to those in the published studies utilized. Based on this and a ''funnel plot'' for the included studies, the authors concluded that there was no indication of publication bias.

After assigning each of the 29 separate estimates of exposure effect a weight proportional to its estimated precision, Bhatia *et al.* (1998) used a fixed-effects ANOVA model to calculate pooled relative risks based on the following groupings: all 29 results; all case-control studies; all cohort studies; cohort studies using internal reference populations; cohort studies making external comparisons; studies adjusted for smoking; studies not adjusted for smoking; and studies grouped by occupation (railroad workers,

equipment operators, truck drivers, and bus workers). Elevated risks of lung cancer were shown for exposed workers overall and within every individual group of studies analyzed. A positive duration-response relationship was observed in those studies presenting results according to employment duration. The weighted, pooled estimates of relative risk were identical for case-control and cohort studies and nearly identical for studies with or without smoking adjustments.

The pooled relative risk from all 29 exposure effects (estimated from 23 studies) was RR = 1.33, with a 95-percent confidence interval (CI), adjusted for heterogeneity, extending from 1.24 to 1.44. For just the smoking-adjusted studies, it was 1.35 (CI: 1.20 to 1.52); and for cohort studies making internal comparisons, it was 1.43 (CI: 1.29 to 1.58). Based on their evaluation of the all the analyses on various subgroups, Bhatia *et al.* (1998) concluded that the elevated risk of lung cancer observed among exposed workers was unlikely to be due to chance, that confounding from smoking was unlikely to explain all of the excess risk, and that ''this meta-analysis supports a causal association between increased risks for lung cancer and exposure to diesel exhaust.''

The pooled relative risks estimated in both meta-analyses equal 1.33 and exceed 1.4 for studies making internal comparisons, or comparisons to similar groups of workers. Both meta-analyses found these results to be statistically significant, meaning that they cannot be explained merely by random or unexplained variability in the risk of lung cancer that occurs among both exposed and unexposed workers. Although both meta-analyses relied, by necessity, on an overlapping selection of studies, the inclusion criteria were different and some studies included in one meta-analysis were excluded from the other. They used different statistical models for deriving a pooled estimate of relative risk, as well as different means of analyzing heterogeneity of effects. Nevertheless, they derived the same estimate of the overall exposure effect and found similar sources of heterogeneity in the results from individual studies.[68] One commenter observed that—

> Lung cancer relative risks for occupational ''control groups'' vary over a range from 0.4 to 2.7 * * *. Therefore, the level of relative risks being reported in the dpm epidemiology fall within this level of natural variation. [IMC Global]

This argument is refuted by the statistical significance of the elevation in risk detected in both meta-analyses in combination with the analyses accounting for heterogeneity of exposure effects.

The EMA objected that MSHA's focus on these two meta-analyses ''presents an incomplete picture because the counter-arguments of Silverman (1998) were not discussed in the same detail.'' IMC global also faulted MSHA for dismissing Dr. Silverman's views without adequate explanation.

In her review,[69] Dr. Silverman characterized Bhatia *et al.* (1998) as a ''careful meta-analysis'' and acknowledged that it ''add[s] to the credibility that diesel exhaust is carcinogenic * * *.'' She also explicitly endorsed several of its most important conclusions. For example, Dr. Silverman stated that ''[t]he authors convincingly show that potential confounding by cigarette smoking is likely to have little impact on the estimated RRs for diesel exhaust and lung cancer.'' She suggested, however, that Bhatia *et al.* (1998) ''ultimately do not resolve the question of causality.'' (Silverman, 1998)

Dr. Silverman imposed an extremely high standard for what is needed to ultimately resolve the question of causality. The precise question she posed, along with her answer, was as follows:

> Has science proven causality *beyond any reasonable doubt?* Probably not. [Silverman, 1998, emphasis added.]

Neither the Mine Act nor applicable case law requires MSHA to prove causality ''beyond any reasonable doubt.'' The burden of proof that Dr. Silverman would require to close the case and terminate research is not the same burden of proof that the Mine Act requires to warrant protection of miners subjected to far higher levels of a probable carcinogen than any other occupational group. In this risk assessment, MSHA is evaluating the collective weight of the best available evidence—not seeking proof ''beyond any reasonable doubt.''[70]

The EMA objected to MSHA's reliance on the two meta-analyses because of ''* * * serious deficiencies in each'' but did not, in MSHA's opinion, identify any such deficiencies. The EMA pointed out that ''most of the original studies in each were the same, and the few that were not common to each were not of significance to the outcome of either meta-analysis.'' MSHA does not regard this as a deficiency. Since the object of both meta-analyses was to analyze the available epidemiologic evidence linking dpm exposure with lung cancer, using defensible inclusion criteria, it is quite understandable that they would rely on overlapping information. The principal differences were in the types and methods of statistical analysis used, rather than in the data subjected to analysis; and MSHA considers it informative that different approaches yielded very similar results and conclusions. It is noteworthy, moreover, that both of the meta-analyses explicitly addressed the EMA's concern by performing analyses on various different sub-groupings of the available studies. The sensitivity of results to the inclusion criteria was also explicitly investigated and considered. MSHA believes that the conclusions of these meta-analyses did not depend on unreasonable inclusion or exclusion criteria.

The EMA also argued that—

> [a] meta-analysis cannot compensate for basic deficiencies in the studies used to create the meta-analysis, and this fact is not clearly stated by MSHA. Instead, MSHA follows the tack of the meta-analysis authors, who claim that the meta-analysis somehow overcomes deficiencies of the individual studies selected and presents a stronger case. This is simply not true. [EMA]

MSHA agrees that a meta-analysis cannot correct for all deficiencies that may be present in individual studies. It

[68] Several commenters suggested that because the two meta-analyses both received direct or indirect funding from the same governmental agency, they were not independently conducted. These commenters speculated that Dr. Allan Smith, a co-author of Cal-EPA (1998) and Bhatia *et al.* (1998), contributed to both meta-analyses. Although an earlier version of Lipsett and Campleman (1999) appeared as an appendix to Cal-EPA (1998), commenters provided no evidence that Dr. Smith contributed anything to that appendix. Dr. Smith is not listed as a co-author of Lipsett and Campleman (1999).

[69] Silverman (1998) reviewed Bhatia *et al.* (1998) but not Lipsett and Campleman (1999) or the earlier version of that meta-analysis (Lipsett and Alexeeff, 1998) cited in MSHA's proposed preamble.

[70] It is noteworthy that, in describing research underway that might resolve the issue of causality, Dr. Silverman stressed the need for studies with quantitative exposure measurements and stated that ''underground miners may, in fact, be the most attractive group for study because their exposure to diesel exhaust is at least five times greater than that of previously studied occupational groups.'' (Silverman, 1998) She then mentioned a study on underground miners in Germany that had recently been initiated. The study of German underground potash miners (Säverin *et al.*, 1999), published after Dr. Silverman's article, utilizes quantitative exposure measurements and is included in MSHA's selection of best available epidemiologic evidence (see Section 3.a.iii(1)(a) of this risk assessment). MSHA also includes in that selection another underground miner study utilizing quantitative exposure measurements (Johnston *et al.*, 1997). The 1997 study was available prior to Dr. Silverman's article but is not listed among her references.

can, however, correct for certain types of deficiencies. For example, individual studies may lack statistical power because of small study populations. By pooling results from several such studies, a meta-analysis may achieve a level of statistical significance not attainable by the individual studies. Furthermore, both of the meta-analyses used well-defined inclusion criteria to screen out those studies with the most severe deficiencies. In addition, they both found that it was the more rigorous and technically more valid studies that reported the strongest associations between excess lung cancer and dpm exposure. They also performed separate analyses that ruled out inflationary effects of such ''deficiencies'' as lack of a smoking adjustment. For example, Lipsett and Campleman (1999) reported a pooled RR = 1.43 for 20 smoking-adjusted results, as compared to a pooled RR = 1.25 for 19 results with no smoking adjustment.

IMC Global and MARG submitted five specific criticisms of the meta-analyses, to which MSHA will respond in turn.

(1) Publication Bias

* * * both studies * * * rely only on published studies. * * * the authors rely on statistical analysis in an attempt to uncover possible publication bias. * * * the only safeguard to protect against possible publication bias is to seek out unpublished results * * *. [IMC Global]

Both meta-analyses compared the results of published and unpublished studies and found them to be similar. Bhatia *et al.* (1998) found several unpublished studies of lung cancer among truck drivers that ''* * * were not included in our analysis; however the risk ratios of these studies are similar to the [sic] those in published studies among truck drivers.'' (Bhatia *et al.*, p. 90) Lipsett and Campleman (1999) checked ''[s]moking-adjusted relative risks for several diesel-exposed occupations'' in an unpublished report on U.S. veterans and found them ''* * * consistent with those reported here.'' They remarked that ''although publication bias cannot be completely ruled out, it is an unlikely explanation for our findings.'' (Lipsett and Campleman, p. 1015) In addition to comparing results directly against unpublished studies, both meta-analyses used the statistical method of ''funnel plots'' as an indirect means of checking for the existence of significant publication bias. It should also be noted that MSHA did not exclude unpublished studies from this risk assessment.

(2) Selection Bias

* * * [the] meta-analyses have to provide a much more convincing rationale as to why all miners were excluded even when the confounders that are mentioned are not likely or important, for example in studies conducted in potash and salt mines. * * * IMC Global sees no reason why the older studies of potash workers [Waxweiler *et al.*, 1973] and more recent studies on New South Wales coal miners [Christie *et al.*, 1995] should not be included * * *. [IMC Global]

Studies were selectively included or excluded, without good or sufficient explanation. [MARG]

Contrary to the commenters' characterization, both meta-analyses listed each study excluded from the analysis of pooled relative risk and gave a good reason for its exclusion. For example, both meta-analyses excluded studies that failed to allow for a minimum 10-year latency period for lung cancer to develop after first exposure. With respect to the exclusion of all studies on miners, Bhatia *et al.* (1998) pointed out that ''[s]ince studies of miners often indicate higher relative risks for lung cancer than those considered in this meta-analysis, this was a conservative exclusion.'' Even if studies on miners had been considered, Waxweiler *et al.* (1973) and Christie *et al.* (1995) would have been excluded from both meta-analyses because of their failure to meet the 10-year minimum latency requirement.

(3) Lack of Actual Exposure Data

* * * [N]ondifferential exposure or disease misclassification can sometimes produce bias away from the null * * * Thus, tests for heterogeneity performed in both these meta-analyses won't detect or correct this problem. [IMC Global]

Lipsett and Campleman acknowledged that ''[e]xposure misclassification is a problem common to all studies of cancer and diesel emissions. In no case were there direct measurements of historical diesel exhaust exposures of the subjects.'' However, as Dr. Silverman pointed out in her review, ''* * * this bias is most likely to be nondifferential, and the effect would probably have been to bias point estimates toward the null value. Thus the summary RR of 1.33 may be an underestimate of the true lung cancer effect associated with diesel exposure.'' (Silverman, 1998)

(4) Smoking as a Confounder

* * * The use of data manipulation and modeling adjustments in both these meta-analyses cannot rectify the flaws in the initial studies. [IMC Global]

* * * misclassification of this exposure [cigarette smoking] could result in residual confounding of individual studies and, consequently, meta-analyses, of those studies. [MARG]

Contrary to the commenter's suggestion, neither of the meta-analyses made any attempt to manipulate or adjust the data in order to rectify what the commenter regards as ''flaws'' in the way smoking or other potential confounders were treated in the initial studies. Both meta-analyses, however, compared the pooled RR for studies with a smoking adjustment to the pooled RR for studies without any such adjustment. Both meta-analysis calculated a pooled RR for the smoking-adjusted studies greater than or equal to that for the unadjusted studies. In addition, Bhatia *et al.* (1998) analyzed the impact of the smoking adjustment for the subgroup of studies reporting results both with and without such an adjustment and found that the ''small reduction in the pooled RR estimates would not be consistent with a major effect from residual confounding.'' Dr. Silverman concluded that ''[t]he authors convincingly show that potential confounding by cigarette smoking is likely to have little impact on the estimated RRs for diesel exhaust and lung cancer.'' (Silverman, 1998)

(5) Inadequate Control in the Underlying Studies for Diet

As noted by Lipsett and Campleman, ''Diet may also confound the diesel-lung cancer association.'' The researchers also caution that this risk factor was not controlled for in the nearly 50 diesel studies they examined. [MARG]

Since inhalation is the primary route of dpm exposure, and the lung is the primary target organ, MSHA considers potential dietary confounding to be of minor importance in the diesel-lung cancer association. Lipsett and Campleman acknowledged that diet might be a relevant consideration for long-haul truck drivers, but stated that ''diet would probably not be an important confounder in studies of other occupations, particularly those using internal or other occupationally active reference populations.'' Studies making internal comparisons, or comparisons to similar groups of workers, are unlikely to be seriously confounded by dietary differences, because the groups of workers being compared are likely to have very similar dietary habits, on average. The pooled relative risk for cohort studies making comparisons internally or to other active workers was 1.48 (95% CI = 1.28 to 1.70). (Lipsett and Campleman, 1999, Table 3) This was considerably higher than the pooled RRs for studies making comparisons against regional or national populations, where dietary differences

(and also differences with respect to other potential confounders) would be more important.

(3) Potential Systematic Biases

Citing failure to account for dietary differences as an example, some commenters argued that the meta-analyses may simply propagate weaknesses shared by the individual studies. These commenters contended that many of the studies MSHA considered in this risk assessment share methodological similarities and that, therefore, a ''deficiency'' causing bias in one study would probably also bias many other studies in the same direction. According to these commenters, no matter how great a majority of studies report a 30- to 40-percent increase in the risk of lung cancer for exposed workers, the possibility of systematic bias prevents the collective evidence from being strong or sufficient.

Although this point has some theoretical foundation, it has no basis in fact for the particular body of epidemiologic evidence relating lung cancer to diesel exposure. The studies considered were carried out by many different researchers, in different countries, using different methods, and involving a variety of different occupations. Elevated risk was found in cohort as well as case-control studies, and in studies explicitly adjusting for potential confounders as well as studies relying on internal comparisons within homogeneous populations. The possibility that systematic bias explains these results is also rendered less plausible by results from studies of a radically different type: the elevated risk of lung cancer associated with chronic environmental exposures to $PM_{2.5}$ (Dockery *et al.* 1993; Pope *et al.*, 1995).

Furthermore, the commenters advancing this argument presented no evidence that the studies shared any deficiencies of a type that would systematically shift results in the direction of showing a spurious association. As explained in Subsection 2.c.i(2)(a), exposure misclassification, healthy worker effect, and low power due to insufficient latency generally have the opposite effect—systematically diluting and masking results. Although many studies may share a similar susceptibility to bias by dietary differences or residual smoking effects,[71] there is no reason to expect that such effects will consistently bias results in the same direction, across all occupations and geographic regions.

Associations between dpm exposure and excess lung cancer are evident in a wide variety of occupational and geographical contexts, and it is unlikely that all (or most) would be biased in the same direction by lifestyle effects. There is no reason to suppose that, in nearly all of these studies, exposed subjects were more likely than unexposed subjects to have lifestyles (apart from their occupations) that increased their risk of lung cancer. On the other hand, exposures to other occupational carcinogens, such as asbestos dust, radon progeny, and silica, could systematically cause studies in which they are not taken into account to exhibit spurious associations between lung cancer and occupational diesel exhaust exposures. Silica dust and radon progeny are frequently present in mining environments (though not usually in potash mines), and this was the reason that studies on miners were excluded from the two meta-analyses.

IMC Global argued that because of the possibility of being misled by systematic biases, epidemiologic evidence can be used to identify only those hazards that, at a minimum, double the risk of disease (i.e., RR ≥ 2.0). IMC Global explained this viewpoint by quoting an epidemiologist as follows:

> * * * [E]pidemiologic methods can only yield valid documentation of large relative risks. Relative risks of low magnitude (say, less than 2) are virtually beyond the resolving power of the epidemiologic microscope. We can seldom demonstrably eliminate all sources of bias, and we can never exclude the possibility of unidentified and uncontrolled confounding. If many studies—preferably based on different methods—are nevertheless congruent in producing markedly elevated relative risks, we can set our misgivings aside. If however, many studies produce only modest increases, those increases may well be due to the same biases in all the studies. [Dr. Samuel Shapiro, quoted by IMC Global]

It is important to note that, unlike IMC Global, Dr. Shapiro did not suggest that results of RR < 2.0 be counted as ''negative.'' He contended only that low RRs do not completely rule out the possibility of a spurious association due to unidentified or uncontrolled confounding. More importantly, however, this restriction would allow workers to be exposed to significant risks and is, therefore, unacceptable for regulatory purposes. For purposes of protecting miners from lung cancer, certainty is not required; and an increase in the relative risk of less than 100 percent can increase the absolute risk of lung cancer by a clearly unacceptable amount. For example, if the baseline risk of lung cancer is six per thousand, then increasing it by 33 percent amounts to an increase of two per thousand for exposed workers.

IMC Global went on to argue that—

> * * * only a few of these studies have relative risks that exceed 2.0, and some of the studies that do exceed 2.0 exhibit biases that make them unsuitable for rulemaking purposes in our opinion. * * * Thus, in IMC Global's opinion, the epidemiologic evidence demonstrates an artificial association that can be explained through common biases probably due to smoking habits and lifestyle factors. [IMC Global]

This line of reasoning leaps from the *possibility* that systematic biases might account for observed results to a conclusion that they actually do so. Furthermore, after proposing to allow for possible biases by requiring that only relative risks in excess of 2.0 be counted as positive evidence, IMC global has ignored its own criterion and discounted results greater than 2.0 for the same reason. Contrary to IMC Global's claim that ''only a few of the studies have relative risks that exceed 2.0,'' Tables III–4 and III–5 show 23 separate results greater than 2.0, applying to independent categories of workers in 18 different studies.

According to Stöber and Abel (1996), the potential confounding effects of smoking are so strong that ''residual smoking effects'' could explain even statistically significant results observed in studies where smoking was explicitly taken into account. MSHA agrees that variable exposures to non-diesel lung carcinogens, including relatively small errors in smoking classification, could bias individual studies. However, the potential confounding effect of tobacco smoke and other carcinogens can cut in either direction. Spurious positive associations of dpm exposure with lung cancer would arise only if the group exposed to dpm had a greater exposure to these confounders than the unexposed control group used for comparison. If, on the contrary, the control group happened to be more exposed to confounders, then this would tend to make the association between dpm exposure and lung cancer appear negative. Therefore, although smoking effects could potentially distort the results of any single study, this effect could reasonably be expected to make only about half the studies that were explicitly adjusted for smoking come out positive. Smoking is unlikely to have been responsible for finding an excess prevalence of lung cancer in 17 out of 18 studies in which a smoking adjustment was applied. Based on a 2-tailed sign test, this possibility can be

[71] The term ''residual smoking effects'' refers to the potentially confounding effects of smoking that may remain after a smoking adjustment has been made.

rejected at a confidence level greater than 99.9 percent.

Even in the 29 studies for which no smoking adjustment was made, tobacco smoke and other carcinogens were important confounders only to the extent that the populations exposed and unexposed to diesel exhaust differed systematically with respect to these other exposures. Twenty-four of these studies, however, reported some degree of excess lung cancer risk for the diesel-exposed workers. This result could be attributed to other occupational carcinogens only in the unlikely event that, in nearly all of these studies, diesel-exposed workers happened to be more highly exposed to these other carcinogens than the control groups of workers unexposed to diesel.

Like IMC Global, Stöber and Abel (1996) do not, in MSHA's opinion, adequately distinguish between a *possible* bias and an *actual* one. Potential biases due to extraneous risk factors are unlikely to account for a significant part of the excess risk in all studies showing an association. Excess rates of lung cancer were associated with dpm exposure in all epidemiologic studies of sufficient size and scope to detect such an excess. Although it is possible, in any individual study, that the potentially confounding effects of differential exposure to tobacco smoke or other carcinogens could account for the observed elevation in risk otherwise attributable to diesel exposure, it is unlikely that such effects would give rise to positive associations in 41 out of 47 studies. As stated by Cohen and Higgins (1995):

> * * * elevations [of lung cancer] do not appear to be fully explicable by confounding due to cigarette smoking or other sources of bias. Therefore, at present, exposure to diesel exhaust provides the most reasonable explanation for these elevations. The association is most apparent in studies of occupational cohorts, in which assessment of exposure is better and more detailed analyses have been performed. The largest relative risks are often seen in the categories of most probable, most intense, or longest duration of exposure. In general population studies, in which exposure prevalence is low and misclassification of exposure poses a particularly serious potential bias in the direction of observing no effect of exposure, most studies indicate increased risk, albeit with considerable imprecision. [Cohen and Higgins (1995), p. 269].

Several commenters identified publication bias as another possible explanation for the heavy preponderance of studies showing an elevated risk of lung cancer for exposed workers. As described earlier, both of the available meta-analyses investigated and rejected the hypothesis of significant publication bias affecting the overall results. This was based on both a statistical technique using ''funnel plots'' and a direct comparison between results of published and unpublished studies. Commenters presented no evidence that publication bias actually exists in this case. After the 1988 NIOSH and 1989 IARC determinations that diesel exhaust was a ''potential'' or ''probable'' human carcinogen, negative results would have been of considerable interest, and, in the absence of any evidence specifically applying to dpm studies, there is no reason to assume they would not have been published.

(4) Causality

MSHA must draw its conclusions based on the weight of evidence. In the absence of any statistical evidence for differential confounding or significant publication bias, the weight of epidemiologic evidence strongly favors a causal connection. On the one side, it is evident that virtually all of the studies that adjusted for smoking and other known confounders, or controlled for them by comparing against similar groups of workers, showed positive associations (i.e., relative risk or odds ratio > 1.0). Also on this side of the balance are all eight of the studies MSHA identified as comprising the best available human evidence. These include three studies reporting positive exposure-response relationships based on quantitative dpm exposure assessments: two recent studies specifically on underground miners (one coal and one potash) and one on trucking industry workers.[72] On the other side of the balance is the possibility that publication bias or other systematic biases may have been responsible for some unknown portion of the overall 30- to 40-percent elevation in lung cancer risk observed—a possibility that, while conceivable, is based on speculation. After considering other viewpoints (addressed here and in the next subsection), MSHA has accepted what in its view is the far more likely alternative: that the vast majority of epidemiologic studies showed an elevated risk in association with occupational exposures to diesel exhaust because such exposures cause the risk of lung cancer to increase. The toxicity experiments discussed in Subsection 2.d.iv of this risk assessment support the causal interpretation that MSHA has placed on the associations observed in epidemiologic studies.

In this risk assessment, MSHA is basing its conclusions primarily on epidemiologic studies. However, the results obtained from animal studies confirm that diesel exhaust can increase the risk of lung cancer in some species and help show that dpm (rather than the gaseous fraction of diesel exhaust) is the causal agent. The fact that dpm has been proven to cause lung cancer in laboratory rats only under conditions of lung overload does not make the rat studies irrelevant to miners. The very high dpm concentrations currently observed in some mines could impair or even overwhelm lung clearance for miners already burdened by respirable mineral dusts, thereby inducing lung cancer by a mechanism similar to what occurs in rats (Nauss et al., 1995). It must also be noted, however, that most of the human studies show an increased risk of lung cancer at dpm levels lower than what might be expected to cause overload. Therefore, the human studies suggest that overload is not a necessary condition for dpm to induce or promote lung cancer among humans. Salvi et al. (1999) reported marked inflammatory responses in the airways of healthy human volunteers after just one hour of exposure to dpm at a concentration of 300 $\mu g/m^3$. Animal studies provide evidence that inhalation of dpm has related effects, such as induction of free oxygen radicals, that could promote the development of human lung cancers by mechanisms not requiring lung overload. (See Sec. III.2.d.iv(2).)

Similarly, the weight of genotoxicity evidence helps support a causal interpretation of the associations observed in the epidemiologic studies. This evidence shows that dpm dispersed by alveolar surfactant can have mutagenic effects, thereby providing a genotoxic route to carcinogenesis that is independent of overloading the lung with particles. After a comprehensive review of the evidence, IPCS (1996) concluded that both the particle core and the associated organic materials have biological activity. The biological availability of carcinogens present in the organic portion of dpm may, however, differ significantly in different species. Chemical byproducts of phagocytosis, which occurs even when the lung is not overloaded, may provide another genotoxic route. Inhalation of diesel emissions has been shown to cause DNA adduct formation in peripheral lung cells of rats and monkeys, and increased levels of human DNA adducts have been found in association with occupational exposures. (See Sec. III.2.d.iv(1)) None of this evidence

[72] These studies (respectively: Johnston et al., 1997; Säverin et al., 1999; Steenland et al., 1998) are discussed in detail in Subsection 2.c.i(2)(a) of this risk assessment.

suggests that a lung cancer threshold exists for humans exposed to dpm, despite its importance in the rat model. Nor does this evidence suggest that lung overload is necessary for dpm to induce lung cancer in humans. Indeed, lung overload may be only one of many mechanisms through which lung cancer is produced in humans.

Results from the epidemiologic studies, the animal studies, and the genotoxicity studies are coherent and mutually supportive. After considering all these results, MSHA has concluded that the epidemiologic studies, supported by the experimental data establishing the plausibility of a causal connection, provide strong evidence that chronic occupational dpm exposure increases the risk of lung cancer in humans.

In a review, submitted by MARG, of MSHA's proposed risk assessment, Dr. Jonathan Borak asserted that MSHA's determination that results from the epidemiologic and toxicity studies were ''coherent and mutually reinforcing'' involved circular reasoning. He supported this assertion by incorrectly attributing to MSHA the view that ''most of the individual [epidemiologic] studies are not very good'' and that their suggestion of an association between dpm and lung cancer is ''made credible in light of the animal data.'' To complete his argument that MSHA relied on circular reasoning, Dr. Borak then suggested that the epidemiologic data provided MSHA's sole basis for considering the animal data relevant to humans. In a similar vein, Kennecott Minerals claimed there was an ''absence of toxicological support for epidemiologic findings that are themselves inconclusive.''

Contrary to Dr. Borak's assertion, MSHA has not characterized most of the epidemiologic studies as ''not very good.'' Nor has MSHA suggested that the epidemiologic evidence would not be credible or plausible in the absence of supporting animal data. As Dr. Borak correctly noted, MSHA acknowledged that ''none of the existing human studies is perfect'' and that ''no single one of the existing epidemiological studies, viewed in isolation, provides conclusive evidence of a causal connection * * *.'' That a study is not ''perfect,'' however, does not imply that it is ''not very good.'' MSHA's position has consistently been that, as demonstrated by the two available meta-analyses, the collective epidemiologic evidence is not merely credible but statistically significant and indicative of a causal association. Although MSHA views the toxicity data as supporting and reinforcing the epidemiologic evidence, MSHA believes that the collective epidemiologic evidence is highly credible in its own right.

Furthermore, MSHA does not consider the animal data relevant to humans simply because of the positive epidemiologic evidence. The animal evidence is also credible in its own right. As MSHA has repeatedly pointed out, dust concentrations in some mines have been measured at levels of the same order of magnitude as those found to have caused lung cancer in rats. Such high exposures, especially when combined with occupational exposures to respirable mineral dusts and exposures to particles in tobacco smoke, could overload the human lung and promote lung cancer by a mechanism similar to that hypothesized for rats. (Hattis and Silver, 1992, Figures 9, 10, 11). Also, many of the animal experiments have elucidated genotoxic effects that, while apparently not responsible for the excess lung cancers observed for rats, may be responsible for some or all of the excess risk reported for humans.

MSHA has not relied on circular reasoning. If either the animal data or the toxicity data had failed to show any link between dpm and effects implicated in the induction or promotion of lung cancer, then MSHA's conclusion would have been weakened. The existence of experimental evidence confirming that there is such a link is not imaginary and is logically independent of the epidemiologic evidence. Therefore, contrary to Dr. Borak's characterization, the ''coherency and reinforcement'' arising from the epidemiologic, animal, and genotoxicity data are not the product of circular reasoning. A more apt description is that the three sources of evidence, like three legs of a tripod, support the same conclusion.

Many commenters argued that a causal connection between dpm exposure and an increased human risk of lung cancer should not be inferred unless there is epidemiologic evidence showing a positive exposure-response relationship based on quantitative measures of cumulative dpm exposure. MSHA does not agree that a quantitative exposure-response relationship is essential in establishing causality. Such a relationship is only one of several factors, such as consistency and biological plausibility, that epidemiologists examine to provide evidence of causality. As mentioned earlier, however, there are three studies providing quantitative exposure-response relationships. One of these studies (Steenland et al., 1998) controlled for age, race, smoking, diet, and asbestos exposure, but relied on ''broad assumptions'' to estimate historical exposure levels from later measurements. Two of the studies, however, (Johnston et al., 1997, and Säverin et al., 1999) utilized measurements that were either contemporaneous with the exposures (Johnston) or that were made under conditions very similar to those under which the exposures took place (Säverin). Both of these studies were conducted on underground miners. The Säverin study used exposure measurements of total carbon (TC). All three of the studies combined exposure measurements for each job with detailed occupational histories to form estimates of cumulative dpm exposure; and all three reported evidence of increasing lung cancer risk with increasing cumulative exposure.

Several commenters, expressing and endorsing the views of Dr. Peter Valberg, incorrectly asserted that the epidemiologic results obtained across different occupational categories were inconsistent with a biologically plausible exposure-response relationship. For example, MARG argued that—

> It is biologically implausible that, if dpm were (causally) increasing lung cancer risk by 50% for a low exposure (say, truck drivers), then the lung cancer risk produced by dpm exposure in more heavily exposed worker populations (railroad shop workers) would fall in this same range of added risk. The added lung-cancer risk for bus garage workers is half that of either railroad workers or truck drivers, but dpm concentrations are considerably higher. [MARG]

Earlier, MARG had argued to the contrary that, due to their lack of concurrent exposure measurements, these studies could not reliably be used for hazard identification. MARG then attempted to use them to perform the rather more difficult task of making quantitative comparisons of relative risk. If cumulative exposures are unknown, as MARG argued elsewhere, then there is little basis for comparing responses at different cumulative exposures.

In an analysis submitted by the West Virginia Coal Association, Dr. Valberg extended this argument to miners as follows:

> * * * If dpm concentrations for truck drivers is in the range of 5–50 μg/m^3, then we can assign the 0.49 excess risk (Bhatia's meta-analysis result) to the 5–50 μg/m^3 exposure. Hence, dpm concentrations for miners in the range of 100–2,000 μg/m^3 should have yielded excess risks forty times larger, meaning that the RR for exposed miners would be expected to be about 21 (i.e., 1 + 19.6), whereas reported risk estimates are less than 3 (range from 0.74

2.67). Such an utter lack of concordance argues against a causal role for dpm in the reported epidemiologic associations.

Based on a similar line of reasoning, IMC Global asserted that ''* * * the assumptions that MSHA used to develop [Figure III–4] * * * do not do make sense in the context of a dose-response relationship between lung cancer and dpm exposure.'' This was one of the reasons IMC Global gave for objecting to MSHA's comparison (in Section III.1.d) of exposure levels measured for miners to those reported for different occupations. IMC Global proposed that, as a consequence of this argument, MSHA should delete this comparison from its risk assessment.

MSHA sees three major flaws in Dr. Valberg's argument and rejects it for the following reasons:

(1) The argument glosses over the important distinction between exposure concentrations (intensity) and cumulative exposure (dose). Total cumulative exposure is the product of intensity and duration of exposure. Depending on duration, high intensity exposure may result in similar (or even lower) cumulative exposure than low intensity exposure. Furthermore, different industries, in different nations, introduced diesel equipment at different times. The studies being considered were carried out in a variety of different countries and covered a variety of different historical periods. Therefore, the same number of years in different studies can correspond to very different durations of occupational exposure.

Many of the miners in the studies Dr. Valberg considered may have been occupationally exposed to dpm for relatively short periods of time or even not at all. Various forms of exposure misclassification would tend to obscure any exposure-response relationship across industries. Such obscuring would result from both exposure misclassification within individual studies and also variability in the degree of exposure misclassification in different industries.

Furthermore, the exposure levels or intensities assigned to the various occupations would not necessarily be proportional to cumulative exposures, even if the average number of years of exposure were the same. Different job conditions, such as longer-than-average work hours, could have major, variable impacts on cumulative exposures. For example, lower dpm concentrations have been measured for truck drivers than for other occupationally-exposed workers. But as a group, the truck drivers who were studied, due to their work conditions, may have been in their trucks for longer than the standard 40-hour work week and therefore have larger cumulative dpm exposures. These truck drivers commonly congregated in parking areas and slept in their trucks with the engines idling, thereby disproportionately increasing their cumulative dpm exposures compared to miners and other types of workers.

(2) The commenters advancing this argument assumed that an exposure-response relationship spanning occupations at different levels of exposure intensity would take the form of a straight line. This assumption is unwarranted, since carcinogens do not necessarily follow such a simple pattern across a broad range of exposure levels. There is little basis for assuming that the relationship between cumulative dpm exposures and the relative risk of lung cancer would appear as a straight line when plotted against exposure levels that may differ by a factor of 100. Steenland et al. (1998) reported a better statistical ''fit'' to the data using a model based on the logarithm of cumulative exposure as compared to simple cumulative exposure. Even across the relatively limited range of exposures within the trucking industry, the logarithmic exposure model exhibits pronounced curvature towards the horizontal at the higher cumulative exposures (Steenland et al., 1998, Fig. 5). If this model is extrapolated out to the much higher exposures currently found in underground mining, then (as shown in Subsection 3.b.ii(3)(b) of this risk assessment) it diverges even more from a straight-line model. Toxicological evidence of curvature in the dose-response relationship has also been reported (Ichinose et al., 1997b, p. 190).

Furthermore, the exposure-response pattern may depend on other aspects of exposure, besides how much is accumulated. For example, the National Research Council (NRC) has adopted a risk model for radon-induced lung cancer in which the relative risk (RR) at any age depends on both accumulated exposure and the rate (reflecting the intensity of exposure) at which total exposure was accumulated. In this model, which was derived empirically from the epidemiologic data, exposures accumulated over long time periods at relatively low rates result in a greater risk of lung cancer than the same total exposures accumulated over shorter time periods at relatively higher rates (NRC, 1999). A similar effect for dpm could cause apparent anomalies in the pattern of relative risks observed for occupations ranked simply with respect to the intensity of their average exposures.

(3) Mean exposures and relative risks reported for miners involved in the available studies were mischaracterized. Although dpm levels as high as 2000 μg/m^3 have been measured in some mines, the levels at most mines surveyed by MSHA were substantially lower (see Figures III–1 and III–2). The average levels MSHA measured at underground mines were 808 μg/m^3 and 644 μg/m^3 for M/NM and coal mines using diesel equipment for face haulage, respectively (Table III–1). However, these were not necessarily the levels experienced by miners involved in the available studies. The mean TC exposure concentration reported by Säverin et al. (1999), for work locations having the highest mean concentration, was 390 μg/m^3—corresponding to a mean dpm concentration of about 490 μg/m^3. In the only other study involving miners for which exposure measurements were available, Johnston et al. (1997) reported dpm concentrations for the most highly exposed category of workers (locomotive drivers), ranging from 44 μg/m^3 to 370 μg/m^3. Therefore, the mean dpm concentration experienced by the most highly exposed miners involved in these two studies was not ''forty times larger'' than the level imputed to truck drivers, but closer to seven times larger.[73] Applying Dr. Valberg's procedure, this yields an ''expected'' relative risk of about 4.4 for the underground miners who happened to work at mines included in these particular studies (1 + 7×(0.49)). Miners exposed at higher levels would, of course, face a greater risk.

Dr. Valberg asserted that the highest relative risk reported for miners was 2.67 (from Boffetta et al., 1988). Dr. Valberg failed to note, however, that the upper 95-percent confidence limit for miners' relative risk in this study was 4.37, so that this result hardly qualifies as an ''utter lack of concordance'' with the 4.4 ''expected'' value for miners. Furthermore, even higher relative risks for miners have been reported in other studies. Burns and Swanson (1991) reported 5.0 for operators of mining machinery, with an upper 95-percent confidence limit of 16.9. The relative risk estimated for the most highly exposed miners in the study by Johnston et al. (1997) was either 5.5 or 11.0, depending on the statistical model used. These results appear to be quite consistent with the data for truck drivers.

[73] The estimate of seven times larger dpm exposure in miners is the result of averaging data from Säverin et al. (1999) with data from Johnston et al. (1997) and comparing the combined average miner dpm exposure to the average truck driver dpm exposure.

(5) Other Interpretations of the Evidence

After reviewing the same body of scientific evidence as MSHA, Dr. Peter Valberg came to a very different conclusion with respect to the likelihood of causality:

> Flawed methodology (lack of adequate control for smoking); values for relative risks (''RR'') that are low and often not statistically elevated above 1.0; inadequate treatment of sources of variability; reliance on multiple comparisons; and inadequate control over how authors choose to define dpm exposure surrogates (that is, job category within a profession, cumulative years of work, age at time of exposure, etc.), all undermine the assignment of causality to dpm exposure.

On the other hand, many scientific organizations and governmental agencies have reviewed the available epidemiologic and toxicological evidence for carcinogenicity and, in accordance with MSHA's conclusion, identified dpm as a probable human carcinogen—at levels far lower than those measured in some mines—or placed it in a comparable category. These include:

YEAR

2000 National Toxicology Program (NTP);
1999 (tentative) U.S. Environmental Protection Agency (EPA)
1998 (tentative) (American Conference of Governmental Industrial Hygienists (ACGIH); Currently on Y2K NIC list. Probable vote in 10/2000.
1998 California Environmental Protection Agency (Cal-EPA);
1998 Federal Republic of Germany;
1996 International Programme on Chemical Safety (IPCS), a joint venture of the World Health Organization, the International Labour Organization, and the United Nations Environment Programme;
1989 International Agency for Research on Cancer (IARC);
1988 National Institute for Occupational Safety and Health (NIOSH).

Nevertheless, several commenters strongly objected to MSHA's conclusion, claiming that the evidence was obviously inadequate and citing scientific authorities who, they claimed, rejected MSHA's inference of a causal connection. In some cases, views were inaccurately attributed to these authorities, and misleading quotations were presented out of context. For example, the Nevada Mining Association stated that its own review of the scientific literature led to—

> * * * the only reasonable conclusion possible: there is no scientific consensus that there is a causal link between dpm exposure and lung cancer. The HEI [1999 Expert Panel] report concludes that the causal link between diesel exhaust and lung cancer remains unproven, and that further study and analysis are clearly required. [Nevada Mining Assoc.]

Although HEI (1999) recommended further study and analysis for purposes of quantitative risk assessment, the report contains no findings or conclusions about the ''causal link.'' To the contrary, the report explicitly states that the panel ''* * * was not charged to evaluate either the broad toxicologic or epidemiologic literature concerning exposure to diesel exhaust and lung cancer for hazard identification purposes, which has been done by others.'' (HEI, 1999, p. 1) Furthermore, the HEI panel ''* * * recognize[d] that regulatory decisions need to be made in spite of the limitations and uncertainties of the few studies with quantitative data currently available.'' (HEI, 1999, p. 20)

MARG, along with the Nevada Mining Association and several other commenters, mischaracterized the Expert Panel's findings as extending beyond the subject matter of the report. This report was limited to evaluating the suitability of the data compiled by Garshick et al. (1987, 1988) and Steenland et al. (1990, 1992, 1998) for quantitative risk assessment. Contrary to the characterization by these commenters, HEI's Expert Panel explicitly stated:

> [The Panel] was not charged to evaluate the broad toxicologic or epidemiologic literature for hazard identification purposes, which has been done by others. State, national, and international agencies have all reviewed the broader animal and human evidence for carcinogenicity and, in either their draft or final reports, have all identified diesel exhaust as [a] probable human carcinogen or placed it in a comparable category.'' [HEI, 1999, p. 1]

The Panel then identified most of the organizations and governmental institutions listed above (HEI, 1999, p. 8).

One commenter (MARG) also grossly misrepresented HEI (1999) as having stated that ''the available epidemiologic work has 'study design flaws, including uncontrolled, confounding and lack of exposure measures, leading to a lack of convincing evidence.' '' (MARG post-hearing comments) The opinion falsely attributed to HEI was taken from a sentence in which HEI's Diesel Epidemiology Expert Panel was describing opinions expressed in ''[s]ome reviews critical of these data.'' (HEI, 1999, p. 10) The Panel did not suggest that these opinions were shared by HEI or by any members of the Panel. In fact, the cited passage came at the end of a paragraph in which the Panel cited a larger number of other review articles that had ''discusse[d] this literature in depth'' and had expressed no such opinions. In the same paragraph, the Panel confirmed that ''[t]he epidemiologic studies generally show higher risks of lung cancer among persons occupationally exposed to diesel exhaust than among persons who have not been exposed, or who have been exposed to lower levels or for shorter periods of time.'' (HEI, 1999, p. 10)

Several commenters noted that the U.S. EPA's Clean Air Scientific Advisory Committee (CASAC) issued a report (CASAC, 1998) critical of the EPA's 1998 draft Health Assessment Document for Diesel Emissions (EPA, 1998) and rejecting some of its conclusions. After the HEI (1999) Expert Panel report was published, the EPA distributed a revised draft of its Health Assessment Document (EPA, 1999). In the 1999 draft, the EPA characterized human exposures to diesel exhaust as ''highly likely'' to be carcinogenic to humans at ambient (i.e., environmental) exposure levels. After reviewing this draft, CASAC endorsed a conclusion that, at ambient levels, diesel exhaust is likely to be carcinogenic to humans. Although CASAC voted to recommend that the designation in the EPA document be changed from ''highly likely'' to ''likely,'' this change was recommended specifically for ambient rather than occupational exposures. The CASAC report states that ''[a]lthough there was mixed opinion regarding the characterization of diesel emissions as 'highly likely' to be a human carcinogen, the majority of the Panel did not agree that there was sufficient confidence (i.e., evidence) to use the descriptor 'highly' *in regard to environmental exposures.''* (CASAC, 2000, emphasis added)

MSHA recognizes that not everyone who has reviewed the literature on lung cancer and diesel exposure agrees about the collective weight of the evidence it presents or about its implications for regulatory decisions. IMC Global, for example, stated:

> After independently reviewing most [of the] * * * epidemiologic studies, the literature reviews and the two meta-analyzes, IMC Global believes * * * MSHA has misrepresented the epidemiologic evidence in the Proposed Rule. The best conclusion that we can reach based on our review of this information is that different reputable studies reach conflicting conclusions * * *. [IMC Global]

IMC Global continued by expressing concern that MSHA had ''dismissed'' opposing arguments critical of the positive studies, especially ''regarding lack of statistical significance; small magnitudes of relative risk * * *; and the impact of confounding factors, especially smoking * * *. [IMC Global]''

MSHA has addressed these three issues, as they relate to the evaluation of individual studies, in Section 2.c.i(2)(a) of this preamble. The argument that confounding factors such as smoking may have been systematically responsible for the positive results was discussed above, under the heading of ''Potential Systematic Biases.'' Statistical significance of the collective evidence is not the same thing as statistical significance of individual studies. Application of the sign test, as described Subsection 3.a.iii(1) above, is one way that MSHA has addressed statistical significance of the collective evidence. Another approach was also described above, under the heading of ''Meta-Analyses.''

IMC Global quoted Morgan et al. (1997) as concluding that ''[a]lthough there have been a number of papers suggesting that diesel fumes may act as a carcinogen, the weight of the evidence is against this hypothesis.'' This conclusion was based largely on the authors' contention, shared by IMC Global, that the epidemiologic results were inconsistent and of insufficient strength (i.e., RR < 2.0) to rule out spurious associations due to potential confounders. MSHA, on the other hand, interprets the epidemiologic studies as remarkably consistent, given their various limitations, and has argued that the strength of evidence from individual studies is less important than the strength of evidence from all studies combined. Dr. Debra Silverman has referred to the ''striking consistency'' of this evidence. (Silverman, 1998)

Ironically, Morgan et al. point out many of the very limitations in individual studies that may actually explain why the studies do not yield entirely equivalent results. The 1997 Morgan article was written before the meta-analyses became available and resolved many, if not all, of the apparent inconsistencies in the epidemiologic results. Since none of the existing human studies is perfect and many contain important limitations, it is not surprising that reported results differ in magnitude and statistical significance. The meta-analyses described earlier showed that the more powerful and carefully designed studies tended to show greater degrees of association. MSHA has addressed the joint issues of consistency and strength of association above, under the heading of ''Consistency of Epidemiologic Evidence.''

The Engine Manufacturers Association (EMA) quoted Cox (1997) as concluding: ''* * * there is no demonstrated biological basis for expecting increased risk at low to moderate levels of [diesel] exposure.'' (Cox, 1997, as quoted by EMA] The EMA, however, prematurely terminated this quotation. The quoted sentence continues: ''* * * low to moderate levels of exposure (those that do not lead to lasting soot deposits, chronic irritation, and perhaps GSH enzyme depletion in the lung).'' MSHA does not regard concentrations of dpm exceeding 200 μg/m^3 as ''low to moderate,'' and the EMA presented no evidence that the effects Dr. Cox listed do not occur at the high exposure levels observed at some mines. Salvi et al. (1999) reported marked inflammatory responses in the airways of healthy human volunteers after just one hour of exposure to dpm at a concentration of 300 μg/m^3. The deleted caveat ending the quotation is especially important in a mining context, since mine atmospheres generally contain respirable mineral dusts that may diminish clearance rates and contribute to meeting thresholds for chronic irritation and inflammation leading to oxidative damage. Based on miners' testimony at the public hearings and workshops, there is, in fact, reason to believe that exposed miners experience lasting soot deposits and chronic irritation as a result of their exposures.

With respect to the epidemiologic evidence, the EMA quoted Dr. Cox as concluding: ''* * * among studies that demonstrate an increased relative risk, it appears plausible that uncontrolled biases in study design and data analysis methods can explain the statistical increases in relative risk without there being a true causal increase.'' (Cox, 1997, quoted by EMA) Dr. Cox refers to non-causal explanations for positive epidemiologic results as ''threats to causal inference.'' In considering Dr. Cox's discussion of the evidence, it is important to bear in mind that his purpose was ''* * * not to establish that any (or all) of these threats do explain away the apparent positive associations between [dpm] and lung cancer risk * * * but only to point out that they plausibly could * * *.'' (Cox, 1997, p. 813) Dr. Cox's stated intent was to identify non-causal characteristics of positive studies that could potentially ''explain away'' the positive results. This is a relatively simple exercise that could misleadingly be applied to even the strongest of epidemiologic studies. As stated earlier, no epidemiologic study is perfect, and it is always possible that unknown or uncontrolled risk factors may have given rise to a spurious association. Neither the EMA nor Dr. Cox pointed out however, that there are characteristics common to the negative studies that plausibly explain why they came out negative: insufficient latency allowance, nondifferential exposure misclassification, inappropriate comparison groups (including healthy worker effect, negative confounding by smoking or other variables. A similar approach could also be used to explain why many of the positive studies did not exhibit stronger associations. As observed by Dr. Silverman, ''an unidentified negative confounder may have produced bias across studies, systematically diluting RRs.''

b. Significance of the Risk of Material Impairment to Miners

The fact that there is substantial and persuasive evidence that dpm exposure can materially impair miner health in several ways does not imply that miners will necessarily suffer such impairments at a significant rate. This section will consider the significance of the risk faced by miners exposed to dpm.

i. Meaning of Significant Risk

(1) Legal Requirements

The benzene case, cited earlier in this risk assessment, provides the starting point for MSHA's analysis of this issue. Soon after its enactment in 1970, OSHA adopted a ''consensus'' standard for exposure to benzene, as authorized by the OSH Act. The standard set an average exposure limit of 10 parts per million over an 8-hour workday. The consensus standard had been established over time to deal with concerns about poisoning from this substance (448 U.S. 607, 617). Several years later, NIOSH recommended that OSHA alter the standard to take into account evidence suggesting that benzene was also a carcinogen. (*Id.* at 619 et seq.). Although the ''evidence in the administrative record of adverse effects of benzene exposure at 10 ppm is sketchy at best,'' OSHA was operating under a policy that there was no safe exposure level to a carcinogen. (*Id.*, at 631). Once the evidence was adequate to reach a conclusion that a substance was a carcinogen, the policy required the agency to set the limit at the lowest level feasible for the industry. (*Id.* at 613). Accordingly, the Agency proposed lowering the permissible exposure limit to 1 ppm.

The Supreme Court rejected this approach. Noting that the OSH Act requires ''safe or healthful employment,'' the court stated that—

> * * * 'safe' is not the equivalent of 'risk-free' * * * a workplace can hardly be considered ''unsafe'' unless it threatens the

workers with a significant risk of harm. Therefore, before he can promulgate any permanent health or safety standard, the Secretary is required to make a threshold finding that a place of employment is unsafe—in the sense that significant risks are present and can be eliminated or lessened by a change in practices. [*Id.*, at 642, italics in original].

The court went on to explain that it is the Agency that determines how to make such a threshold finding:

First, the requirement that a 'significant' risk be identified is not a mathematical straitjacket. It is the Agency's responsibility to determine, in the first instance, what it considered to be a 'significant' risk. Some risks are plainly acceptable and others are plainly unacceptable. If, for example, the odds are one in a billion that a person will die from cancer by taking a drink of chlorinated water, the risk clearly could not be considered significant. On the other hand, if the odds are one in a thousand that regular inhalation of gasoline vapors that are 2% benzene will be fatal, a reasonable person might well consider the risk significant and take appropriate steps to decrease or eliminate it. Although the Agency has no duty to calculate the exact probability of harm, it does have an obligation to find that a significant risk is present before it can characterize a place of employment as ''unsafe.'' [*Id.*, at 655].

The court noted that the Agency's ''* * * determination that a particular level of risk is 'significant' will be based largely on policy considerations.'' (*Id.*, note 62).

Some commenters contended that the concept of significant risk, as enunciated by the Supreme Court in the Benzene case, requires support by a quantitative dose-response relationship. For example, one commenter argued as follows:

* * * OSHA had contended in * * * [the benzene] case that ''because of the lack of data concerning the linkage between low-level exposures and blood abnormalities, it was impossible to construct a dose-response curve at this time''. 448 U.S. at 632–633. The court rejected the Agency's attempt to support a standard based upon speculation that ''the benefits to be derived from lowering'' the permissible exposure level from 10 to 1 ppm were 'likely' to be 'appreciable'.'' 448 U.S. at 654.

One year after the Benzene case, the Court in American Textile Mfr's Inst. v. Donovan, 452 U.S. 490 (1981), upheld OSHA's ''cotton dust'' standard for which a dose-response curve had been established by the Agency. The Court relied upon the existence of such data to find that OSHA had complied with the Benzene mandate, stating: ''In making its assessment of significant risk, OSHA relied on dose-response curve data * * * It is difficult to imagine what else the agency could do to comply with this Court's decision in the Benzene case.'' *Id.* at 505, n. 25. See also *Public Citizen Research Group* v. *Tyson,* 796 F. 2d 1479, 1496, 1499 (D.C. Cir. 1986) (where a dose response curve was constructed for the ethylene oxide standard and the agency [had] gone to great lengths to calculate, within the bounds of available scientific data, the significance of the risk); *United Steelworkers of America* v. *Marshall,* 647 F. 2d 1189, 1248 (D.C. Cir. 1980), cert. denied, 453 U.S. 913 (1981) (where in promulgating a new lead standard ''OSHA amassed voluminous evidence of the specific harmful effects of lead at particular blood levels and correlated these blood lead levels with air lead levels''). [NMA]

A dose-response relationship has been established between exposure to $PM_{2.5}$ (of which dpm is a major constituent) and the risk of death from cardiovascular, cardiopulmonary, or respiratory causes (Schwartz et al.,1996; EPA, 1996). Furthermore, three different epidemiologic studies, including two carried out specifically on mine workers, have reported evidence of a quantitative relationship between dpm exposure and the risk of lung cancer (Johnston et al., 1997, Steenland et al., 1998, Säverin et al., 1999). However, the Secretary has carefully reviewed the legal references provided by the commenters and finds there is no requirement in the law that the determination of significant risk be based on such a relationship. The cited court rulings appear to describe sufficient means of establishing a significant risk, rather than necessary ones. Indeed, as stated earlier in this section, the Benzene court explained that:

* * * the requirement that a ''significant'' risk be identified is not a mathematical straitjacket. It is the Agency's responsibility to determine, in the first instance, what it considered to be a ''significant'' risk. * * * the Agency has no duty to calculate the exact probability of harm * * *.

The Agency has set forth the evidence and rationale behind its decision to propose a rule restricting miner exposure to dpm, obtained an independent peer review of its assessment of that evidence, published the evidence and tentative conclusions for public comment, held hearings, kept the record open for further comments for months after the hearings, and re-opened the record so that stakeholders could comment on the most recent evidence available. Throughout these proceedings, the Agency has carefully considered all public comments concerning the evidence of adverse health effects resulting from occupational dpm exposures. Based on that extensive record, and the considerations noted in this section, the Agency is authorized under the statute and relevant precedents to act on this matter—despite the fact that a more conclusive or definitively established exposure-response relationship might help address remaining doubts among some members of the mining community.

As the Supreme Court pointed out in the benzene case, the appropriate definition of significance also depends on policy considerations of the Agency involved. In the case of MSHA, those policy considerations include special attention to the history of extraordinary occupational risks leading to the Mine Act. That history is intertwined with the toll to the mining community of silicosis and coal workers' pneumoconiosis (CWP or ''black lung''), along with billions of dollars in Federal expenditures.

(2) Standards and Guidelines for Risk Assessment

Several commenters suggested that this risk assessment, as originally proposed, deviated from established risk assessment guidelines, because it did not provide a sufficiently quantitative basis for evaluating the significance of miners's risks due to their dpm exposures. One of these commenters (Dr. Jonathan Borak) maintained that a determination of significant risk based on a ''qualitative'' assessment ''has no statistical meaning.''

MSHA recognizes that a risk assessment should strive to provide as high a degree of quantification and certainty as is possible, given the best available scientific evidence. However, in order to best protect miners' health, it is not prudent to insist on a ''perfect'' risk assessment. Nor is it prudent to delay assessing potentially grave risks simply because the available data may be insufficient for an ideal risk assessment. The need for regulatory agencies to act in the face of uncertainty was recognized by the HEI's Diesel Epidemiology Expert Panel as follows: ''The Panel recognizes that regulatory decisions need to be made in spite of the limitations and uncertainties of the few studies with quantitative data currently available.'' (HEI, 1999) When there is good, qualitative evidence—such as the sight and smell of heavy smoke—that one's house is on fire, an inference of significant risk may be statistically meaningful even without quantitative measurements of the smoke's density and composition.

Moreover, as will be demonstrated below, the question of whether a quantitative assessment is or is not essential is, in this case, moot: this risk assessment does, in fact, provide a quantitative evaluation of how significant the risk is for miners occupationally exposed to dpm.

ii. Significance of Risk for Underground Miners Exposed to dpm

An important measure of the significance of a risk is the likelihood that an adverse effect actually will occur. A key factor in the significance of risks that dpm presents to miners is the very high dpm concentrations to which a number of those miners are currently exposed—compared to ambient atmospheric levels in even the most polluted urban environments, and to workers in diesel-related occupations for which positive epidemiologic results have been reported. Figure III–4 compared the range of median dpm exposure levels measured for mine workers at various mines to the range of medians estimated for other occupations, as well as to ambient environmental levels. Figure III–7 presents a similar comparison, based on the highest mean dpm level observed at any individual mine, the highest mean level reported for any occupational group other than mining, and the highest monthly mean concentration of dpm estimated for ambient air at any site in the Los Angeles basin.[74] As shown in Figure III–7, underground miners are currently exposed at mean levels up to 10 times higher than the highest mean exposure reported for other occupations, and up to 100 times higher than the highest mean environmental level even after adjusting the environmental level upwards to reflect an equivalent occupational exposure.

Given the significant increases in mortality and other acute health effects associated with increments of 25 μg/m^3 in fine particulate concentration (see Table III–3), the relative risk of acute effects for some miners (especially those already suffering respiratory problems) appears to be extremely high. Acute responses to dpm exposures have been detected in studies of stevedores, whose exposures were likely to have been less than one tenth the exposure of some miners on the job. Likewise, the risk of lung cancer due to dpm exposure would appear to be far greater for those underground miners who are exposed at such high levels than for other workers or general urban populations.

[74] For comparability with occupational lifetime exposure levels, the environmental ambient air concentration has been multiplied by a factor of approximately 4.7. This factor reflects a 45-year occupational lifetime with 240 working days per year, as opposed to a 70-year environmental lifetime with 365-days per year, and assumes that air inhaled during a work shift comprises half the total air inhaled during a 24-hour day.

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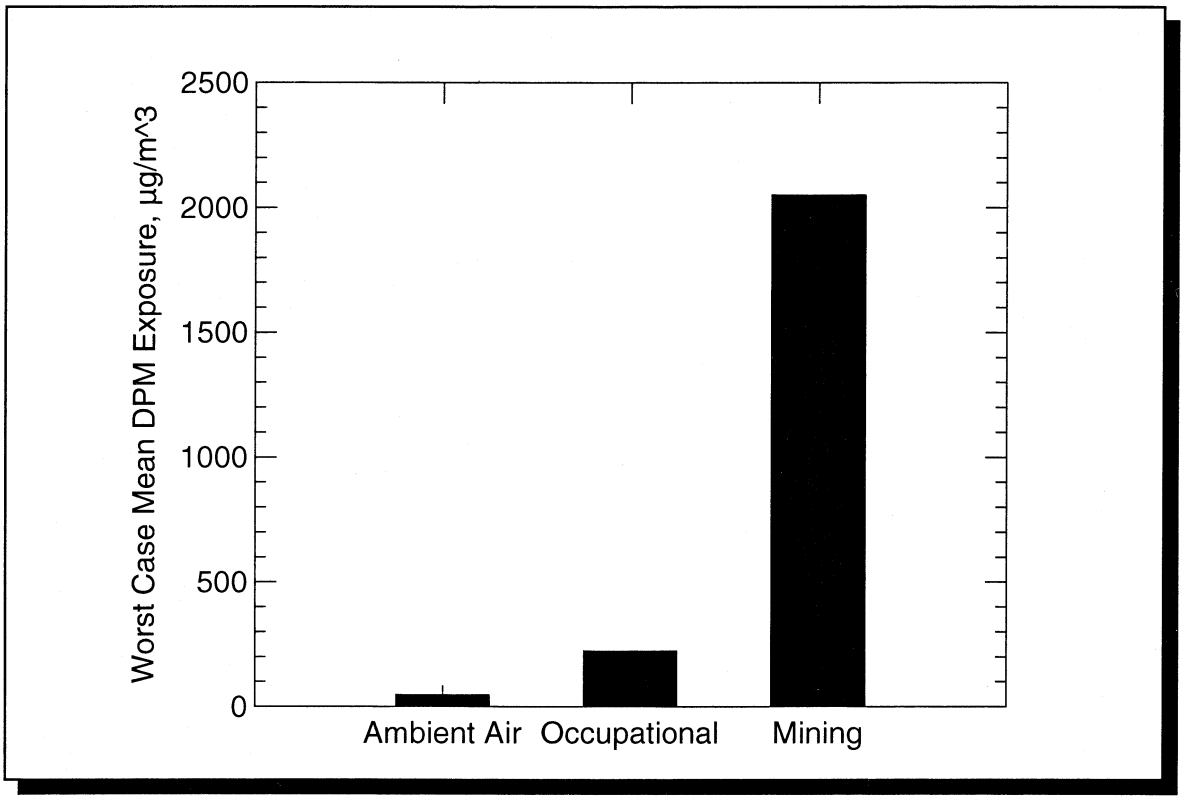

Figure III-7. — Worst case observed or reported mean diesel particulate exposure concentrations for urban ambient air, occupations other than mining, and mining. Worst case for mining is mean dpm measured within an underground mine. Worst case for occupations other than mining is mean respirable particulate matter, other than cigarette smoke, reported for railroad workers classified as hostlers (Woskie et al., 1988). Worst case for ambient air is mean estimated for peak months at most heavily polluted site in Los Angeles area (Cass and Gray, 1995), multiplied by 4.7 to adjust for comparability with occupational lifetime exposure levels. For additional information on means and ranges see Section III.1.d.

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Several commenters asserted that current dpm exposures in underground mines are lower than they were when MSHA conducted its field surveys and that MSHA had not taken this into account when assessing the significance of dpm risk to miners. A related comment was that MSHA had not designed its sampling studies to provide a statistically representative cross section of the entire industry but had nevertheless used the results in concluding that the risk to underground miners was significant.

In accordance with § 101.(a)(6) of the Mine Act, MSHA is basing this risk assessment on the best available evidence. None of the commenters provided evidence that dpm levels in underground metal/nonmetal mines had declined significantly since MSHA's field studies, or provided quantitative estimates of any purported decline in average dpm concentrations, or submitted data that would better represent the range of dpm concentrations to which underground miners are typically exposed at the present time. Although MSHA's field studies were not designed to be statistically representative in a way that can be readily quantified, they were performed at locations selected, according to MSHA's best engineering judgement, to be typical of the type of diesel equipment used. Furthermore, as will be shown below, MSHA's evaluation of the significance of risks presented to underground metal/nonmetal miners by their dpm exposures does not rely on the highest levels, or even the average levels, that MSHA has measured. As documented in Section 1.d of this risk assessment, some of the highest of MSHA's measurements were made as recently as 1996–1997. It is important to note, as is shown below, the cancer risks of dpm exposure are clearly significant even at a concentration of 300 $\mu g/m^3$—less than half of the average level that MSHA observed in its field studies. Therefore, MSHA believes that a reduction in exposure of more than 50 percent in the last couple of years is highly implausible.

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A number of other governmental and nongovernmental bodies have concluded that, even at the far lower levels evident in other occupational environments or in ambient air, the health risks of dpm exposure are of sufficient significance that exposure should be limited:

(1) In 1988, after a thorough review of the scientific literature, the National Institute for Occupational Safety and Health (NIOSH) recommended that diesel exhaust be controlled to the *lowest feasible exposure level*. The document did not contain a recommended exposure limit.

(2) In 1996, the Federal Republic of Germany classified dpm as "probably carcinogenic for humans" and established legally binding technical limits on dpm concentrations in occupational environments. The classification requires that the "best available technology" be used for emission reduction. The technical concentration limits, applying to all workplaces except coal mines, are the lowest limits thought to be feasible in Germany with current technology. Expressed as limits on elemental carbon (EC), they are: 300 $\mu g/m^3$ for tunneling and non-coal mining; 100 $\mu g/m^3$ for all other workplaces (except coal mines).

(3) An ad hoc committee of the Canada Centre for Mineral and Energy Technology (CANMET) has recommended that a limit of 500 $\mu g/m^3$ RCD be adopted as a goal for underground mining environments.

(4) The International Programme on Chemical Safety (IPCS), which is a joint venture of the World Health Organization, the International Labour Organisation, and the United Nations Environment Programme, performed a comprehensive evaluation of the scientific evidence linking diesel exhaust with adverse health effects (IPCS, 1996). IPCS concluded that inhalation of diesel exhaust is of concern with respect to both neoplastic and non-neoplastic diseases and that the particulate phase appears to have the greatest effect on health. As a result of this evaluation, the IPCS recommended that "in the occupational environment, good work practices should be encouraged, and adequate ventilation must be provided to prevent excessive exposure."

(5) In light of the significant health risks associated with environmental exposures to fine particulates ($PM_{2.5}$), in 1997 the U.S. Environmental Protection Agency revised national air quality standards regulating PM to include $PM_{2.5}$ in the ambient air. Diesel particulate matter was a major constituent of $PM_{2.5}$ in many of the areas forming the basis of the EPA's health risk assessment. (EPA, 1996)

(6) In 1998, the California Environmental Protection Agency identified dpm as a toxic air contaminant, as defined in their Health and Safety Code, Section 39655. According to that section, a toxic air contaminant is an air pollutant which may cause or contribute to an increase in mortality or in serious illness, or which may pose a present or potential hazard to human health. This conclusion, unanimously adopted by the California Air Resources Board and its Scientific Review Panel on Toxic Air Contaminants, initiates a process of evaluating strategies for reducing dpm concentrations in California's ambient air.

(7) In 1999, the American Conference of Governmental Industrial Hygienists (ACGIH) proposed a Threshold Limit Value of 50 $\mu g/m^3$ for the dpm component of diesel exhaust and placed dpm on its Notice of Intended Changes. This ACGIH proposal was based on a determination that occupational exposure levels exceeding 50 $\mu g/m^3$ would present a significant "incremental" or excess risk of lung cancer.

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Earlier in this risk assessment, MSHA identified three types of material impairment that can result from occupational exposures to dpm. The next three subsections present the Agency's evaluation of how much of a risk there is that miners occupationally exposed to dpm will actually incur such consequences. Each part addresses the risk of incurring one of the three types of material impairment identified earlier.

(1) Sensory Irritations and Respiratory Symptoms (Including Allergenic Responses)

It is evident from the direct testimony of numerous miners working near diesel equipment that their exposures pose a significant risk of severe sensory irritations and respiratory symptoms. This was underscored during the workshops and public hearings by several miners who noted that such effects occurred immediately and consistently after episodes of intense exposure (Section 2.b.i). There is also persuasive experimental evidence that exposure at levels found in underground mines frequently cause eye and nose irritation (Rudell et al., 1996) and pulmonary inflammation (Salvi et al., 1999). Section 2.a.ii and 3.a.i of this risk assessment explain why these effects constitute ''material impairments'' under the Mine Act and why they threaten miners' safety as well as health. Therefore, it is clear that even short-term exposures to excessive concentrations of dpm pose significant risks.

MSHA's quantitative evaluation of how significant the risks of sensory irritations and respiratory symptoms are for miners is limited, by the quantitative evidence available, to acute respiratory symptoms linked to fine particulate exposures ($PM_{2.5}$) in ambient air pollution studies. MSHA recognizes that, for miners exposed to dpm, this type of risk cannot be quantified with great confidence or precision based on the available evidence. This is because $PM_{2.5}$ is not solely comprised of dpm and also because miners, as a group, have different demographic and health characteristics from the general populations involved in the relevant studies. However, MSHA believes that the quantitative evidence suffices to establish a lower bound on the significance of this type of risk to miners exposed to dpm. Even at this lower bound, which is likely to substantially underestimate the degree of risk, the probability that a miner's occupational exposure to dpm will cause adverse respiratory effects is clearly significant.

As shown in Table III–3, the risk of acute lower respiratory tract symptoms has been reported to increase, at a 95-percent confidence level, by 15 to 82 percent (RR = 1.15 to 1.82) for each incremental increase of 20 μg/m³ in the concentration of $PM_{2.5}$ in the ambient air. This means that the relative risk estimated for a given $PM_{2.5}$ concentration ranges between $(1.15)^k$ and $(1.82)^k$, where k = the concentration of $PM_{2.5}$ divided by 20 μg/m³. For example, for a $PM_{2.5}$ concentration of 40 μg/m³, the RR is estimated to be between $(1.15)^2$ and $(1.82)^2$, or 1.32 to 3.31. MSHA believes that part of the reason why the range is so wide is that the composition of $PM_{2.5}$ varied in the data from which the estimates were derived.

MSHA acknowledges that there are substantial uncertainties involved in converting 24-hour environmental exposures to 8-hour occupational exposures. However, since mining often involves vigorous physical activity (thereby increasing breathing depth and frequency) and sleep is characterized by reduced respiration, it is highly likely that miners would inhale at least one-third of their total 24-hour intake of air during a standard 8-hour work shift. If it is assumed that the acute respiratory effects of inhaling dpm at a concentration of 60 μg/m³ over an 8-hour workshift are at least as great as those at a concentration of 20 μg/m³ over a 24-hour period, then it is possible to estimate a lower bound on the relative risk of such effects.

Based solely on the fact that dpm consists almost entirely of particles much smaller than 2.5 micrometers in diameter, the dpm would be expected to penetrate the lower respiratory tract at least as effectively as $PM_{2.5}$. Also, given the complex chemical composition of dpm, and its generation within a confined space, there is no reason to suspect that dpm in an underground mining environment is less potent than ambient $PM_{2.5}$ in inducing respiratory symptoms. Under these assumptions, a short-term environmental exposure to $PM_{2.5}$ at a concentration of 20 μg/m³ would correspond to a short-term occupational exposure to dpm at a concentration of 60 μg/m³. Consequently, the RR at an occupational exposure level of Y μg/m³ would equal the RR calculated for an ambient exposure level of 20×(Y/60) μg/m³. For example, the relative risk (RR) of acute lower respiratory symptoms at an occupational exposure level of 300 μg/m³ dpm would, at a minimum, correspond to the RR at an ambient exposure level equal to 5×20 μg/m³ $PM_{2.5}$. (See Table III–3) A dpm concentration of 300 μg/m³ happens to be the level at which Salvi et al. (1999) found a marked pulmonary inflammatory response in healthy human volunteers after just one hour of exposure.

Under these assumptions, the risk of lower respiratory tract symptoms for a miner exposed to dpm for a full shift at a concentration of 300 μg/m³ or more, would be at least twice the risk of ambient exposure (i.e., RR = $(1.15)^5$ = 2.01). This would imply that for miners exposed to dpm at or above this level, the risk of acute lower respiratory symptoms would double, at a minimum. The Secretary considers such an increase in risk to be clearly significant.

(2) Premature Death From Cardiovascular, Cardiopulmonary, or Respiratory Causes

As in the case of respiratory symptoms, the nature of the best available evidence limits MSHA's quantitative evaluation of how large an excess risk of premature death, due to causes other than lung cancer, there is for miners exposed to dpm. As before, this evidence consists of acute effects linked to fine particulate exposures ($PM_{2.5}$) in ambient air pollution studies. Therefore, the analysis is subject to similar uncertainties. However, also as before, MSHA believes that the quantitative evidence suffices to place a lower bound on the increase in risk of premature mortality for miners occupationally exposed to dpm. As will be shown below, even this lower bound, which is likely to substantially underestimate the degree of increase, indicates that a miner's occupational exposure to dpm has a clearly significant impact on the likelihood of premature death.

Schwartz et al. (1996) found an average increase of 1.5 percent in daily mortality associated with each increment of 10 μg/m³ in the daily concentration of fine particulates. Higher increases were estimated specifically for ischemic heart disease (IHD: 2.1 percent), chronic obstructive pulmonary disease (COPD: 3.3 percent), and pneumonia (4.0 percent). The corresponding 95-percent confidence intervals for the three specific estimates were, respectively, 1.4% to 2.8%, 1.0% to 5.7%, and 1.8% to 6.2%, per increment of 10 μg/m³ in daily $PM_{2.5}$ exposure. Within the range of dust concentrations studied, the response appeared to be linear, with no threshold. The investigators checked for but did not find any consistent or statistically stable relationship between increased mortality and the atmospheric concentration of ''course'' respirable

particles—i.e., those with aerodynamic diameter greater than 2.5 micrometers but less than 10 micrometers.

As explained earlier, it is highly likely that miners would inhale at least one-third of their total 24-hour intake of air during a standard 8-hour work shift. Therefore, under the same assumptions made in the previous subsection, the 24-hour average concentrations of $PM_{2.5}$ measured by Schwartz et al. are no more potent, in their impact on mortality risk, than eight-hour average concentrations that are three times as high. As discussed in Section 2.a.iii of this risk assessment, underground miners may be less, equally, or more susceptible than the general population to the acute mortality effects of fine particulates such as dpm. However, miners who smoke tobacco and/or suffer various respiratory ailments fall into groups identified as likely to be especially sensitive (EPA, 1996). Consequently, for such miners occupationally exposed to dpm, the relative risk of each type of premature mortality would be at least equal to the corresponding lower 95-percent confidence limit specified above.

Therefore, MSHA estimates that, on average, each increment of 30 $\mu g/m^3$ in the dpm concentration to which miners are exposed increases the risk of premature death due to IHD, COPD, and pneumonia by a factor of at least 1.4 percent, 1.0 percent, and 1.8 percent, respectively. As noted earlier, these estimates are based on the evidence of acute effects linked to fine particulate exposures ($PM_{2.5}$) in ambient air pollution studies. A lower bound on the increased risk expected at an occupational dpm concentration greater than 30 $\mu g/m^3$, is obtained by raising the relative risks equivalent to these factors (i.e., 1.014, 1.01, and 1.018) to a power, k, equal to the ratio of the concentration to 30 $\mu g/m^3$. For a concentration of 300 $\mu g/m^3$, k = 10; so MSHA estimates the lower bounds on relative risk to be: $(1.014)^{10} = 1.149$ for IHD; $(1.01)^{10} = 1.105$ for COPD; and $(1.018)^{10} = 1.195$ for pneumonia. This means that for miners exposed to dpm at or above this level, MSHA expects the risks to increase by at least 14.9 percent for IHD, 10.5 percent for COPD, and 19.5 percent for pneumonia. The Secretary considers increases of this magnitude to be clearly significant, since the causes of death to which they apply are not rare among miners.

(3) Lung Cancer

In contrast to the two types of risk discussed above, the available epidemiologic data can be used to relate the risk of lung cancer directly to dpm exposures. Therefore, the significance of the lung cancer risk can be evaluated without having to make assumptions about the relative potency of dpm compared to the remaining constituents of $PM_{2.5}$. This removes an important source of uncertainty present in the other two evaluations.

There are two different ways in which the significance of the lung cancer risk may be evaluated. The first way is based on the relative risk of lung cancer observed in the best available epidemiologic studies involving miners (identified as such in Subsections 3.a.iii(1) (b) and (d) of this risk assessment). As will be explained below, this approach leads to an estimated tripling of lung cancer risk for miners exposed to dpm, compared to a baseline risk for unexposed miners. The second way is to calculate the lung cancer risk expected at exposure levels MSHA has observed in underground mines, assuming a specified occupational lifetime and using the exposure-response relationships estimated for underground miners by Johnston et al. (1997) and Säverin et al. (1999). As will be explained further below, this second approach yields a wide range of estimates, depending on which exposure-response relationship and statistical model is used. All of the estimates, however, show at least a doubling of baseline lung cancer risk, assuming dpm exposure for a 45-year occupational lifetime at the average concentration MSHA has observed. Most of the estimates are much higher than this. If the exposure-response relationship estimated for workers in the trucking industry by Steenland et al. (1998) is extrapolated to the much higher exposure levels for miners, the resulting estimates fall within the range established by the two mine-specific studies, thereby providing a degree of corroboration. Since lung cancer is not a rare disease, the Secretary considers even the very lowest estimate—a doubling of baseline risk—to represent a clearly significant risk.

Both of these methods provide quantitative estimates of the degree by which miners' risk of lung cancer is increased by their occupational dpm exposures. The estimate based on exposure-response relationships is more refined, in that it ties the increased risk of lung cancer to specific levels of cumulative dpm exposure. However, this added refinement comes at the price of an additional source of uncertainty: the accuracy of the exposure-response relationship used to calculate the estimate. This additional uncertainty is reflected, in MSHA's evaluation, by a broad range of relative risk estimates, corresponding to the range of exposure-response relationships derived using different statistical models and epidemiologic data. The next two subsections present the details of MSHA's two approaches to analyzing lung cancer risk for miners exposed to dpm, along with MSHA's responses to the relevant public comments.

(a) Risk Assessment Based on Studies Involving Miners

As one commenter pointed out, the epidemiologic evidence showing an elevated risk of lung cancer for exposed workers is mostly based on occupations estimated to experience far lower exposure levels, on average, than those observed in many underground mines:

> * * *[U]nderground coal, metal and non-metal miners face a significant risk of lung cancer from occupational exposure to diesel particulate. Numerous epidemiologic studies of workers exposed to levels far below those experienced by coal, metal and non-metal miners have found the risk for exposed workers to be 30–50% greater than for unexposed workers. [Washington State Dept. of Labor and Industries]

Indeed, although MSHA recognizes that results from animal studies should be extrapolated to humans with caution, it is noteworthy that dpm exposure levels recorded in some underground mines (see Figures III–1 and III–2) have been well within the exposure range that produced tumors in rats (Nauss et al., 1995).

Both existing meta-analyses of the human studies relating dpm exposure and lung cancer excluded studies on miners but presented evidence showing that, averaged across all other occupations, dpm exposure is responsible for an increase of about 40 percent in lung cancer risk (See Section 3.a.iii(2) of this risk assessment). Even a 40-percent increase in the risk of lung cancer would clearly be significant, since this would amount to more than two cases of lung cancer per year per thousand miners at risk, and to an even greater risk for smoking miners. The best available evidence, however, indicates (1) that exposure levels in underground mines generally exceed exposures for occupations included in the meta-analyses and (2) that lung cancer risks for exposed miners are elevated to a greater extent than for other occupations.

As Dr. Valberg and other commenters pointed out, the epidemiologic studies used in the meta-analyses involved much lower exposure levels than those depicted for mines in Figures III–1 and III–2. The studies supporting a 40-percent excess risk of lung cancer were

conducted on populations whose average exposure is estimated to be less than 200 μg/m³—less than one tenth the average concentration MSHA observed in some underground mines. More specifically, average exposure levels in the two most extensively studied industries—trucking (including loading dock workers) and railroads—have been reported to be far below the levels observed in underground mining environments. For workers at docks employing diesel forklifts—the occupational group estimated to be most highly exposed within the trucking industry—the highest average dpm concentration reported was about 55 μg/m³ EC at an individual dock (NIOSH, 1990). As explained in Subsection 1.d of this risk assessment, this corresponds to less than 150 μg/m³ of dpm, on average. Published dpm measurements for railworkers have generally also been less than 150 μg/m³ (measured as respirable particulate matter other than cigarette smoke). The reported mean of 224 μg/m³ for hostlers displayed in Figure III–7 represents only the worst-case occupational subgroup (Woskie et al., 1988). In contrast, in the study on underground potash miners by Säverin et al. (1999), the mean TC concentration measured for production areas was 390 μg/m³—corresponding to a mean dpm concentration of about 490 μg/m³. As shown in Table III–1, the mean dpm exposure level MSHA observed in underground production areas and haulageways was 644 μg/m³ for coal mines and 808 μg/m³ for M/NM.

In accordance with the higher exposure levels for underground miners, the five studies identified in Section III.3.a.iii(1)(d) as comprising the best available epidemiologic evidence on miners all show that the risk of lung cancer increased for occupationally exposed miners by substantially more than 40 percent. The following table presents the relative risk (RR) of lung cancer for miners in these studies, along with the geometric mean based on all five studies:

Study	Relative risk of lung cancer
Boffetta et al., 1988	2.67
Burns & Swanson, 1991	5.03
Johnston et al., 1997 (mine-adjusted model applied at highest cumulative exposure)	5.50
Lerchen et al., 1987	2.1
Säverin et al., 1999 (highest vs least exposed)	2.17
geometric mean	3.2

As shown in this table, the estimated RR based on these five studies is 3.2 for miners exposed to dpm. In other words, the risk of lung cancer for the highly exposed miners is estimated to be 3.2 times that of a comparable group of occupationally unexposed workers. The geometric mean RR remains 3.2 if the two studies on which MSHA places less weight (by Burns & Swanson and by Lerchen) are excluded from the calculation. This represents a 220-percent increase in the risk of lung cancer for exposed miners, in contrast to the 40-percent increase estimated, on average, for other occupationally exposed workers. The Secretary believes that a 40-percent increase in the risk of lung cancer already exceeds, by a wide margin, the threshold for a clearly significant risk. However, a 220-percent increase to more than three times the baseline rate is obviously of even greater concern.

Some commenters questioned whether increased lung cancer risks of this magnitude were plausible, since they were not aware of any unusually high lung cancer rates among workers at mines with which they were familiar and which used diesel equipment. There are several reasons why an elevated risk of lung cancer might not currently be conspicuous among U.S. miners exposed to dpm. Lung cancer not only may require a latency period of 30 or more years to develop, but it may also not develop until beyond the normal retirement age of 65 years. Cases of lung cancer developing after retirement may not all be known to members of the mining community. Also, in a population that includes many tobacco smokers, it may be difficult to discern cases of lung cancer specifically attributable to dpm exposure when they first begin to become prevalent. Two commenters expressed some of the relevant considerations as follows. Although they were referring to coal miners, the same points apply to M/NM miners.

Because the latency period for lung cancer is so long, and diesel-powered equipment has only been used extensively in U.S. coal mines for about 25 years, the epidemic may well be progressing unnoticed. [UMWA]

If dpm exposure will cause cancer, there is a huge population of miners here in the West that have already been exposed. Considering the latency periods indicated by MSHA, these miners should be beginning to develop cancers. [Canyon Fuels]

(b) Risk Assessment Based on Miners' Cumulative Exposure

Although it is evident that underground miners currently face a significant risk of lung cancer due to their occupational exposure to dpm, there are certain advantages in utilizing an exposure-response relationship to quantify the degree of risk at specific levels of cumulative exposure. As some commenters pointed out, for example, dpm exposure levels may change over time due to changes in diesel fuel and engine design. The extent and patterns of diesel equipment usage within mines also has changed significantly during the past 25 years, and this has affected dpm exposure levels as well. Furthermore, exposure levels at the mines involved in epidemiologic studies were not necessarily typical or representative of exposure levels at mines in general. A quantitative exposure-response relationship provides an estimate of the risk at any specified level of cumulative exposure. Therefore, using such a relationship to assess risk under current or anticipated conditions factors in whatever differences in exposure levels may be relevant, including those due to historical changes.

(i) Exposure-Response Relationships from Studies Outside Mining

Stayner et al. (1998) summarized quantitative risk assessments based on exposure-response relationships for dpm published through 1998. These assessments were broadly divided into those based on human studies and those based on animal studies. Depending on the particular studies, assumptions, statistical models, and methods of assessment used, estimates of the exact degree of risk varied widely even within each broad category. However, as presented in Tables III and IV of Stayner et al. (1998), all of the very different approaches and methods published through 1998 produced results indicating that levels of dpm exposure measured at some underground mines present an unacceptably high risk of lung cancer for miners—a risk significantly greater than the risk they would experience without the dpm exposure.[75]

[75] In comments submitted by MARG, Dr. Jonathan Borak asserted that MSHA had ''misrepresented the findings of a critical study'' by stating that all methods showed an ''unacceptably high risk'' at exposure levels found at some mines. Dr. Borak claimed that Stayner et al. (1998) had described an analysis by Crump et al. ''that reached an opposite conclusion.'' Dr. Borak failed to distinguish between a finding of high risk and a finding of changes in that risk corresponding to changes in estimated exposures. The findings to which Dr. Borak referred pertained only to the exposure-response relationship within the group of exposed workers. Garshick (1981), Crump (1999), and HEI (1999) all noted that the risk of lung cancer was nevertheless elevated among the exposed workers, compared to unexposed workers in the same cohort,

Continued

Quantitative risk estimates based on the human studies were generally higher than those based on analyses of the rat inhalation studies. As indicated by Tables 3 and 4 of Stayner et al. (1998), a working lifetime of exposure to dpm at 500 μg/m^3 yielded estimates of excess lung cancer risk ranging from about 1 to 200 excess cases of lung cancer per thousand workers based on the rat inhalation studies and from about 50 to 800 per thousand based on the epidemiologic assessments. Stayner et al. (1998) concluded their report by stating:

> The risk estimates derived from these different models vary by approximately three orders of magnitude, and there are substantial uncertainties surrounding each of these approaches. Nonetheless, the results from applying these methods are consistent in predicting relatively large risks of lung cancer for miners who have long-term exposures to high concentrations of DEP [i.e., dpm]. This is not surprising given the fact that miners may be exposed to DEP [dpm] concentrations that are similar to those that induced lung cancer in rats and mice, and substantially higher than the exposure concentrations in the positive epidemiologic studies of other worker populations.

Restricting attention to the exposure-response relationships derived from human data, Table IV of Stayner et al. (1998) presented estimates of excess lung cancer risk based on exposure-response relationships derived from four different studies: Waller (1981) as analyzed by Harris (1983); Garshick et al. (1987) as analyzed by Smith and Stayner (1991); Garshick et al. (1988) as analyzed by California EPA (1998); and Steenland et al. (1998). Harris (1983) represented upper bounds on risk; and all of the other estimates represented the most likely value for risk, given the particular data and statistical modeling assumptions on which the estimate was based. Three different ranges of estimates were presented from the California EPA analysis, corresponding to various statistical models and assumptions about historical changes in dpm exposure among the railroad workers involved. As mentioned above and in the proposed version of this risk assessment, the low end of the range of estimates was 50 lung cancers per 1000 workers occupationally exposed at 500 μg/m^3 for a 45-year working lifetime. This estimate was one of those based on railroad worker data from Garshick et al. (1988).

Several commenters objected to MSHA's reliance on any of the exposure-response relationships derived from the data compiled by Garshick et al. (1987) or Garshick et al. (1988). These objections were based on re-analyses of these data by Crump (1999) and HEI (1999), using different statistical methods and assumptions from those used by Cal-EPA (1998). For example, the NMA quoted HEI (1999) as concluding:

> At present, the railroad worker cohort study * * * has very limited utility for QRA [quantitative risk assessment] of lifetime lung cancer risk from exposure to ambient levels of diesel exhaust * * * [NMA, quoting HEI (1999)]

From this, the NMA argued as follows:

> What then is the relevance of this data to the proceedings at issue? Simply put, there is no relevance. The leading epidemiologist [sic], including Dr. Garshick himself, now agree that the data are inappropriate for conducting risk assessment. [NMA]

MSHA notes that the HEI (1999) conclusion cited by the NMA referred to quantitative risk assessments at ambient, not occupational, exposure levels. Also, HEI (1999) did not apply its approach (i.e., investigating the correlation between exposure and relative risk within separate job categories) to the Armitage-Doll model employed by Cal-EPA in some of its analyses. (Results using this model were among those summarized in Table IV of Stayner et al., 1998). Therefore, the statistical findings on which HEI (1999) based its conclusion do not apply to exposure-response relationships estimated using the Armitage-Doll model. Furthermore, although HEI concluded that the railroad worker data have ''very limited utility for *QRA * * * at ambient levels*'' [emphasis added], this does not mean, even if true, that these data have ''no relevance'' to this risk assessment, as the NMA asserted. Even if they do not reliably establish an exposure-response relationship suitable for use in a quantitative risk assessment, these data still show that the risk of lung cancer was significantly elevated among exposed workers. This is the only way in which MSHA is now using these data in this risk assessment.

In the proposed risk assessment, MSHA did not rely directly on the railroad worker data but did refer to the lowest published quantitative estimate of risk, which happened, as of 1998, to be based on those data. MSHA's reasoning was that, even based on the lowest published estimate, the excess risk of lung cancer attributable to dpm exposure was clearly sufficient to warrant regulation. If risk assessments derived from the railroad worker data are eliminated from consideration, the lowest estimate remaining in Table IV of Stayner et al. (1998) is obviously even higher than the one that MSHA used to make this determination in the proposed risk assessment. This estimate (based on one of the analyses performed by Steenland et al., 1998) is 89 excess cases of lung cancer per year per thousand workers exposed at 500 μg/m^3 for a 45-year working lifetime.

HEI (1999) also evaluated the use of the Steenland data for quantitative risk assessment, but did not perform any independent statistical analysis of the data compiled in that study. Some commenters pointed out HEI's reiteration of the cautionary remark by Steenland et al. (1998) that their exposure assessment depended on ''broad assumptions.'' The HEI report did not rule out the use of these data for quantitative risk assessment but suggested that additional statistical analyses and evaluations were desirable, along with further development of exposure estimates using alternative assumptions. MSHA has addressed comments on various aspects of the analysis by Steenland et al., including the exposure assumptions, in Section 2.c.i(2)(a) of this risk assessment.

One commenter noted that Steenland et al. (1998) had recognized the limitations of their analysis and had, therefore, advised that the results ''should be viewed as exploratory.'' The commenter then asserted that MSHA had nevertheless used these results as ''the basis for a major regulatory standard'' and that ''[t]his alone is sufficient to demonstrate that MSHA's proposal lacks the necessary scientific support.'' [Kennecott Minerals]

The Secretary does not accept the premise that MSHA should exclude ''exploratory'' results from its risk assessment, even if it is granted that those results depend on broad assumptions possibly requiring further research and validation before they are widely accepted by the scientific community. Steenland et al. (1998) estimated risks associated with specific cumulative exposures, based on estimates of historical exposure patterns combined with data originally described by Steenland et al., 1990 and 1992. Regardless of whether the cumulative exposure estimates used by Steenland et al. (1998) are sufficiently reliable to permit pinpointing the risk of lung cancer at any given exposure level, the quantitative analysis indicates that as cumulative exposure increases, so does the risk. Therefore, the 1998 analysis adds significantly to the weight of evidence supporting a causal

and they all identified reasons why the data used in this study might fail to detect a positive exposure-response relationship among the exposed workers.

relationship. However, MSHA did not use or propose to use exposure-response estimates derived by Steenland et al. (1998) as the sole basis for any regulatory standard.

The exposure-response relationships presented by Steenland et al. were derived from exposures estimated to be far below those found in underground mines. As Stayner et al. (1998) point out, questions are introduced by extrapolating an exposure-response relationship beyond the exposures used to determine the relationship. The uncertainties implicit in such extrapolation are demonstrated by comparing results from two statistical models based on five-year lagged exposures—one using simple cumulative exposure and the other using the natural logarithm of cumulative exposure (Steenland et al., 1998, Table II).

Assuming that, on average, EC comprises 40 percent of total dpm,[76] the formula for calculating a relative risk (RR) using Steenland's simple cumulative exposure model is RR = exp(0.4×0.389×CumExp), where CumExp is occupationally accumulated dpm exposure (expressed in mg-yr/m^3), ignoring the most recent five years. Again assuming EC=0.4×dpm, the corresponding formula using Steenland's Log(CumExp) model is: RR = exp(0.1803×(Log(0.4×1000×CumExp + BG) − Log(BG))), still ignoring occupational dpm exposure in the most recent five years.[77]

The risk estimates from these two models are similar at the cumulative exposure levels estimated for workers involved in the study, but the projected risks diverge markedly at the higher exposures projected for underground miners exposed to dpm for a 45-year occupational lifetime. For example, a cumulative dpm exposure of 2.5 mg-yr/m^3 (i.e., 45 years of occupational exposure at an average dpm concentration of about 55.6 μg/m^3) is within the range of cumulative exposures from which these exposure-response relationships were estimated. At this level of cumulative exposure, the models (both lagged five years) yield relative risk estimates of 1.48 (based on simple cumulative exposure) and 1.64 (based on the logarithm of cumulative exposure, with BG=70 μg-yr/m^3). On the other hand, 45 years of occupational exposure at an average dpm concentration of 808 μg/m^3 amounts to a cumulative dpm exposure of 36,360 μg-yr/m^3, or about 36.4 mg-yr/m^3. At this level, which lies well beyond the range of data used by Steenland et al. (1998), the simple and logarithmic exposure models produce relative risk estimates of about 300 and 2.6, respectively.

Despite the divergence of these two models at high levels of cumulative exposure, they can provide a useful check of excess lung cancer risks estimated using exposure-response relationships developed from other studies. For highly exposed miners, the Steenland models both produce estimates of lung cancer risk within the range established by the two miner studies discussed below. This corroborates the upper and lower limits on such risk as estimated by the various statistical models used in those two studies.

(ii) Exposure-Response Relationships from Studies on Miners

As described in Section 2.c.i(2)(a) of this risk assessment, two epidemiologic studies, both conducted on underground miners, provide exposure-response relationships based on fully quantitative dpm exposure assessments. Johnston et al. (1997) conducted their study on a cohort of 18,166 underground coal miners, and Säverin et al. (1999) conducted theirs on a cohort of 5,536 underground potash miners. Each of these studies developed a number of possible exposure-response relationships, depending on the statistical model used for analysis and, in the case of Saverin et al. (1999), inclusion criteria for the cohort analyzed. For purposes of this risk assessment, MSHA has converted the units of cumulative exposure in all of these exposure-response relationships to mg-yr/m^3.

Two exposure-response relationships derived by Johnston et al. (1997) are used in this risk assessment, based on a ''mine-adjusted'' and a ''mine-unadjusted'' statistical model. In both of these models, cumulative dpm exposure is lagged by 15 years.[78] This reflects the long latency period required for development of lung cancer and means that the most recent 15 years of exposure are ignored when the relative risk of lung cancer is estimated. The exposure-response relationships, as reported by the investigators, were expressed in terms of g-hr/m^3 of cumulative dpm exposure. MSHA has converted the exposure units to mg-yr/m^3 by assuming 1920 work hours per year.

Two different methods of statistical analysis were applied by Saüverin et al. (1999) to both the full cohort and to a subcohort of 3,258 miners who had worked underground, in relatively stable jobs, for at least ten years. Thus, the investigators developed a total of four possible exposure-response relationships from this study. Since they were based on measurements of total carbon (TC), these exposure-response relationships were expressed in terms mg-yr/m^3 of cumulative TC exposure. MSHA has converted the exposure units to mg-yr/m^3 of cumulative dpm exposure by assuming that, on average, TC comprises 80 percent of total dpm.

The following table summarizes the exposure-response relationships obtained from these two studies. Each of the quantitative relationships is specified by the unit relative risk (RR) per mg-yr/m^3 of cumulative dpm exposure. To calculate the relative risk estimated for a given cumulative dpm exposure (CE), it is necessary to raise the unit RR to a power equal to CE. For example, if the unit RR is 1.11 and CE = 20, then the estimated relative risk is $(1.11)^{20}$ = 8.1. Therefore, the estimated relative risk of lung cancer increases as CE increases. For the two Johnston models, CE does not include exposure accumulated during the 15 years immediately prior to the time in a miner's life at which the relative risk is calculated.

[76] The assumption is that, on average, EC = TC/2 and TC = 0.8×dpm.

[77] BG, expressed in μg-yr/m^3, accounts for an assumed background (i.e., non-occupational) EC exposure level of 1.0 μg/m^3. At age 70, after a 45-year worklife and an additional 5-year lag after retirement, BG is assumed to equal 70 μg-yr/m^3. ''Log'' refers to the natural logarithm, and ''exp'' refers to the antilogarithm of the subsequent quantity.

[78] The 15-year lagged mine-unadjusted and mine-adjusted models are respectively denoted by M/03 and M/06 in Table 11.2 of Johnston et al. (1997). As explained earlier, the individual mines considered in this study differed significantly with respect to both dpm exposures and lung cancer experience. The investigators could not determine exactly how much, if any, of the increased lung cancer risk associated with dpm exposure depends on other, unknown factors differentiating the individual mines. The mine-adjusted model allocates a significant number of the lung cancers otherwise attributable to dpm exposure to the ''norm'' for specific mines. Therefore, if the differences in lung cancer prevalence between mines is actually due to corresponding differences in mean dpm exposure, then this model will mask a significant portion of the risk due to dpm exposure. After adjusting for miners' age and smoking habits, the mine-unadjusted model attributes differences in the prevalence of lung cancer between mines to corresponding differences in mean dpm exposure. However, the mine-adjusted model has the advantage of taking into account differences between mines with respect to potentially confounding factors, such as radon progeny and silica levels.

EXPOSURE-RESPONSE RELATIONSHIPS OBTAINED FROM TWO STUDIES ON UNDERGROUND MINERS.

Study and statistical model	Unit RR per mg-yr/m³ dpm
Säverin et al. (1999)[1]:	
Poisson, full cohort	1.024
Cox, full cohort	1.089
Poisson, subcohort	1.110
Cox, subcohort	1.176
Johnston et al. (1997)[2]:	
15-year lag, mine-adjusted	1.321
15-year lag, mine-unadjusted	1.479

[1] Unit RR calculated from Tables III and IV, assuming TC = 0.8×dpm.
[2] Unit RR calculated from Table 11.2, assuming 1920 work hours per year.

For example, suppose a miner is occupationally exposed to dpm at an average level of 500 μg/m³. Then each year of occupational exposure would contribute 0.5 mg-yr/m³ to the miner's cumulative dpm exposure. Suppose also that this miner's occupational exposure begins at age 45 and continues for 20 years until retirement at age 65. Consequently, at or above age 65, this hypothetical miner would have accumulated a total of 10 mg-yr/m³ of occupational dpm exposure. According to the Säverin-Cox-subcohort model, the relative risk estimated for this miner after retirement is RR = $(1.176)^{10}$ = 5.1. This means that, at or above age 65, the retired miner's risk of lung cancer is estimated (by this model) to be about five times that of another retired miner having the same age and smoking history but no occupational dpm exposure.

Since the two Johnston models exclude exposure within the last 15 years, it is instructive to calculate the relative risk using these models for the same hypothetical retiree at age 75. Since this miner retired at age 65, immediately after 20 years of occupational exposure, the cumulative exposure used in applying the Johnston models must be reduced by the 2.5 mg-yr/m³ accumulated from age 60 to age 65. Therefore, according to the Johnston mine-adjusted model, the relative risk estimated for this retired miner at age 75 is RR = $(1.321)^{7.5}$ = 8.1. At age 80 or above, however, this model predicts that the relative risk would increase to RR = $(1.321)^{10}$ = 16.2.

The six exposure-response relationships obtained from these two studies establish a range of quantitative risk estimates corresponding to a given level of cumulative dpm exposure. This range provides lower and upper limits on the risk of lung cancer for workers exposed at the given level, relative to similar workers who were not occupationally exposed. The lower limit of this range is established by Säverin's full cohort Poisson model. Therefore, the lowest estimate of relative risk after 45 years of occupational dpm exposure is RR = $(1.024)^{45\times0.644}$ = 2.0 at a mean concentration of 644 μg/m³ or RR = $(1.024)^{45\times0.808}$ = 2.4 at mean concentration of 808 μg/m³. These exposure levels correspond to the averages presented in Table III–1 for underground coal and underground M/NM mines, respectively.

A relative risk of 2.0 amounts to a doubling of the baseline lung cancer risk, and all of the models project relative risks of at least 2.0 after 45 years of exposure at these levels. Therefore, MSHA expects that underground miners exposed to dpm at these levels for a full 45-year occupational lifetime would, at a minimum, experience lung cancer at a rate twice that of unexposed but otherwise similar miners. Five of the six statistical models, however, predict a relative risk much greater than 2.0 after 45 years at a mean dpm concentration of 644 μg/m³. The second-lowest estimate of relative risk, for example, is RR = $(1.089)^{45\times0.644}$ = 11.8, predicted by Säverin's full cohort Cox model.[79]

In the next subsection of this risk assessment, relative risks will be combined with baseline lung cancer and mortality data to estimate the lifetime probability of dying from lung cancer due to occupational dpm exposure.

(iii) Excess Risk at Specific dpm Exposure Levels. The ''excess risk'' discussed in this subsection refers to the lifetime probability of dying from lung cancer resulting from occupational exposure to dpm for 45 years. This probability is expressed as the expected excess number of lung cancer deaths per thousand miners occupationally exposed to dpm at a specified level. The excess is calculated relative to baseline, age-specific lung cancer mortality rates taken from standard mortality tables. In order to properly estimate this excess, it is necessary to calculate, at each year of life after occupational exposure begins, the expected number of persons surviving to that age with and without dpm exposure at the specified level. At each age, standard actuarial adjustments must be made in the number of survivors to account for the risk of dying from causes other than lung cancer.

Table III–7 shows the excess risk of death from lung cancer estimated across the range of exposure-response relationships obtained from Säverin et al. (1999) and Johnston et al. (1997). Estimates based on the 5-year lagged models from Steenland et al. (1998) fall within this range and are included for comparison. Based on each of the eight statistical models, the excess risk was estimated at four levels of dpm exposure: 200 μg/m³, 500 μg/m³, 644 μg/m³ (the mean dpm concentration observed by MSHA at underground coal mines, as shown in Table III–1), and 808 μg/m³ (the mean dpm concentration observed by MSHA at underground M/NM mines, as shown in Table III–1).

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[79] Some commenters contended that MSHA cannot establish a reliable exposure-response relationship because of potential interferences in MSHA's dpm concentration measurements. More specifically, some of these commenters claimed that MSHA's dpm measurements in underground coal mines were significantly inflated by submicrometer coal dust.

As explained in Subsection 1.a of this risk assessment, the sampling device MSHA used to measure dpm in underground coal mines was designed specifically to allow for the submicrometer fraction of coal dust. Both the size-selective and RCD methods are reasonably accurate when dpm concentrations exceed 300 μg/m³. Moreover, neither of these methods was used to establish the exposure-response relationships presented by Säverin et al. (1999) or Johnston *et al.* (1997).

Table III-7. — Lifetime excess risk of lung cancer mortality at specific dpm exposure levels.

Study and Statistical Model	Excess Lung Cancer Deaths per 1000 Occupationally Exposed Workers†			
	200 μg/m³	500 μg/m³	644 μg/m³	808 μg/m³
Säverin et al. (1999)				
Poisson, full cohort	15	44	61	83
Cox, full cohort	70	280	422	577
Poisson, subcohort	93	391	563	693
Cox, subcohort	182	677	761	802
Steenland et al. (1998)				
5-year lag, log of cumulative exposure	67	89	95	101
5-year lag, simple cumulative exposure	159	620	721	771
Johnston et al. (1997)				
15-year lag, mine-adjusted	313	724	770	800
15-year lag, mine-unadjusted	513	783	811	830

† Assumes 45-year occupational exposure at 1920 hours per year from age 20 to retirement at age 65. Lifetime risk of lung cancer adjusted for competing risk of death from other causes and calculated through age 85. Baseline lung cancer and overall mortality rates from NCHS (1996).

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All of the estimates in Table III–7 assume that occupational exposure begins at age 20 and continues until retirement at age 65. Excess risks were calculated through age 85 as in Table IV of Stayner et al. (1998). Table III–7 differs from Table IV of Stayner et al. in that results from Johnston et al. and Säverin et al. are substituted for results based on the two studies by Garshick et al. Nevertheless, at 500 μg/m³, the range of excess risks shown in Table III–7 is nearly identical to the range (50 to 810 μg/m³) presented in Table IV of Stayner et al. (1998).

MSHA considers the exposure levels shown in Table III–1 to be typical of current conditions in underground coal mines using diesel face equipment. At the mean dpm concentration observed by MSHA at underground M/NM mines (808 μg/m³), the eight estimates range from 83 to 830 excess lung cancer deaths per 1000 affected miners. At the mean dpm concentration observed by MSHA at underground coal mines (644 μg/m³), the estimates range from 61 to 811 excess lung cancer deaths per 1000 affected miners. MSHA recognizes that these risk estimates involved extrapolation beyond the exposure experience of the miner cohorts in Säverin et al. (1999) and Johnston et al. (1997). However, the degree of extrapolation was less for those two studies than the extrapolation that was necessary for the diesel-exposed truck drivers in Steenland et al. The lowest excess lung cancer risk in dpm exposed miners found in Table III–7 is 61/1000 per 45-year working lifetime. Based on the quantitative rule of thumb established in the benzene case, this estimate indicates a clearly significant risk of lung cancer attributable to dpm exposure at current levels. [*Industrial Union* vs. *American Petroleum;* 448 U.S. 607, 100 S.Ct. 2844 (1980)].

c. The Rule's Expected Impact on Risk

MSHA strongly disagrees with the views of some commenters who asserted that the proposed rules would provide no known or quantifiable health benefit to mine workers. On the contrary, MSHA's assessment of the best available evidence indicates that reducing the very high exposures currently existing in underground mines will significantly reduce the risk of three different kinds of material impairment to miners: (1) Acute sensory irritations and respiratory symptoms (including allergenic responses); (2) premature death from cardiovascular, cardiopulmonary, or respiratory causes; and (3) lung cancer. Furthermore, as will be shown below, the reduction in lung cancer risk expected as a result of the rule can readily be quantified based on the estimates of excess risk at exposure levels given in Table III–7.

Using exposure-response relationships and assumptions described in Subsections 3.b.ii(1) and 3.b.ii(2) of this risk assessment, MSHA estimated lower bounds on the significance of risks faced by miners occupationally exposed to dpm with respect to (1) acute sensory irritations and respiratory symptoms or (2) premature death from cardiovascular, cardiopulmonary, or respiratory causes. MSHA expects the rules to significantly and substantially reduce all three kinds of risk. However, MSHA is unable, based on currently available data, to quantify with confidence the reductions expected for the first two kinds. A 24-hour exposure at 20 μg/m³ may not have the same short-term effects as an 8-hour exposure at 60 μg/m³. Furthermore, this concentration is only 30 percent of the maximum dpm concentration that MSHA expects once the rules are fully implemented and represents an even smaller fraction of average dpm concentrations many underground miners currently experience. It is unclear whether the same incremental effects on acute respiratory symptoms and premature mortality would apply at the much higher exposure levels found in underground mines. Additionally, as MSHA suggested in the proposed preamble and several commenters repeated, the toxicity of dpm and $PM_{2.5}$ may differ because of differences in composition. Finally, underground miners as a group may differ significantly from the populations for which the $PM_{2.5}$ exposure-response relationships were derived.

Therefore, MSHA's quantitative assessment of the rule's impact on risk is restricted to its expected impact on the third kind of risk—the risk of lung cancer. The rule will limit dpm concentrations to which miners in underground M/NM mines are exposed. The rule will limit these dpm concentrations to approximately 200 μg/m³ by limiting the measured concentration of total carbon to 160 μg/m³. Assuming that, in the absence of this rule, underground M/NM miners would be occupationally exposed to dpm for 45 years at a mean level of 808 μg/m³, the following table contains the estimated reductions in lifetime risk expected to result from full implementation of the rule, based on the various exposure-response relationships obtained from Säverin et al. (1999) and Johnston et al. (1997). These estimates were obtained by calculating the difference between the corresponding estimates of excess lung cancer mortality, at 808 μg/m³ and 200 μg/m³, shown in Table III–7. The Regulatory Impact Analysis (RIA), presented later in this preamble, contains further quantitative discussion of the benefits anticipated from this rule.

REDUCTION IN LIFETIME RISK OF LUNG CANCER MORTALITY EXPECTED AS RESULT OF REDUCING EXPOSURE LEVEL FROM 808 μG/M³ TO 200 μG/M³.

Study and statistical model	Expected reduction in lung cancer deaths per 1000 affected miners[1]
Säverin et al. (1999):	
Poisson, full cohort	68
Cox, full cohort	507
Poisson, subcohort	600
Cox, subcohort	620
Johnston et al. (1997):	
15-year lag, mine-adjusted	487
15-year lag, mine-unadjusted	317

[1] Calculated from Table III–7.

Although the Agency expects that health risks will be substantially reduced by this rule, the best available evidence indicates that a significant risk of adverse health effects due to dpm exposures will remain even after the rule is fully implemented. As explained in Part V of this preamble, however, MSHA has concluded that, due to monetary costs and technological limitations, the underground M/NM mining sector as a whole cannot feasibly reduce dpm concentrations further at this time.

4. Conclusions

MSHA has carefully considered all of the evidence and public comment submitted during these proceedings to determine whether dpm exposures, at levels observed in some mines, present miners with significant health risks. This information was evaluated in light of the legal requirements governing regulatory action under the Mine Act. Particular attention was paid to issues and questions raised by the mining community in response to the Agency's ANPRM and NPRM and during workshops on dpm held in 1995. Based on its review of the record as a whole, the agency has determined that the best available evidence warrants the following conclusions:

1. Exposure to dpm can materially impair miner health or functional capacity. These material impairments include acute sensory irritations and respiratory symptoms (including allergenic responses); premature death

from cardiovascular, cardiopulmonary, or respiratory causes; and lung cancer.

2. At dpm levels currently observed in underground mines, many miners are presently at significant risk of incurring these material impairments due to their occupational exposures to dpm over a working lifetime.

3. By reducing dpm concentrations in underground mines, the rule will substantially reduce the risks of material impairment faced by underground miners exposed to dpm at current levels.

In its response to MSHA's proposals, the NMA endorsed these conclusions to a certain extent, as follows:

> The members of NMA have come to recognize that it would be prudent to limit miners' exposure to the constituents of diesel exhaust in the underground environment. [NMA]

A number of commenters, however, urged MSHA to defer rulemaking for either the coal or M/NM sector, or both, until results were available from the NCI/NIOSH study currently underway. For example, referring to the M/NM proposal, one commenter stated:

> Vulcan agrees with MSHA that underground miner dpm exposure needs to be addressed by mine operators. Vulcan agrees with MSHA that a permissible exposure level (PEL) should be established, but disagrees that adequate information is currently available to set a PEL. [Vulcan Materials]

MSHA believes that expeditious rulemaking, in both underground mining sectors, is necessary for the following reasons:

(1) The NCI/NIOSH study currently in progress will eventually provide additional information on lung cancer mortality. Non-cancer health effects, such as sensory irritations, respiratory symptoms, or premature death from cardiovascular, cardiopulmonary, or respiratory causes will not be addressed. MSHA believes that these non-cancer effects constitute material impairments.

(2) NIOSH itself has recommended that, "* * * given the length of time to complete this study and the current state of knowledge regarding dpm exposures and health effects in miners," MSHA should "proceed with rulemaking based on the evidence currently available as presented in this FR notice." [NIOSH testimony by Paul Schulte, dated 5/27/99]

(3) Given the very high exposure levels measured at some underground mines, miners should not be required to serve as human guinea pigs in order to remove all doubts about the excess risks of dpm exposures in underground mines. While additional studies are in progress, miners should be protected by reducing dpm concentrations to a level more nearly commensurate with exposures in other industries.

Referring to some commenters' position that further scientific study was necessary before regulatory action could be justified, a miner at one of the dpm workshops held in 1995 said:

> * * * if I understand the Mine Act, it requires MSHA to set the rules based on the best set of available evidence, not possible evidence * * * Is it going to take us 10 more years before we kill out, or are we going to do something now * * *? (dpm Workshop; Beckley, WV, 1995).

Similar concern with the risk of waiting for additional scientific evidence was expressed by another miner, who testified:

> * * * I got the indication that the diesel studies in rats could no way be compared to humans because their lungs are not the same * * * But * * * if we don't set the limits, if you remember probably last year when these reports come out how the government used human guinea pigs for radiation, shots, and all this, and aren't we doing the same thing by using coal miners as guinea pigs to set the value? (dpm Workshop; Beckley, WV, 1995).

MSHA shares these sentiments. That is why MSHA considers it imperative to protect miners based on the weight of existing evidence, rather than to wait for the results of additional studies.

IV. Section by Section Discussion of Final Rule

This part of the preamble describes the provisions of the final rule on a section-by-section basis. As appropriate, this part references discussions in other parts of this preamble: in particular, the background discussions on measurement methods and controls in part II, and the feasibility discussions in part V.

The final rule would add nine new sections to 30 CFR Part 57 immediately following § 57.5015. It would not amend any existing sections of that part.

Many provisions of the final rule are identical to the proposed rule, but some provisions have been changed. The following table provides a quick overview of the key changes:

Section	Final rule (changes from proposal)
57.5060	When specified conditions have been met and various precautions have been taken (including use of proper PPE), miners performing certain inspection, maintenance and repair activities may be granted permission from MSHA to work in certain areas where miners normally work and travel, but where the dpm concentration limit is exceeded (not authorized in proposed rule)
57.5061	Compliance sampling must always be done with submicrometer impactor (unspecified in proposed rule)
57.5067	Engines meeting the applicable EPA requirements as per a table provided in the rule may be introduced underground after rule's effective date (under proposal, only MSHA approved engines were so allowed)

Section 57.5060 Limit on Concentration of Diesel Particulate Matter

Summary. This section of the final rule limits the concentration of dpm in underground metal and nonmetal mines. It has six subsections.

Subsection (a) provides that 18 months after the date of promulgation, dpm concentrations would be limited by restricting total carbon to 400 micrograms per cubic meter of air ($400_{TC}\mu g/m^3$). The reason why the concentration limit for dpm is expressed in terms of total carbon is explained below. A total carbon limit of $400_{TC}\mu g/m^3$ is the equivalent of about 500 micrograms per cubic meter of air of dpm ($500_{DPM}\mu g/m^3$). This limit would apply only for a period of 42 months; accordingly, it is sometimes referred to in this preamble as the "interim" concentration limit. The final rule is the same as the proposed rule in this regard.

Subsection (b) provides that five years after the date of promulgation, the concentration limit would be reduced, restricting total carbon to 160 micrograms per cubic meter of air ($160_{TC}\mu g/m^3$, or about $200_{DPM}\mu g/m^3$). This is sometimes referred to in this preamble as the "final" concentration limit. The final rule is the same as the proposed rule in this regard.

Subsection (c) provides for a special extension of up to two additional years in order for a mine to comply with the final concentration limit. This special extension is only available when the mine operator can establish that the final concentration limit cannot be met

within the five years allotted due to technological constraints. The final rule establishes the information that must be contained in the application for an extension, the procedure to follow to make application, and the conditions that must be observed during the special extension period. Subsection (c) of the final rule refers to this extension as ''special'' because the final rule provides all mines in this sector with an extension of time (five years) to meet the final concentration limit. The final rule is the same as the proposed rule in this regard.

Subsection (d) provides that under certain conditions, a miner engaged in inspection, repair or maintenance activities in certain areas of a mine may work in concentrations of dpm in excess of the applicable concentration limit. Among the conditions that must be met in order for such work to be permitted is the use of proper personal protective equipment. This exception was not included in the proposed rule.

Subsection (e) provides that apart from the extraordinary circumstances where the use of such controls may be authorized under subsections (c) and (d), an operator must not utilize personal protective equipment to comply with either the interim or final concentration limit. The wording in the final rule clarifies the intent of the proposed rule, and accommodates new subsection (d).

Subsection (f) provides that an operator must not utilize administrative controls to comply with either the interim or final concentration limit. The proposed rule included the same requirement, but in the final rule this has been separated into a separate paragraph.

General Comments. Some commenters questioned MSHA's rationale for establishing concentration limits at this time. They pointed out that a large scale study by NIOSH of the health risks of dpm exposure is still on-going. Accordingly, they accused MSHA of acting prematurely, and urged delaying implementation of any limits until the health risks of dpm exposure are fully quantified. MSHA was also challenged to justify the specific numerical values chosen for the limits; several commenters suggested that these limits are based on unsubstantiated and unquantified health risks, and that therefore, the levels chosen cannot be justified. But another commenter suggested that the health risks are sufficiently documented to justify even lower limits than were contained in the proposed rule. This commenter suggested 100 μg and 50 μg for the interim and final limits, respectively. As these comments involve questions about the risk to underground metal and nonmetal miners, they are addressed in Part III of this preamble.

Some commenters also objected to the proposed concentration limits because they argued that MSHA lacked evidence that the limits were technologically feasible and economically feasible, and some objected to the use of unvalidated simulations to demonstrate the feasibility of compliance. An alternative to concentration limits was proposed wherein mine operators would ''Examine and adopt technically and economically feasible methods of preventing potentially hazardous or irritating exposure to diesel exhaust.'' But another commenter argued that the metal and nonmetal industry could feasibly meet even lower concentration limits than those proposed. And another suggested that a concentration limit alone will not adequately protect miner health because, given the freedom to choose control options, mine operators may elect to boost ventilation rather than cut emissions. As these comments concern feasibility, they are generally discussed in part V of this preamble.

A number of commenters argued that MSHA should allow operators considerable additional flexibility dealing with dpm. Some felt operators should be left complete flexibility on controls, and that a concentration limit at all was inappropriate. Others argued that the range of operator choice of controls should include personal protective equipment as well as administrative controls. These comments are discussed below in connection with this section (§ 57.5060).

Still other commenters argued that concentration limits should not be proposed, or should be much higher, because they argue MSHA lacks a method to measure dpm concentrations in underground metal and nonmetal mines that provides the accuracy, consistency, and reliability that are needed for compliance determinations. These comments are discussed in this part in connection with § 57.5061.

Another commenter expressed concern about the interplay between this rule and those already in effect for diesel gases. This commenter expressed concern that, in addition to complying with the interim and final dpm concentration limits, mine operators would be required to comply with a concentration limit that considers the additive effect of diesel particulate matter and the principal gaseous emissions from a diesel engine (carbon monoxide, carbon dioxide, nitric oxide, and nitrogen dioxide).

MSHA's risk assessment in part III does not specifically evaluate the possible additive effects of diesel particulate matter and diesel gases. Accordingly, the agency does not at this time have a basis upon which to enforce either the interim or final dpm concentration limit in combination with any other substance or substances, including diesel exhaust gases. MSHA will, of course, continue to enforce the limits applicable to diesel gases, but this enforcement will be separate from the enforcement of the dpm concentration limits under the final dpm rule. The Agency understands that Canada does consider the additive effect of diesel exhaust gases and particulate, and will notify the mining community if it decides to look into this matter further based upon additional information.

Finally, the Agency notes it received only two comments on a related matter on which it specifically sought comment—whether to establish an ''Action Level'' for dpm (63FR 58119). An ''Action Level'' is a defined contaminant level (usually one-half of the compliance limit) which, if exceeded, triggers actions that must be taken to effectuate control of the contaminant. In the preamble to the proposed rule, MSHA noted it had considered the possibility of establishing an Action Level because the dpm concentration at which exposure does not result in adverse health effects is not known at this time. If an Action Level were in place and compliance sampling results exceeded this level, certain remedial steps, or ''best practices,'' would have to be initiated by management to reduce exposures, such as limits on fuel type, idling, and engine maintenance—whatever steps MSHA determined would be feasible at the Action Level for this sector as a whole. One comment that addressed this approach recommended against establishing an Action Level because the commenter was of the view that no limits at all could be justified at this time based on available health risk data. The other commenter suggested that an Action Level should be adopted in lieu of a rule incorporating a concentration limit requiring mandatory compliance.

After further consideration, MSHA determined it does not have enough information to proceed with an Action Level at this time, although it notes that the concept of an Action Level is well recognized in occupational health protection and included in many other standards. Furthermore, MSHA determined that these ''best practices'' are technologically and economically feasible for all mines, so there is no reason to withhold their

implementation until an Action Level is reached. The rationale for requiring these ''best practices'' is discussed in more detail later in this section under ''Meeting the concentration limit: operator choice of controls.''

Concentration limit expressed as an ''average eight-hour equivalent full shift airborne concentration.'' MSHA recognizes that work shifts longer than eight hours are common in the underground metal and nonmetal mining industry. It is for this reason that MSHA expressed its concentration limit as an ''average eight-hour equivalent full shift airborne concentration.'' Health-related standards for airborne contaminants are typically established on the basis of an eight-hour work shift. Standard industrial hygiene practice, and MSHA's past practice for metal and nonmetal health sampling, involve adjusting the actual measured concentration of an airborne contaminant to an eight-hour equivalent concentration when work shifts are longer than eight hours. This adjusts an exposure occurring over an extended workshift (*e.g.,* 10 or 12 hours) to enable a valid comparison to an established exposure limit that is based on an 8-hr workshift.

The mathematical formula for making this adjustment is thoroughly described in the MSHA Metal and Nonmetal Health Inspection Procedures Handbook. This formula is as follows:

$$\frac{\text{Contaminant mass}}{(\text{sampling pump flow rate}) \times (480 \text{ minutes}) \times (0.001 \text{ m}^3/\text{l})}$$

When the sampling pump flow rate is expressed in units of liters per minute, the formula results in a contaminant concentration expressed in units of mg or µg per cubic meter. The factor of 480 minutes is used regardless of actual shift duration so as to adjust the actual concentration to an eight-hour equivalent concentration that can be appropriately compared to a standard limit.

MSHA specifically asked for comment on whether a more explicit definition is required in this regard (63 FR 58183). The agency did not receive any such suggestions. However, it is apparent that the term may be confusing to some. For example, one commenter observed that ''miners working overtime hours would be exposed to more dpm than miners on a normal eight-hour shift,'' and that a formula to determine eight-hour equivalency should be included. Another commenter expressed concern that the final rule would place a restriction on the number of hours or overtime hours miners could work.

MSHA disagrees with these interpretations of the rule. The only impact of the rule relative to work hours is the aforementioned determination of ''average eight-hour equivalent full shift airborne concentration'' for dpm-exposed miners whose work shifts exceed eight hours. Although the Agency has no suggestions for a more clear formulation, it will endeavor to clarify this matter further for operators in its compliance guide.

Dpm concentration limits expressed in terms of total carbon. The purpose of the interim and final concentration limits is to limit the amount of diesel particulate matter; but the limit is being expressed in terms of a restriction on the amount of total carbon. The reason for this involves the measurement method that MSHA intends to utilize to determine the concentration of dpm. As discussed in connection with § 57.5061(a), the final rule specifies that MSHA will use a sampling and analytical method developed by NIOSH (NIOSH Method 5040) to measure dpm concentrations for compliance purposes. Using NIOSH's analytical method, the amount of total carbon (TC) contained in a dpm sample from any underground metal and nonmetal mine can be determined; the method does not directly yield the amount of dpm in a particular sample. However, as explained in detail in Part II of this preamble, TC represents approximately 80–85 percent of the total mass of dpm emitted in the exhaust of a diesel engine. The remaining 15–20 percent consists of sulfates and the various elements bound up with the organic carbon to form the adsorbed hydrocarbons. Using the lower boundary of this range, limiting the concentration of total carbon to 400 micrograms per cubic meter (400_{TC} µg/m^3) effectively limits the concentration of whole diesel particulate to about 500 $_{DPM}$ µg/m^3. Similarly, limiting the concentration of total carbon to 160_{TC} µg/m^3 effectively limits the concentration of whole diesel particulate to about 200_{DPM} µg/m^3. Expressing the concentration limit in terms of total carbon enables miners, mine operators and inspectors to directly compare a measurement result with the applicable limit.

Where the concentration limit applies. The concentration limits—both interim and final—would apply *only* in areas where miners normally work or travel. The purpose of this restriction is to ensure that mine operators do not have to monitor and control dpm concentrations in areas where miners do not normally work or travel—*e.g.,* abandoned areas of a mine where, for example, the roof may not be monitored for safety or ventilation may not be provided. At the same time, it should be noted that the interim and final concentration limits apply in any and all areas of a mine where miners *normally* work or travel—not just where miners might be present at any particular time.

MSHA generally intends for inspectors to determine which portions of a given mine are subject to the concentration limit based on whether normal work or travel activities routinely do, or could occur there, whether areas are designated as ''abandoned'' on mine maps, whether areas are made ''off limits'' through the use of signs or barricades, etc.

MSHA has, however, in the final rule (§ 57.5060(d)), explicitly authorized the Secretary, upon making certain findings and ensuring that certain protections are in place for miners, to allow miners engaged in certain inspection, maintenance or repair activities to work in areas of a mine which are considered areas in which miners normally work or travel but that exceed the concentration limits. These situations are discussed immediately below.

Exception: Specific mining activities which may be conducted in areas which exceed the concentration limit. Although feasible engineering and work practice controls were found to exist for most underground metal and nonmetal mining situations, MSHA did determine that certain maintenance and repair activities might have to be performed in areas where feasible engineering and work practice controls may not be capable of maintaining the dpm concentration at or below the applicable concentration limit. Therefore, in the final rule, § 57.5060(d) under certain conditions permits miners to work in areas where the concentration limit is exceeded, and only when specified precautions have been implemented to protect affected miners. As explained in

detail below, principal among these precautions is the use by all affected miners, of proper personal protective equipment (*i.e.*, respiratory protection devices) within the context of a comprehensive respiratory protection program.

More specifically, § 57.5060(d)(1) permits, with the pre-approval of the Secretary, employees engaged in inspection, maintenance, or repair activities to work in concentrations of dpm exceeding the applicable limit if they are protected by appropriate respiratory protective equipment. This provision applies only to miners performing the identified activities, and only when certain mandatory protections are implemented. If respiratory protective equipment is used, the final rule requires implementation of a respiratory protection program consistent with the minimum requirements established in § 56/57.5005 (a) and (b), which address such factors as selection, maintenance, training, fitting, supervision, and cleaning. These requirements include by reference, the elements of a minimally acceptable respiratory protection program as delineated in the American National Standard on ''Practices For Respiratory Protection'' (ANSI Z88.2–1969).

The rule specifies that areas for which a request to allow employees to work in areas that exceed the concentration limit are limited to—areas where miners work or travel infrequently or for brief periods of time for equipment or mine inspection; areas where miners otherwise work exclusively inside of enclosed and environmentally controlled cabs, booths and similar structures with filtered breathing air; and in shafts, inclines, slopes, adits, tunnels and similar workings that are designated as return or exhaust air courses and that are also used for access into, or egress from an underground mine.

The standard applies in areas of the mine where miners ''normally'' work or travel. Normally does not equate to frequency, but rather to the nature of the area. Areas where miners work or travel infrequently are treated by the rule no differently than areas where miners work or travel frequently. For example, if a remote pump is checked on a weekly basis, the area in which that pump is located would be considered an area where miners normally work or travel, even though the area is visited infrequently.

Approval to allow miners to work in areas that exceed the concentration limit would be contingent on the Secretary determining that engineering controls are not feasible, and that adequate safeguards would be employed by the mine operator to prevent hazardous exposure to dpm. The final rule requires mine operators to submit a plan to the Secretary to justify the infeasibility of engineering controls, and to explain the circumstances of the job, the location where work will be performed, resulting dpm exposures, and controls to be used, including, but not necessarily limited to personal protective equipment.

In order for MSHA to determine the reasonableness of a mine operator's request for approval under 5060(d), certain details regarding the work need to be provided. These include the types of inspection, maintenance or repair activities planned, the locations of such activities, the dpm concentrations at these locations, the reasons why engineering controls would not be feasible, the anticipated frequency of these activities, the anticipated number of miners involved, and the safeguards the mine operator will employ to minimize dpm exposures. These factors will tend to change over time as the mine develops, as new equipment or procedures are introduced, as ventilation system parameters change, etc. MSHA believes that an annual updating of these factors is necessary to insure that approval is granted only where justified by the actual circumstances.

In essence, this exemption allows the use of personal protective equipment as a substitute for engineering controls under a limited number of circumstances. Many commenters suggested MSHA permit the use of PPE much more broadly in lieu of engineering controls; MSHA's review and reaction to these comments is discussed below.

One commenter, a mine operator, agreed with MSHA's approach that stresses engineering controls first and foremost. The commenter stated that, ''engineering controls, as close to the source of the diesel emission as possible, must be the first line of DPM exposure control.'' The commenter further suggested that, ''The proposed rule should allow personal protective equipment to be used as a last resort. The proposed rule should require written documentation explaining how the mine determined the appropriate exposure controls. This written documentation should clearly explain why engineering controls, commonly used in industry to control diesel emissions, are not technically or economically feasible.''

Although MSHA has embraced the commenter's basic idea of requiring written documentation when personal protective equipment is proposed as an alternative to engineering controls, the final rule includes other necessary safeguards to insure that this option is used only when absolutely necessary and that appropriate steps are taken to insure that respirator wearers are adequately protected. The final rule requires such plans to identify, at a minimum, the types of anticipated inspection, maintenance, and repair activities that must be performed for which there are no feasible engineering controls sufficient to comply with the concentration limit, the locations where such activities could take place, the concentration of dpm in these locations, the reasons why engineering controls are not feasible, the anticipated frequency of such activities, the anticipated duration of such activities, the anticipated number of miners involved in such activities, and the safeguards that will be employed to limit miner exposure to dpm, including, but not limited to the use of respiratory protective equipment.

The final rule requires mine operators to utilize all feasible engineering and work practice controls, however, the exception under subsection (d) permits such controls to be supplemented with respirator use in certain limited situations where reliance solely on feasible engineering and work practice controls would be inadequate to control exposures below the applicable concentration limit. The proposal's prohibition on administrative controls under any and all circumstances is retained in the final rule in subsection (e).

Examples of situations where MSHA believes engineering controls might not be feasible include cleaning up a roof fall in an exhaust air course, replacing a conveyor belt idler in a conveyor tunnel that is carrying exhaust air, or shaft inspection in an exhaust air shaft. The provisions of subsection (d) are not intended to suggest that MSHA believes these and similar activities should automatically be considered exempt from the requirement to utilize engineering and work practice controls to comply with the concentration limit. Rather, MSHA recognizes that under certain site specific circumstances, feasible engineering and work practice controls alone may not be capable of achieving compliance with the concentration limit. Therefore, MSHA agrees that respirator use should be permitted if the applications are sufficiently justified and approved in advance.

MSHA does not intend that plans submitted for advance approval need to identify specifically and individually

every activity for which advance approval is sought. The intent is that plans must identify, in a generic sense, the types of activities and related circumstances as can reasonably be anticipated, sufficient to enable the Secretary to determine whether advance approval is warranted.

Meeting the concentration limit: operator choice of engineering controls. The final rule contemplates that an operator of an underground metal or nonmetal mine have considerable discretion over the controls utilized to bring down dpm concentrations to the interim and final concentration limits. For example, an operator could filter the emissions from diesel-powered equipment, install cleaner-burning engines, increase ventilation, improve fleet management, use traffic controls, or use a variety of other readily available controls. A combination of several control measures, including both engineering controls and work practices, may be necessary, depending on site specific conditions.

MSHA intends for engineering controls to refer to controls that remove the dpm hazard by applying such methods as substitution, isolation, enclosure, and ventilation. MSHA intends for work practice controls to refer to specified changes in the way work tasks are performed that reduce or eliminate a hazard, such as traffic controls (speed limits, one-way travel, etc.), prohibiting unnecessary engine idling, or designating areas that are off-limits for diesel equipment operations. As discussed below, the final rule does not permit utilization of administrative controls as a means of complying with the dpm concentration limit. In the context of this rule, MSHA intends for administrative controls to refer to controls that limit a miner's exposure to dpm by distributing the exposure among other miners through various work scheduling and worker rotation practices.

Some commenters asserted that implementation of certain dpm control measures may create other, unrelated health or safety problems. One example given concerned the complications and safety trade-offs of increasing ventilation to control dpm concentrations. The increased ventilation would tend to dry out roadways, causing increased problems with respirable silica bearing dust exposure. This problem, would, in turn, require application of greater amounts of water on the roadways for dust control, which, in turn, would create traction problems for vehicles. Increased ventilation might also accelerate the drying out of certain roof strata, creating roof control problems. Another commenter worried that enclosed cabs can reduce an equipment operator's field-of-view, and dirt or glare on windows can obscure visibility, possibly creating safety problems.

MSHA acknowledges that dpm control measures need to be selected and implemented carefully, both to insure they achieve the desired effect on dpm concentrations, and to minimize or avoid undesirable effects on other aspects of the mine's health and safety environment. In most cases, implementation of a given control will not have any undesirable effects. In other isolated cases, the undesirable effects of a given control can most likely be negated through additional work practice controls or other measures. For example, the increased application of water on roadways to reduce dust control problems caused by higher ventilation rates may require that equipment be operated at slower speeds. Roof control problems resulting from the accelerated drying out of strata may require a reassessment of the mine's roof control plan, such as its roof bolting practices. Vehicle operator field-of-view and visibility problems could be addressed by instituting new traffic controls, requiring slower speeds, and use of window washers. For these reasons, MSHA does not wish to explicitly deny operators a particular type of engineering control because in some circumstances an adjustment to customary mining practices may have to be made.

Because information on available controls has been described in other parts of this preamble (part II and part V), further discussion is not provided here. Mine operators are also directed to the MSHA ''estimator'' model to help them determine which control or combination of controls would be best able to produce the reduction in dpm concentrations necessary to comply with the appropriate concentration limit. The ''estimator'' mathematically calculates the effect of any combination of engineering and ventilation controls on existing dpm concentrations in a given production area of a mine. This model is in the form of a spreadsheet template permitting instant display of outcomes as inputs are altered. The model and some examples illustrating its potential utility are described in Part V of this preamble.

Several commenters expressed disappointment that the proposal did not embrace what they sometimes referred to as ''MSHA's toolbox approach.'' In some cases, this appears to mean the commenters want operators to have the flexibility to use personal protective equipment and administrative controls, as well as engineering and work practice controls, to meet the required concentration limits. In other cases, however, it appears the commenters meant that MSHA should allow them the discretion not only to choose the controls they wish, but to choose whether or not to use controls at all. In other words, to these commenters, the ''toolbox approach'' means voluntary implementation of controls without enforcement of a concentration limit.

By way of background, in 1997, MSHA published a pocket-sized handbook called, ''Practical Ways to Reduce Exposure to Diesel Exhaust in Mining—-A Toolbox.'' This handbook describes and discusses a variety of emission control equipment, methods, and strategies, both in terms of laboratory emissions testing and in-mine experience. The rationale for a ''toolbox approach'' to controlling diesel emissions is explained in the handbook. ''A toolbox offers a choice of tools, each with a specific purpose. One tool after another may be used to find a solution to a problem, or several tools may be tried at the same time.* * * Reducing exposure to diesel emissions lends itself to a toolbox approach because no single method or approach to reducing exposure may be suitable for every situation.'' Since its publication, this handbook, which is referred to simply as the ''MSHA toolbox'' or ''toolbox'' has become quite well known and is widely used in the mining industry.

Commenters who urged MSHA to adopt a ''toolbox approach'' in its rulemaking praised the approach taken in MSHA's publication, and indicated that they had successfully implemented some of the control strategies discussed. They urged MSHA to maintain this flexibility. One commenter suggested that, ''The toolbox is just simply best practices, if you would. If we're doing this, this, and this, then we're doing all we can without enforcement.* * * That's what a toolbox is. A toolbox is not an enforcement tool.''

The MSHA Toolbox was issued before this rulemaking, in which, after considering all the evidence, MSHA has concluded that miners are at significant risk of material impairment at the concentration levels still found in underground metal and nonmetal mines. When MSHA makes such a finding, it is required to act to protect miners to the extent feasible. MSHA has concluded that requiring operators to comply with a concentration limit using engineering controls is necessary to protect miners and feasible for the mining industry as a whole, while still

providing underground metal and nonmetal mine operators with maximum flexibility to address this problem. Thus, MSHA believes the final rule does incorporate the ''toolbox approach'' by allowing mine operators to choose, from among numerous alternatives, the mix of control measures most suitable for the site specific conditions at a given mine—provided that the controls bring exposures down to the required limit.

MSHA has determined that certain types of controls discussed in the toolbox—PPE and administrative controls—are not considered acceptable ways to meet a concentration limit. PPE does not reduce the concentrations of a contaminant in the environment, though such equipment does offer limited protection to miners who must work in areas where the applicable concentration limit cannot be achieved using feasible engineering or work practice controls. The rule permits PPE to be used to protect miners in those limited situations where it permits work to take place despite dpm concentrations in excess of the concentration limit (special extension of time to meet final concentration limit under paragraph (c), discussed below, and special permission to perform inspection, maintenance and repair activities in areas that exceed the concentration limit under paragraph (d), discussed above.) Administrative controls (*e.g.,* limiting the hours worked by a particular miner in a high concentration area) simply spread risk among miners. The reasons for MSHA's position in this regard are discussed in detail below.

MSHA has also determined that certain other types of dpm control measures discussed in the toolbox must be implemented at all underground metal and nonmetal mines that use diesel equipment, regardless of the dpm concentration level, to minimize miner risks. These ''best practices'' include such requirements as low sulfur content diesel fuel, limits on unnecessary idling of diesel engines, maintenance standards, and a requirement for newly introduced engines to be MSHA approved or meet certain EPA standards. MSHA's rationale for why it is mandating such ''best practices'' is summarized below. Further detail is provided in the preamble to the proposal (63FR 58119), and in the sections of this Part which discuss the individual practices themselves (diesel fuel (§ 57.5065(a)), maintenance (§ 57.5066), and engines that are MSHA approved or meet EPA standards (§ 57.5067).

In the proposal, MSHA explained that it had considered implementing an ''Action Level'' for dpm, possibly at a level one-half of the final concentration limit, or 80_{TC} μg/m³ because the dpm concentration at which exposure does not result in adverse health effects is not known at this time. Under this approach, when dpm levels exceeded the Action Level, implementation of certain ''best practice'' controls, such as limits on fuel types, idling, and engine maintenance would have been required. However, this approach was not incorporated into the proposal, nor has it been incorporated into the final rule. MSHA determined it does not have enough information to proceed with an Action Level at this time, although it notes that the concept of an Action Level is well recognized in occupational health protection and included in many other standards. Instead, MSHA determined that these ''best practices'' would be required for all mines at all times.

MSHA followed this course for several reasons, including: (1) Sampling by both mine operators and MSHA would have been much more frequent under an approach incorporating an Action Level; (2) tracking equipment maintenance requirements would have been much more complicated, as diesel equipment could move from an area of the mine where the dpm concentration was less that the Action Level, to another area where the Action Level had been exceeded; (3) these ''best practices'' are already in place, and have proven to be workable and practical in coal mines; (4) given the history of lung problems associated with the mining industry, and considering that these practices were determined to be economically and technologically feasible for the industry as a whole, a more protective course seemed prudent; and (5) a number of the work practices appear to have significant benefits, such as improving the efficiency of maintenance operations.

One commenter suggested that other ''best practices'' related to mine ventilation should be mandated in the final rule. This commenter recommended requiring mine operators to provide details on the design and operating parameters of auxiliary ventilation systems, that they be required to utilize an appropriate air measurement and recording program, and that they properly attend to uncontrolled recirculations and leakages. MSHA believes that existing ventilation regulations adequately address these concerns, and that mine operators, in utilizing a ''toolbox approach'' to implement dpm control measures, have the option of incorporating ventilation system improvements if they are judged to be feasible, practical, desirable, and appropriate to the site specific conditions at a given mine. Thus, MSHA did not include a mandate to use such ventilation ''best practices'' in the final rule.

Concentration limit: time to meet. As noted, the dpm limitation requires metal and nonmetal mines to reduce total carbon concentrations in areas where miners normally work or travel to 160 micrograms per cubic meter of air (equating to about 200 micrograms of dpm per cubic meter of air.) § 57.5060 provides for an extension of time for underground metal and nonmetal mines to meet the concentration limit. Mines do not have to meet any limit for the first 18 months after the final rule is promulgated. Instead, this period will be used to provide compliance assistance to the metal and nonmetal mining community to ensure it understands how to measure and control diesel particulate matter concentrations in individual operations. Moreover, the rule provides all mines in this sector an extension of three and a half additional years to meet the final concentration limit established by § 57.5060(b). During this extension, however, all mines will have to bring total carbon concentrations down to 400 micrograms per cubic meter, equating to a limit of 500 micrograms per cubic meter in dpm.

Comments on the implementation schedule for the concentration limits focused on the technological and economic feasibility of complying within the time frames established. Commenters expressed the view that the rule is technology forcing, and that the mining sector of the economy is too small to justify the expense by manufacturers (mining equipment, diesel engines, aftertreatment devices, etc.) to develop the necessary products to enable mine operators to fully comply by the deadlines contained in the final rule.

MSHA provided these phase-in times for meeting the interim and final concentration limits after carefully reviewing comments on the economic and technological feasibility of requiring all mines in this sector to meet the applicable limits using available controls. This review is presented in Part V of this preamble. MSHA has studied a number of metal and nonmetal mines in which it believed dpm might be particularly difficult to control. The Agency has concluded that in combination with the ''best practices'' required under other provisions of the

final rule (§§ 57.5065, 57.5066 and 57.5067), engineering and work practice controls are available that can bring dpm concentrations in all underground metal and nonmetal mines down to or below 400_{TC} μg/m³ within 18 months. Moreover, the Agency has concluded that controls are available to bring dpm concentrations in all underground metal and nonmetal mines down to or below 160_{TC} μg/m³ within 5 years. The Agency has concluded that it is not feasible to require this sector, as a whole, to lower dpm concentrations further, or to implement the required controls more swiftly.

Despite its conclusions on the feasibility of these timeframes for the underground metal and nonmetal industry as a whole, MSHA has included a provision in the final rule to allow an additional two years for mines experiencing difficulty in complying due to technological problems. A discussion of this special extension follows.

Special extension. Pursuant to § 5060(c), an operator may request more than five years to comply with the final concentration limit only in the case of technological problems. In light of the risks to miners posed by dpm, however, the Agency has concluded that the economic constraints of a particular operator are not an adequate basis for a further extension of time for that operator, and the final rule does not provide for any extension grounded in economic concerns. Moreover, if it is technologically feasible for an operator to reduce dpm concentrations to the final limit within the established five year compliance period, no extension would be permitted even if a more cost effective solution might be available in the future for that operator.

However, the Agency has determined that if an operator can actually demonstrate that there is no technological solution that could reduce the concentration of dpm to 160_{TC} μg/m³ within five years, a special extension would be warranted.

Extension application. § 57.5060(c)(1) provides that if an operator of an underground metal or nonmetal mine can demonstrate that there is no combination of controls that can, due to technological constraints, be implemented within five years to reduce the concentration of dpm to the limit, MSHA may approve an application for an extension of time to comply.

Such a special extension is available only once, and is limited to 2 years. In this regard, MSHA does not anticipate that an extension will automatically last 2 years, and the agency will closely scrutinize applications to determine how much time is really required to implement a technological solution. To obtain a special extension, an operator must show that diesel powered equipment was used in the mine prior to publication of the rule, demonstrate that there is no off-the-shelf technology available to reduce dpm to the limit specified in § 57.5060, and establish the lowest concentration of dpm attainable. In this regard, the Agency reiterates that cost is not a consideration; thus, simply because a more cost-effective solution will become available in the future is not an acceptable reason for an extension.

One commenter questioned whether it is reasonable to limit mine operators to one special extension when the necessary technology to comply with the concentration limits does not exist today. This commenter suggests a five to ten year compliance schedule is more realistic to allow time to develop the technology and to phase in the replacement of equipment. MSHA believes that very few, if any, underground metal and nonmetal mining operations should need a special extension, based on the feasibility information discussed in part V of this preamble. Despite this information, the final rule makes specific provision for a special extension for the very few mines that might experience technical problems that cannot be foreseen at this time. In the unlikely event any mines experience such technical problems, MSHA believes that a two year extension, in addition to the five years granted in the final rule for all mines, will be sufficient for them to achieve compliance.

The final rule further requires that to establish the lowest achievable concentration, the operator must provide sampling data obtained using NIOSH Method 5040 (the method MSHA will use when determining concentrations for compliance purposes; this sampling method is further discussed in connection with § 57.5061(a)).

The application would also require the mine operator to specify the actions that are to be taken to ''maintain the lowest concentration of diesel particulate achievable'' (such as ensuring strict adherence to an established control plan) and to minimize miner exposure to dpm (*e.g.,* such as providing and requiring the use of suitable respirators at mines or areas of mines under extension). MSHA's intent is to ensure that personal protective equipment is permitted only as a last and temporary resort to bridge the gap between what can be accomplished with engineering and work practice controls and the concentration limit. It is not the Agency's intent that personal protective equipment be permitted during the extension period as a substitute for engineering and work practice controls that can be implemented immediately.

Filing, posting and approval of extension application. The final rule requires that an application for an extension be filed no later than 6 months (180 days) in advance of the date of the final concentration limit (160_{TC} μg/m³), and a copy of the extension be posted at the mine site for the duration of the extension period. In addition, a copy of the application would also have to be provided to the designated representative of the miners.

The application must be approved by MSHA before it becomes effective. While pre-approval of plans is not the norm in this sector, an exception to the final concentration limit cannot be provided without careful scrutiny. Moreover in some cases, the examination of the application may enable MSHA to point out to the operator the availability of solutions not considered to date. MSHA notes that it received no comments on this requirement for pre-approval.

While the final rule is not explicit on the point, it is MSHA's intent (as set forth in the preamble to the proposed rule, 63 FR 58184) that primary responsibility for processing of the operator's application for an extension will rest with MSHA's District Managers. This ensures familiarity with the mine conditions, and provides an opportunity to consult with miners as well. At the same time, MSHA recognizes that District Managers may not have the expertise required to keep fully abreast of the latest technologies and of solutions being used in similar mines elsewhere in the country. Accordingly, and again consistent with the preamble to the proposed rule, the Agency intends to establish, within its Technical Support Directorate a special panel to consult on these issues and to provide assistance and guidance to its District Managers. In the preamble to the proposed rule (63 FR 58184) the Agency requested comment on whether further specifics regarding this approach to approving applications for special extensions should be incorporated into the final rule, however, no such comments were received.

The rule specifies that a mine operator shall comply with the terms of any approved application for a special extension, and provides that a copy of the approved application be posted at the mine site for the duration of the application.

Personal protective equipment and administrative controls. In the proposal, mine operators were expressly forbidden to use personal protective equipment (*e.g.,* respirators) or administrative controls (*e.g.,* job rotation) to comply with either the interim or final dpm concentration limit. MSHA's rationale for these provisions was that limiting individual miner exposure through the use of respirators or job rotation would not reduce the airborne concentrations of dpm in the mine. Rather, in the proposal, MSHA chose to incorporate the widely accepted industrial hygiene concept of ''hierarchy of controls'' which places the highest priority on eliminating or minimizing hazards at the source through implementation of engineering and work practice controls.

The ''hierarchy of controls'' paradigm regards administrative controls and the use of personal protective equipment to be inherently inferior methods of controlling contaminant exposures in the workplace. Support for this position is virtually universal in the field of industrial hygiene. *Patty's Industrial Hygiene and Toxicology* (Vol I, General Principles) states, ''Evidence of the importance of engineering control of the work environment among the various alternative solutions to industrial hygiene problems is found in every current industrial hygiene text: all list the possible solutions in priority fashion as engineering controls, administrative controls, and as a last resort, use of personal protective equipment.'' The National Safety Council's *Fundamentals of Industrial Hygiene* states, ''Engineering controls should be used as the first line of defense against workplace hazards whenever feasible. Such built-in protection, inherent in the design of a process, is preferable to a method that depends on continual human implementation or intervention.''

This text goes on to describe administrative controls as, ''not as satisfactory as engineering controls,'' and notes that such controls ''have been criticized by some as a means of spreading exposures instead of reducing or eliminating the exposure.'' This latter statement is particularly relevant to dpm, and to carcinogens in general, because administrative controls, such as job rotation, result in placing more workers at risk. Among the reasons *Patty's Industrial Hygiene and Toxicology* recommends that a given chemical should not be controlled by administrative reduction of exposure time is that it may be a carcinogen.

In the proposed rule, MSHA prohibited administrative controls as an acceptable dpm control method because they fail to eliminate the exposure hazard and result in placing more miners at risk. Since MSHA determined that compliance with the interim and final dpm concentration limits was feasible for the underground metal and nonmetal mining industry as a whole using exclusively engineering and work practice controls, the Agency logically chose to prohibit personal protective equipment as a compliance option as well.

In the Preamble to the proposed rule, MSHA stated that it intended that the normal meaning be given to the terms personal protective equipment and administrative controls, and asked for comment as to whether more specificity would be useful. MSHA noted that it assumed the mining community understands, for example, that an environmentally controlled cab for a piece of equipment is an engineering control and not a piece of personal protective equipment.

Numerous commenters took issue with the proposal's prohibition on administrative controls and personal protective equipment as compliance options. They noted that both administrative controls and personal protective equipment are accepted industrial hygiene exposure control methods that should be permitted under the rule. Most commenters agreed that engineering controls would be the preferred option for reducing an occupational health exposure, but that engineering controls sufficient to reduce dpm concentrations below the applicable concentration limit might not be the most cost-effective approach, and more importantly, that engineering controls may not be feasible in all situations. They argued that prohibiting administrative controls and personal protective equipment would, as a result, place mine operators in an impossible compliance dilemma.

It is significant to note that the commenters did not disagree with MSHA's fundamental reasoning for using the ''hierarchy of controls'' concept as the basis for prohibiting administrative controls and personal protective equipment. Likewise, there was no direct disagreement with MSHA's endorsement of the widely accepted industrial hygiene principle that administrative controls are inappropriate in the case of exposure to carcinogens because job rotation will expose more miners to the hazard.

Rather, commenters argued that administrative controls and personal protective equipment should be permitted simply to give mine operators greater flexibility in dealing cost effectively with a workplace contaminant, and because certain situations exist where no feasible engineering control would be available to enable compliance with the concentration limit.

Regarding the question of affording greater operator flexibility, a typical commenter observed that, ''If MSHA's goal is protection of miners, in the context of a viable and profitable industry, it should encourage flexible control approaches to the control of dpm exposure, and not penalize operators for using all effective means available—including administrative controls and PPE.'' Another commenter asked MSHA to, ''reconsider the use of personal protective equipment as a cost effective solution when appropriate.'' MSHA responds to these comments by noting that it did incorporate compliance flexibility into the requirements for this rule. As noted earlier under the discussion on ''Meeting the concentration limit: operator choice of engineering controls,'' mine operators do have considerable freedom to choose the control, or combination of controls necessary to achieve and maintain compliance with the applicable concentration limit in their mines. However, this freedom is not total, particularly with respect to administrative controls and personal protective equipment. Operator flexibility, convenience, or cost effectiveness are not acceptable bases for permitting dpm control methods that are widely acknowledged to be inherently inferior to engineering and work practice controls.

Regarding the question of the feasibility of controls, several commenters argued that there are situations where engineering controls are either economically infeasible, technologically infeasible, or both. Some typical examples of these comments include a mining company that objected to, ''the Agency's continued downgrading of administrative controls and the use of personal protective equipment in favor of considerably more expensive, presently infeasible, engineering controls.'' Another commenter complained that, ''the standard must be attained with engineering controls alone,'' and that, ''personal protective equipment and other means cannot be used even where compliance with engineering controls is not feasible.'' Still another commenter observed that, ''The proposal is not [economically or technologically] feasible for metal mines * * * which are designed specifically for use of diesel equipment. In these

mining scenarios, use of electric equipment is not cost-effective, and elimination of diesel equipment would eliminate the process for which the mines were designed.''

The question of economic feasibility will be discussed separately from the question of technological feasibility. MSHA acknowledges that administrative controls or the use of personal protective equipment may be less costly than engineering or work practice controls in certain situations. However, a difference in cost between two approaches is simply that—a difference in cost. MSHA does not regard a cost difference per se as prima facia proof that an approach is economically infeasible simply because a less expensive alternative exists.

Commenters also questioned MSHA's compliance cost estimates, asserting that compliance costs will actually be much higher. MSHA's compliance cost estimates are discussed in the REA. However, in answer to this comment, MSHA determined that exclusive reliance on engineering and work practice controls are economically feasible for the underground metal and nonmetal mining industry as a whole (with the exception of the situations addressed in § 57.5050(d)). Thus, MSHA rejects the argument that administrative controls and the use of personal protective equipment should be permitted based on consideration for economic feasibility.

Regarding the question of the technological feasibility of engineering and work practice controls, the high number of comments addressing this issue suggested that the underground metal and nonmetal mining industry considered it to be of vital importance. Despite their number, however, none of these comments identified specific equipment or mining situations where exclusive reliance on engineering or work practice controls to achieve and maintain compliance with the applicable dpm concentration limit would be impossible due to technological infeasibility.

In the preamble to the proposed rule, MSHA provided extensive information on how mine operators might use a computer program known as the ''Estimator'' to conduct assessments of controls that might be necessary to deal with problems in individual mines, and requested comments based on such specific information. The comments that were received were critical of the ''Estimator'' because it produces an estimate of average dpm concentration in a given area, not the specific concentration that might exist at a specified sampling location; and because its accuracy depends on the quality of the input data, which is suspect due to the perceived inherent inaccuracy of the dpm sampling methods which must be used to obtain the input data.

Regarding the first criticism, MSHA notes that the average dpm concentration in a given area, which is the output obtained from the ''Estimator,'' is a more accurate indicator of the potential dpm hazard than a specific concentration that might exist at a specified sampling location. Since compliance is based on a shift weighted average concentration produced by diesel equipment that is normally in constant motion throughout the shift, the average dpm concentration in a given area is a better predictor of compliance or noncompliance than a determination of specific concentration that might exist at a specified sampling location. It might also be advisable to consider relocating a miner who, by virtue of their specific work location, is thought to be at risk of being exposed to a concentration of dpm that is greater than the average for that area (for example, move the miner from being in the direct line of the exhaust stream). Finally, MSHA notes that the ''Estimator'' is just that, a means of *estimating* dpm concentration. It was never claimed that this model could predict dpm concentrations with pinpoint accuracy. However, in verification testing of the model, MSHA has observed good agreement between predicted and measured dpm concentrations (as discussed in part II, section 3 of this preamble).

Regarding the second criticism, MSHA notes that users have the option of inputting actual dpm data, or estimating such values. If users desire to input in-mine measurements of dpm concentrations, MSHA is confident that dpm sampling and analysis using the NIOSH Method 5040, as described elsewhere in this preamble, will accurately represent actual dpm concentrations.

Nonetheless, MSHA reevaluated the feasibility of engineering and work practice controls as the exclusive means of complying with the applicable dpm concentration limits. This reevaluation identified potential compliance problems related to performing certain inspection, repair, and maintenance work if only engineering and work practice controls were permitted as means of achieving compliance. Therefore, the Agency has adjusted the final rule to allow such work, when sufficiently justified and preapproved by the Secretary, to be performed using personal protective equipment as a supplement to engineering and work practice controls. But apart from these very limited situations, the Agency has concluded that the use of engineering controls to meet the concentration limit is both economically and technologically feasible for the underground mining industry as a whole, and in light of the health risks to miners, and the superiority of engineering controls, the Agency has concluded that they (and not PPE or administrative controls) must be utilized to meet the concentration limit.

57.5061 Compliance Determinations

Summary. This section of the final rule establishes the criteria for determining compliance with the concentration limits. It has three subsections.

Subsection (a) provides for compliance sampling to be performed by MSHA directly, requires that such compliance sampling be done in accordance with the other requirements of this section, and further provides that a single such sample will be adequate to establish a violation. This is consistent with the proposed rule.

Subsection (b) provides that MSHA will collect dpm samples using a respirable dust sampler equipped with a submicrometer impactor, and analyze such samples for the amount of total carbon (TC) using NIOSH Method 5040 (or by using any method of collection and analysis subsequently determined by NIOSH to provide equal or improved accuracy for the measurement of dpm in underground metal and nonmetal mines). This is like the proposed rule except that the final rule explicitly requires a submicrometer impactor to be used in collecting all dpm compliance samples in underground metal and nonmetal mines.

Subsection (c) provides for MSHA inspectors to determine the appropriate sampling strategy for compliance determinations—personal sampling, occupational sampling, or area sampling—based on the circumstances of the particular exposure or exposures to be evaluated. This provision was not explicitly stated in the proposed rule; it was, however, stated in the preamble to the proposed rule as MSHA's intent. The final rule makes explicit MSHA's discretion in this regard.

As discussed in more detail in Part II, section 3, an important factor in the agency's decision as to which sampling practice to utilize in a particular situation, and how the sampling should be conducted (*e.g.,* how far away from a smoker or source of oil mist), is a careful review of other sources of total carbon in the environment to be

sampled which could cast doubt on whether the sample result was based solely on the amount of dpm present. MSHA will provide guidance in this regard to metal and nonmetal inspectors and the mining community—based on the information noted already in Part II, section 3 of this preamble, such new information as may be developed, and continued experience in this regard—so as to avoid wasting the limited resources of the Agency and its counsel, the Mine Safety and Health Review Commission, and the underground metal and nonmetal mining community by taking compliance samples whose validity is questionable.

Numerous comments were received on this section—addressing the validity of single samples for determining compliance with an occupational health standard; the accuracy, precision, appropriateness, and practicality of using the NIOSH Method 5040 for determining dpm concentrations for enforcement purposes; and the legitimacy of using area sampling to determine compliance with a health standard. These comments, and MSHA's response to them, are discussed below.

Single sample compliance determination. Pursuant to § 57.5061(a), a single dpm sample showing that the applicable TC concentration limit has been exceeded on any individual shift will constitute a citable violation. Such a violation will also trigger further action pursuant to § 57.5062, as discussed below in connection with that section.

As is standard practice with other health compliance measurements, MSHA intends to account for normal variability in the sampling and analytical process by allowing a margin of error in the sampling result before issuing a citation. This margin of error will be based on the accuracy of the sampling and analytical method (Method 5040) used to measure the total carbon (TC) concentration in the mine environment, after correcting for potential interferences.

The variability associated with Method 5040, as expressed by the relative standard deviation (RSD), decreases with increased load on the filter. Based on a laboratory experiment, NIOSH has determined that, at a TC concentration as low as 23 $\mu g/m^3$, the variability associated with an 8-hour sample using Method 5040 and a pump flow rate of 2.0 L/min is approximately 8.5 percent. (NIOSH Manual of Analytical Methods, Method 5040, Issue 2, 1998)

MSHA will issue a citation for exceeding the applicable concentration limit only when such a citation can be issued at a confidence level of at least 95 percent. Each measurement made for purposes of compliance determination may be adjusted, if necessary, to compensate for any expected biases due to interferences such as tobacco smoke and oil mist. To account for sampling and analytical variability associated with Method 5040, the adjusted measurement will then be compared to the appropriate level established in § 57.5060 multiplied by an ''error factor.'' The error factor will be calculated so as to achieve the required 95-percent confidence that a violation has actually occurred. Based on the standard normal distribution for measurement errors, this will be 1 + 1.645 times the variability of the sampling and analytical method, as expressed by its RSD.

For example, assuming the 8.5-percent limit on the RSD established by NIOSH under laboratory conditions, the error factor would be $1 + 1.645 \times .085 = 1.14$. Suppose MSHA takes a sample during the interim period when the limit is 400_{TC} $\mu g/m^3$. Then, if expected interferences are negligible, MSHA would cite noncompliance only if the TC measurement exceeded $1.14 \times 400 = 456$ $\mu g/m^3$.

MSHA recognizes that measurement uncertainty may be higher for samples collected under mining conditions than under laboratory conditions. Therefore, MSHA intends to base the margin of error required to achieve a 95-percent confidence level for all noncompliance determinations on samples collected under field conditions. The Agency anticipates that the sampling and analytical error factor will be somewhere between 1.1 and 1.2. The Agency will, however, be governed by the actual data obtained to establish an appropriate margin of error.

Several comments were received regarding the value of the error factor for dpm sampling using NIOSH Method 5040. One commenter asserted that it will be impossible to establish a meaningful error factor, stating, ''* * * there is insufficient information available to quantify the margin of error with any level of certainty.'' Another commenter expressed confusion with respect to the various ways in which measurement uncertainty was quantified in the proposal. This commenter argued as follows:

> MSHA states on page 58116 that the 5040 Method meets NIOSH's accuracy criteria that measurements come within 25% of the concentration at least 95% of the time. This standard is for a known particle size distribution in a laboratory setting, not a mine environment. Then on page 58184 states that, ''the variability associated with the Method 5040 to be approximately 6% (one relative standard deviation)''! These do not compare! Then it states MSHA will issue a citation if the measured value was 10% over the established level! There is a contradiction somewhere in the MSHA proposal—how can MSHA take 25% NIOSH laboratory criteria and shrink it to 6% in a mining environment?

This commenter has apparently misunderstood the NIOSH Accuracy Criterion. Any unbiased method for which the RSD is known to be less than 12.75 percent meets the criterion, because any RSD less than 12.75 percent implies (assuming no measurement bias) that measurements will come within 25 percent of the true value at least 95 percent of the time. An RSD of 6 percent meets the NIOSH accuracy criterion, simply because 6 percent is less than 12.75 percent. In order to achieve 95-percent confidence that a specific measurement demonstrates noncompliance, a 6-percent RSD would, nevertheless, have to be multiplied by a 1-tailed 95-percent confidence coefficient of 1.645, yielding the 10-percent adjustment to which the commenter was referring. Therefore, these quantities are internally consistent. As stated earlier, however, MSHA intends to base its estimate of the RSD on data appropriate for field conditions in underground mining environments.

Another commenter suggested that the NIOSH Method 5040 is prone to excessive errors because it is ''complex and requires highly skilled technicians.'' The inherent capacity of the method to produce accurate results was criticized by one commenter who stated, ''* * * it is not possible to evaluate the accuracy of the method. In fact, the method has been shown to produce massive errors when side-by-side samples and control filters are analyzed. Even blank filters produce high and widely-varying readings for TC.''

Based on MSHA's extensive experience using NIOSH Method 5040 and related sampling practices, the Agency is confident that such sampling and analysis will meet or exceed MSHA's accuracy criteria. This is discussed in detail in Part II, section 3, and later in this section under ''Using NIOSH Method 5040 for compliance determinations.''

Regarding the issue of uncertainty in the sampling and analytical process for field measurements, MSHA has not yet completed its determination of an appropriate error factor for this method. As noted above, MSHA will determine an appropriate factor and apply it when enforcing the applicable compliance

limit. As a matter of general practice, however, the Agency does not include error factors in occupational health rules, since the accuracy of measurement methods may change over time. When this determination is made, the error factor, along with its derivation, will be promptly communicated to the underground metal and nonmetal mining industry through the appropriate channels.

MSHA recognizes that in recent years courts have closely scrutinized Agency actions to ensure they are consistent with the requirements of the Administrative Procedures Act and, in MSHA's case, with the requirements of the Mine Safety and Health Act as well. Courts have held that certain actions, traditionally regarded as enforcement policies issued at an agency's discretion, require notice and comment and even the development of feasibility analyses. MSHA has carefully considered its obligations in light of these precedents and has concluded that the determination of a margin of error to be allowed before issuing a citation remains among the type of actions left to Agency discretion. To require the Agency to go through rulemaking each time such an error factor is established or updated based upon improved sampling or analytical methods would not serve the best interests of the mining community. Therefore, MSHA wishes to emphasize that the Agency does not regard the determination of an appropriate margin of error as a necessary part of this rulemaking, but rather as strictly a matter of enforcement policy. As noted explicitly in the rule, the Agency is retaining discretion to switch to better techniques should NIOSH certify that they provide ''equal or improved accuracy for the measurement of diesel particulate matter in'' underground metal and nonmetal mines. (§ 57.5061(b))

Notwithstanding its decision not to be explicit in this standard about the error factor to be used, MSHA recognizes the strong interest the underground metal and nonmetal mining community has in this issue and will ensure the matter is fully discussed with that community before the concentration limits are scheduled to go into effect. In working with this community on diesel particulate matter controls (see the history of this rulemaking in Part II of this preamble), the Agency has repeatedly demonstrated its commitment to good communications in this regard—*e.g.,* the workshops, the advance and final circulation of the diesel toolbox, the use of the Agency's web site and direct notification in appropriate cases.

As explained elsewhere in this preamble, MSHA has determined that it is feasible for underground M/NM mines to maintain dpm concentrations at or below the limits specified in § 57.5060 on each and every shift, everywhere that miners normally work or travel, with the exception of the circumstances defined in § 57.5060(d). Therefore, MSHA will protect miners' health to the maximum extent feasible by citing a violation whenever a single sample demonstrates that the limit has been exceeded on a full shift at any appropriate sampling location. This single-sample enforcement strategy is consistent with all other occupational health enforcement practices in the metal and nonmetal sector. As per long-standing policy in this sector, single out-of-compliance samples for dust (*e.g.,* silica-bearing respirable dust, total nuisance particulate, etc.), gas (*e.g.,* CO, NO_2, solvent vapors, etc.), mist (*e.g.,* cutting oil mist, spray paint, etc.), fume (*e.g.,* welding fumes, fumes from melting furnaces, etc.), and noise are all considered citable violations of the respective standards. Nevertheless, the Agency decided it would be best, in this rulemaking, to avoid any possible ambiguity in this regard by explicitly stating in the rule itself that a single sample by the Agency would provide the basis for a citation. MSHA highlighted this matter in the preamble of its proposed rule (63 FR 58117, part of Question and Answer 12).

Some commenters suggested that MSHA should collect numerous samples and base noncompliance determinations on the average value of all samples collected. These commenters argued that a single sample is not a statistically valid representation of the subject's ''typical'' or ''normal'' exposure to the contaminant. The commenters noted that a single sample, if taken on a randomly selected work day, could result in an unusually high measurement (unusual with respect to a ''typical'' or ''normal'' day). Therefore, a single sample could give rise to a noncompliance determination, even if the environment being sampled is in compliance on most shifts. These commenters contended that such a sample was ''unrepresentative'' of typical exposure concentrations and should not, therefore, be used as a basis for a noncompliance determination.

MSHA recognizes that the day-to-day exposure of a miner will not be constant and that on some days the sample collected over a single shift may be lower than the miner's long term average and on other days higher. However, MSHA has several compelling reasons for considering noncompliance on any individual shift to be a citable violation of the dpm concentration limit.

First, MSHA has identified significant risks associated with short-term dpm exposures (i.e., exposures over a 24-hour period). As documented in Part III of this preamble, adverse health effects associated with short-term exposures include (1) acute sensory irritations and respiratory symptoms (including allergenic responses) and (2) premature death from cardiovascular, cardiopulmonary, or respiratory causes. These risks alone would fully justify enforcing the concentration limits established in § 57.5060 on each and every shift.

Second, the concentration limits that MSHA has established are not expected to fully protect miners from these risks or from the excess risk of lung cancer associated with chronic dpm exposure. Instead, they are based on what can be feasibly achieved at this time to control dpm. By requiring compliance with the concentration limit on each shift measurement, it is MSHA's intent to protect miners to the maximum extent feasible.

Third, it is not MSHA's objective, when sampling for compliance determination purposes, to estimate average dpm concentrations for any period greater than the shift sampled or for any mine location other than the location sampled. Some commenters confused the objective of estimating cumulative exposures for purposes of risk assessment with the objective of limiting cumulative exposures for purposes of risk management. MSHA's objective is to limit exposures to protect miners against both short- and long-term effects. It is not practical for MSHA to track miners' cumulative exposures over an occupational lifetime. Therefore, as a practical matter of enforcement policy, MSHA can best protect miners from both the health risks associated with acute exposures and from the excess lung cancer risk due to chronic dpm exposure by limiting exposure on each shift wherever miners normally work or travel.

In addition, MSHA wants to emphasize that compliance limits in the metal and nonmetal sector, whether personal exposure limits or concentration limits, apply to every individual work shift. Every full-shift exposure, not just the typical, or ''average'' exposure, must be in compliance with the limit. Basing compliance on the typical, or ''average'' shift would permit frequent or sustained exposures to the contaminant at concentrations significantly higher than the compliance limit.

Although MSHA's dpm compliance limit was not derived from any corresponding ACGIH TLV©, the explanation of the proper interpretation and application of TLV©'s provided in the 1999 TLV©'s and BEI©'s booklet (American Conference of Governmental Industrial Hygienists, 1999), is relevant to this discussion. Compliance limits are specifically intended to be applied over a conventional eight-hour work day and forty-hour workweek, and not to the average exposure received during a series of consecutive work shifts or workweek. Although an allowance is made in some instances for calculating exposures on the basis of a workweek average concentration, MSHA believes such an exception should not apply to dpm because of (1) the seriousness of associated health risks (such as lung cancer and premature death from cardiovascular, cardiopulmonary, or respiratory causes) and (2) the significant risk of adverse health effects associated with short-term exposures).

The only circumstance in which a single, out-of-compliance sample would not be used as the basis for a non-compliance determination is if the sample itself were considered invalid; for example, an inspector following an improper sampling procedure. MSHA is of course concerned primarily with the health and safety of miners so the magnitude of any citation for a single out-of compliance sample will take into account the actual risk posed to miners.

MSHA's policy on health inspections requires inspectors to rigorously follow established sampling procedures to ensure the validity of samples collected. As a practical matter, MSHA will not sample for diesel particulate at the tailpipe of any diesel powered equipment in metal and nonmetal underground mines. As discussed below, MSHA's sampling strategy for determining operator compliance is established in paragraph (c) of Section 57.5062. That section specifically states that MSHA will conduct personal sampling, occupational sampling, and/or area sampling, depending upon the circumstances of the particular exposure. Because MSHA has an environmental exposure limit, MSHA is interested in obtaining the level of diesel particulate in the environment where miners normally work or travel. In the alternative, MSHA may conduct personal sampling where circumstances necessitate it. For example, if a mine operator has a miner working inside a cab and there are no other workers in that area working outside the cab, MSHA will conduct personal sampling of the cab operator and not conduct environmental sampling outside the cab in the same area of the mine. Moreover, MSHA's sampling would be conducted inside the cab rather than outside the cab. On the other hand, if there are miners working outside the enclosed cab, MSHA will sample the environment to determine the level of exposure to dpm for these miners. Also, if an operator has a miner who is operating a shuttle car, and that miner is replaced by another miner during that shift, MSHA intends to place the sampler on the shuttle car in the vicinity of the miner and not at the tailpipe. However, in no case will area sampling be performed closer than five feet to a piece of operating diesel equipment, and no tailpipe sampling will be performed to determine compliance with any concentration limit.

Among other precautions, sampling equipment is maintained and operated in strict accordance with manufacturer recommendations, and pumps are calibrated before and after samples are collected. Sampling media are blank-corrected, and all laboratory handling and analytic procedures are in accordance with AIHA laboratory certification. Sample integrity is ensured through chain-of-custody seals. If any breach in procedure occurs, all affected samples are invalidated.

In order to assure compliance with the limit, mine operators need to implement controls sufficient to ensure that the entire range of concentration values is always safely below the compliance limit. The purpose of both MSHA sampling and mine operator monitoring is to verify, on an on-going basis, that this limit is always met on every shift.

When mine operators implement effective engineering controls, the range of the concentration values becomes narrower so that once control of dpm is demonstrated, it is unlikely that the concentration limit will be exceeded.

MSHA believes the same justification for determining noncompliance based on a single sample applies to dpm as to other contaminants and noise. Therefore, MSHA has retained the provision permitting a noncompliance determination to be based on a single sample.

Using NIOSH Method 5040 for compliance determinations. Pursuant to paragraph (b) of section 5061 of the final rule, MSHA will collect dpm samples for compliance using a respirable dust sampler equipped with a submicrometer impactor, and analyze such samples for the amount of total carbon using NIOSH Method 5040 (or by using any method of collection and analysis subsequently determined by NIOSH to provide equal or improved accuracy) for the measurement of dpm in underground metal and nonmetal mines. As noted above, this is like the proposed rule except that the final rule explicitly requires that a submicrometer impactor be used in collecting all dpm compliance samples in underground metal and nonmetal mines.

Section 3 of part II of this preamble discusses alternative methods for measuring dpm concentrations, and reviews the many comments MSHA received on this topic. As noted in that discussion, methods other than NIOSH Method 5040 do not at this time provide the accuracy required to support compliance determinations at the concentration levels required to be achieved under this rule. Moreover, after a careful review of the comments and hearing record, the available technical information submitted in response to MSHA's proposed rule, and the results of studies performed by agency experts to ascertain the veracity of those comments and submissions, MSHA has determined that NIOSH method 5040 provides an accurate method of determining the total carbon content of a sample collected in any underground metal or nonmetal mine when a submicron impactor is used with the otherwise prescribed sampling procedure, and when sampling strategies avoid sampling under circumstances that could compromise the integrity of the analytical process. Accordingly, MSHA will use this method for determining TC concentrations for compliance purposes, and the rule has been specifically amended to require that such samples be taken with a submicron impactor.

As indicated in the discussion of the proposed rule (p. 58129), utilizing the submicron impactor—a device that limits particles entering the sampler to those less than 0.9 micron in size when operated at a flow rate of 1.7 LPM—does cause a reduction in the amount of dpm that can enter the sampler, since some dpm is larger than 0.9 microns. Thus, in making this amendment, MSHA recognizes that underground metal and nonmetal miners will be exposed to more dpm than will be ascertained by these compliance measurements. However, for the reasons noted in section 3 of Part II, MSHA has determined that requiring use of the impactor is the only way to ensure that certain potential interferences (sources of total carbon other than dpm) are avoided at this time. Thus, to ensure the integrity of the sampling method, the agency has determined that it must use such an impactor.

One commenter suggested that, in addition to basing concentration limit compliance determinations on samples collected pursuant to § 57.5061, samples collected and analyzed in accordance with § 7.89 should also be used as a basis for compliance determinations. Section 57.5061 is the compliance determination for the ambient concentrations in the mine. Based on the ventilation being supplied, the number of engines being used, the condition of the engines, the duty cycle of the machines, the sample will show if the mine is in compliance with the dpm standard. Section 7.89 is the laboratory test for the diesel in engine in the lab to measure the raw dpm from the engine. The § 7.89 test data is used to calculate the particulate index for a single engine. Section 7.89 data can give the mine operator an idea of the dpm being emitted from the single engine and can use this data in the ''Estimator'' to calculate an estimated dpm ambient concentration. However, as explained elsewhere in the preamble, this is an estimate to set up proper ventilation when adding other pieces of equipment or deciding on which engine to buy. The section 7.89 dpm concentration does not take into account the duty cycle of the engine. Section 7.89 tests all engines on a specific test cycle. Section 7.89 test data can only be used to estimate dpm, cannot be used to know exactly what the concentration is in a mine at any given time. The test in 57.5061 is used for that determination. MSHA believes this procedure is inappropriate for determining compliance with the concentration limits and provision for doing so has not been included in the final rule.

Sampling strategy—personal, occupational, and area sampling. Subsection (c) of section 5061 provides for MSHA inspectors to determine the appropriate sampling strategy for compliance determinations: personal sampling (attaching a sampler to an individual miner within the miner's breathing zone), area sampling (sampling at a fixed location where miners normally work or travel), or occupational sampling (locating the sampler on a piece of equipment where a miner may work).

Personal sampling is well understood in the metal and nonmetal sector because it is commonly used by MSHA to determine compliance with TLV©'s for silica-bearing respirable dust, welding fumes, and other airborne contaminants. Area sampling is less well known in this sector, but it is used by MSHA for compliance determinations in some situations, such as where miners are exposed to a contaminant having a ceiling limit. Occupational sampling is not well known in the metal and nonmetal sector because it is not currently used by MSHA for compliance determinations in this sector. However, MSHA does employ occupational sampling in the coal sector for compliance determinations.

Occupational sampling is a method which measures the exposure of an occupation to a given contaminant, as opposed to personal sampling, which measures the exposure of an individual, or area sampling, which measures the contaminant concentration at a fixed location throughout the working shift. All three methods determine contaminant concentration on a shift weighted average basis (see previous discussion of ''Concentration limit expressed as an average eight hour equivalent full shift airborne concentration'' under § 57.5060). In occupational sampling, a full-shift sample is collected from the working environment of the occupation. The sampling apparatus (sample pump, size selection devices, sample filter, etc.) remains in the environment of the work position being sampled rather than with the individual miner, even when miners change positions or alternate duties during the shift.

A very common example of where occupational sampling would be the appropriate sampling method is where the sampling objective is to determine the full shift exposure of the operator of a particular piece of equipment, but where two or more individuals alternate operating the equipment. Personal sampling would capture both the exposure received while the equipment is being operated, as well as the exposure received while performing other duties. Area sampling would be limited to measuring the contaminant concentration in the general area where the equipment is operated, but would not capture the operator's exposure. In this example, occupational sampling, with the sample apparatus remaining in the cab or operator's compartment of the equipment throughout the shift, would be the only sampling method that could satisfy the sampling objective.

As noted above, the provision for utilizing either personal sampling, area sampling, or occupational sampling was not explicitly stated in the proposed rule. It was, however, clearly stated in the preamble to the proposed rule as MSHA's intent; indeed, a specific Question and Answer was devoted to the topic. (63 FR 58117, Question and Answer 14; the topic is further explored at 63 FR 58185). Moreover, in explaining its adoption of a ''concentration limit'', MSHA noted that its intention was to emulate the approach taken with coal mine dust, where inspectors have similar discretion (63 FR 58184) in the preamble to the proposal). Accordingly, the mining community was fully informed in this regard. The topic was the subject of considerable discussion at the hearings and received considerable comment.

After evaluating the comments, and reviewing the verification data on possible interferences discussed in Part II of this preamble, MSHA determined that its proposed position in this regard should be explicitly incorporated into the final rule. At the same time, as a result of the comments, the Agency has refined its thinking as to when various types of sampling would be appropriate. The Agency will provide further information in this regard in its compliance guide, but is using this opportunity to inform the underground metal and nonmetal mining community of its current views on how it will initially approach this matter.

Numerous commenters expressed concern about the proposed rule's provision for using either personal sampling or area sampling for determining compliance with the concentration limit for dpm. They pointed out that area sampling was a departure from previous enforcement practice in metal and nonmetal mines. They also questioned whether it was appropriate to use area sampling to determine compliance when there may be no one exposed (or very limited miner exposure) to dpm at the time and in the location where the area sample is taken, as well as in situations where miners work in enclosed cabs with filtered breathing air, and in other areas where engineering controls are not feasible. One commenter also argued that sampling at a fixed location (area sampling) and then equating the results with a personal exposure was invalid.

Commenters also asserted that the superiority of personal sampling for quantifying worker exposures is a commonly accepted industrial hygiene principle. Some commenters noted that in underground mines which use mobile diesel equipment, the positions of diesel-powered vehicles with respect to intake and return air streams vary from hour to hour. Therefore, they asserted, it is virtually impossible to obtain meaningful information from stationary instruments. One commenter stated that area sampling was appropriate as a screening tool to determine whether personal sampling would be warranted, or to evaluate the effectiveness of controls, but that it

should not be used to determine compliance with a mandatory limit.

In responding to these comments, MSHA would like to emphasize to the metal and nonmetal mining community, as it did in the preamble to the proposed rule, that while the concept of a concentration limit is new for this sector, it is a well established concept in the mining industry, and has been implemented for many years with respect to coal dust. Questions about whether a particular sampling method are appropriate in a given situation have been raised and resolved many times.

Moreover, the courts have upheld MSHA's use of area sampling for enforcing compliance. In a 1982 decision (*American Mining Congress* v. *Secretary of Labor,* Nos. 80–1581 and 80–2166), the U.S. Court of Appeals, Tenth Circuit ruled that the decision to employ area sampling for respirable dust compliance determinations was a reasonable exercise of MSHA's discretion and authority. The court stated:

''Nothing in the record supports the conclusion that either type of sampling provides a perfect measure of exposure to respirable dust. Since there is no perfect sampling method, the Secretary has discretion to adopt any sampling method that approximates exposure with reasonable accuracy. The Secretary is not required to impose an arguably superior sampling method as long as the one he imposes is reasonably calculated to prevent excessive exposure to respirable dust. On this record, the difference between area and personal sampling is not shown to be so great as to make Secretary's choice of an area sampling program irrational. Keeping in mind that our task is not to determine which method is better, we hold that the Secretary's choice of area sampling over personal sampling is not legally arbitrary and capricious.''

''We are not unmindful that area sampling may effectively require lower dust levels than might be required under a personal sampling program.''

''The fact that in theory the regulation may require operators to maintain a dust level below [the limit] in its person-by-person impact does not render the regulation arbitrary and capricious. We repeat that all proposed sampling methods are less than perfect and are designed to provide only estimates of actual exposure. Since measurement error is inherent in all sampling, the very fact that Congress authorized a sampling program indicates that it intended some error to be tolerated in enforcement of the dust standard. The method selected by the Secretary, while perhaps more burdensome in its impact on mine operators than other methods, is not beyond the scope of his discretion.''

In addition to affirming MSHA's discretion to employ area sampling on the basis that it can be ''reasonably calculated to prevent excessive exposure,'' the court also observed that area sampling can be considered superior to personal sampling for enforcement purposes:

''The area sampling program has several advantages over a personal sampling program. The most important advantage is that area sampling not only measures the concentration of respirable dust, it allows identification and thus control of dust generation sources. Control of dust at the source will obviously contribute to reducing the level of personal exposure. By contrast, the results of personal samples do not allow identification of dust sources due to the movement of miners through various areas of the mine during the course of a working shift. Thus, while a personal sampling system makes possible the identification of discrete individuals who have been overexposed, it does nothing to ensure reduction of dust generation because the source of the dust cannot be determined. Therefore, it clearly appears that area sampling can rationally be found to be superior to personal sampling as a means of enforcing (as opposed to merely measuring) compliance with [the standard].''

Although this decision relates specifically to respirable dust, it is clear that the Court of Appeals did not find that area sampling is inherently unreliable. Moreover, the logic expressed by the Court in describing the application of area sampling to respirable coal mine dust applies equally to dpm. Both are solid particulates that are produced from discrete sources during mining and are transported via the mine's ventilation system and inhaled by miners.

Accordingly, the fact that some in the metal and nonmetal sector, or some not engaged in mining at all, may not be familiar with this approach does not make it invalid or inappropriate.

Implementation by MSHA of its discretion. For the reasons noted above, MSHA has determined that personal sampling, occupational sampling, and area sampling are all viable sampling methods, and that inspectors should have the discretion to utilize whichever sampling strategy is appropriate in a given situation to determine compliance with the concentration limit for dpm. Accordingly, all three approaches are permitted in the final rule.

The Agency will provide further information about how these approaches should be used for dpm sampling in its compliance guide; however, it is using this opportunity to inform the underground metal and nonmetal mining community of its current views on some common situations.

For example, one commenter noted that an area sample could be taken adjacent to where a piece of diesel equipment was accelerating at low RPM, which is the time that an engine is working at its lowest efficiency. This commenter expressed concern that such a sample could indicate that the applicable dpm concentration was exceeded, even though the duty cycle as a whole for that equipment might be in compliance. MSHA believes this situation shouldn't result in a violation, because such an area sample would be taken for an entire shift, not just for the short time period when the piece of diesel equipment passes by the sampler.

Moreover, MSHA recognizes that it would not provide an accurate measure of the concentration of dpm to place a sampler in the area immediately around a machine's tailpipe when no workers would be in that location for any great length of time. An area sample would not be taken in that manner. But if a worker were assigned to work in a location on or immediately adjacent to diesel equipment, a personal or occupational sample might well be appropriate to determine if the limit is being exceeded for that worker or for such occupation.

Similarly, the agency would not consider it appropriate to conduct area sampling for compliance determinations in areas where dpm exposures, if any, would be infrequent and brief; in areas where miners work exclusively inside enclosed cabs; and in shafts, inclines, slopes, adits, tunnels and similar workings that are designated as return or exhaust air courses and that are also used for access into, or egress from an underground mine.

Examples of the first situation would be work areas that are visited infrequently and briefly, such as a remote pump that needs to be checked weekly, or a remote area where roof conditions need to be inspected at periodic intervals. These areas would clearly be subject to the concentration limit because miners ''normally work or travel'' there. Area sampling in such areas would be inconsistent with the regulation's intent to, '' * * * limit the concentration of [dpm] to which miners are exposed * * *,'' because exposure would occur for only a few minutes per week, or possibly less.

Examples of the second situation would be production areas or haulageways where the only miners present work inside of enclosed and isolated cabs with appropriate filtration of breathing air, and underground crushing stations where crusher operator booths or similar fixed structures are provided with appropriately filtered breathing air. Area sampling outside such cabs or structures, which would have been permitted under the proposed rule,

would be inconsistent with the regulation's intent to, '' * * *limit the concentration of [dpm] to which miners are exposed * * *,'' because miners in these areas are not exposed; they are already protected by an accepted engineering control. This approach is consistent with MSHA's intent as stated in the preamble to the proposed rule (63 FR 58184). It also reflects MSHA's awareness that enclosed cabs may provide many other important health and safety benefits, such as reducing noise exposure and reducing exposure to silica bearing respirable dust.

However, as a result of the comments concerning whether NIOSH method 5040 can effectively be used to determine compliance when miners are smoking, the agency recognizes that it faces a particular difficulty in sampling miners when they smoke inside an enclosed cab or booth, whether such sampling is area, occupational, or personal. As noted in Part II, section 3, MSHA has verified that sampling using NIOSH method 5040 immediately adjacent to smokers can undermine the validity of the sample result—since some of the total carbon detected may be from the smoke). While MSHA can generally avoid this problem by not sampling immediately near smokers, as discussed in that section of this preamble, it does face a problem when the area to be sampled is an enclosed cab or booth: it can neither sample inside nor outside an enclosed cab or booth if the subject miner smokes. The Agency intends to address this problem by obtaining the concurrence of the miner not to smoke while sampling the environment of the cab.

MSHA is troubled that, under certain circumstances, it will need to rely on miners voluntarily refraining from smoking in order to perform compliance sampling for dpm. Since miners are usually free to choose to smoke if they wish, this need to rely on the voluntarily cooperation of miners could seriously limit the agency's ability to sample when and where it desires. Though MSHA has determined that sampling of nonsmokers would usually be unaffected by the presence of smokers elsewhere in the mine, there will be situations where sampling of a specifically targeted area, occupation, or person would be prevented due to the presence of a smoker at that immediate location. Therefore, MSHA intends to continue to search for a means to reliably measure dpm concentrations despite the presence of cigarette, cigar, and pipe smoke in close proximity to the sampling equipment.

As noted in Part II, section 3, MSHA has determined that samples analyzed only for elemental carbon are unaffected by the presence of cigarette smoke. At this time, however, MSHA cannot limit its analysis to elemental carbon, because no consistent quantitative relationship has been established between elemental carbon concentration and the concentration of whole dpm.

MSHA intends to implement any newly developed sampling procedure and/or analytical method that is capable of directly or indirectly measuring the concentration of whole dpm in the presence of cigarette, cigar, and pipe smoke, provided such procedure and/or method is determined by NIOSH to provide equal or improved accuracy compared to the NIOSH Method 5040. If MSHA decides that such a change in sampling procedure and/or analytic method should be adopted, the agency will utilize standard communication channels to provide specific notification of its intention in this regard to the underground metal and nonmetal mining industry. However, MSHA wishes to be clear that, in accordance with § 57.5061(b), implementing such a change does not require new rulemaking.

Examples of the third situation include return or exhaust air courses that are shafts, inclines, slopes, adits, tunnels, etc. which terminate on the surface, but which are also used for mine access or egress by mine personnel.

Since the purpose of a return or exhaust air course is to collect and remove contaminated air from the mine, one would expect such an air course could contain high dpm levels. However, being a major travelway, one would naturally consider them to be areas ''where miners normally work or travel.'' As miners travel into the mine at the beginning of the shift and out of the mine at the end of the shift through these mine openings, relatively brief exposures to potentially high dpm levels could be expected. Full shift area sampling in such a location would likely indicate dpm levels in excess of the concentration limit. Should area sampling in such an air course result in a determination of noncompliance (which would be highly likely), the mine operator would be required to implement a change of some kind to bring the area into compliance, such as requiring that miners use a different access to the mine that is an intake or neutral air course, or that the ventilation system would need to be changed so that the access in question is no longer a return or exhaust air course. Since neither of these options may be feasible, the operator would be placed in an impossible compliance situation.

In such situations, MSHA believes that it would not be appropriate to use area sampling; rather, personal sampling would be more appropriate. Personal sampling would capture the exposure as miners travel into the mine at the beginning of the shift and depart at the end of the shift. Since the exposure time is brief, overexposure on a full-shift basis would be unlikely (assuming dpm levels in the working places are in compliance). Also, since exposure time is brief, the health risk associated with the exposure would be minimal.

It should be noted, however, that miners whose jobs require them to spend significant periods of time in these areas would continue to be at risk of overexposure if the dpm levels are high. For example, a haulage truck driver that spends much of the shift driving in and out of the mine through exhaust air hauling material to a surface dump point or crusher may need to be protected with an enclosed cab that is provided with filtered breathing air. Personal sampling on miners who engage in such activities would reveal the problem.

Another situation requiring clarification as to MSHA's intended compliance sampling procedures concerns miners who perform multiple work tasks during a shift. If a miner's work on a given shift includes a task or tasks for which the sampling procedures would not provide an accurate measurement of the dpm, MSHA would not use that measurement for the basis of a compliance determination. An example would be a miner who begins the shift operating a diesel-powered loader, and who finishes the shift operating a jack leg drill equipped with an in-line oil bowl. While operating the loader, MSHA would consider a personal or occupational sampling procedure to be acceptable for obtaining an accurate measurement for compliance purposes. However, as noted in Section II, MSHA would not consider personal or occupational sampling to be acceptable for sampling a miner who is operating a jack leg drill equipped with an in-line oil bowl, because there is the potential that oil mist emitted from the drill may be collected on the sample filter causing an inaccurate measurement of dpm to be made.

In this case, full shift area sampling would be performed at a location where the oil mist would not interfere with the measurement of dpm. If the drilling operation takes place in a different location from the loading operation (a different stope, for example), MSHA would consider full shift area sampling in both locations, if appropriate.

However, if no source of dpm is present at the drilling location, the inspector would probably choose to sample only the location where the loader is operating.

The agency considered whether it would be appropriate to deal with these situations through an amendment of the rule, and decided this would not be appropriate. The specific facts in a specific situation should determine the appropriateness of the sampling approach; trying to lock down this situation or that in the rule would prove very complex and restrict the flexibility to react to developments in the industry. The rule reserves to MSHA the flexibility to adjust the use of sampling approaches for any situation where use of one or another method might not be appropriate.

At the same time, the Agency wishes to make it clear that in putting explicitly into the rule that the Agency can use any of the three methods specified, it intends by that action to ensure that any policy that would broadly restrict the use of one or another of these methods would have to be the subject of new rulemaking. Thus, for example, any policy to significantly restrict the use of area sampling to enforce compliance with this rule would have to be the subject of new rulemaking action, as the availability of that method was a key consideration in MSHA's decision that it could implement a concentration limit.

Section 57.5062 Diesel Particulate Matter Control Plan

Under the final rule, a determination of noncompliance with either the interim or final concentration limit prescribed by § 57.5060 would trigger two requirements: first, the operator must establish a diesel particulate matter control plan (dpm control plan) meeting certain basic requirements—or modify the plan if one is already in effect; and second, the operator must demonstrate that the new or modified plan will be effective in controlling the concentration of dpm to the applicable concentration limit. The final rule also sets forth a number of other specific details about such plans, and states that failure of an operator to comply with the provisions of a plan or to conduct required verification sampling will be a violation of Part 57 without regard for the concentration of dpm that may be present. In all respects, this section of the final rule is essentially the same as in the proposed rule.

Only a few comments were directed specifically at § 57.5062. Some of those were supportive of the concept, such as the remark by one mine operator that, ''Generally, the Diesel Particulate Matter Control Plan (DPMCP) contained in § 57.5062 is well conceived.'' One commenter noted that once a plan is in place, failure to abide by its provisions is a citable violation, even if dpm levels are below the applicable concentration limit. Another commenter recommended that rather than a single out-of-compliance sample triggering the requirement to implement a plan, the provisions of § 57.5062 should not be triggered unless there is a significant history of non-compliance with the limit. Another commenter questioned why a determination of non-compliance requires MSHA to obtain only one non-compliant sample, whereas proof of operator compliance (both with respect to § 57.5062 and § 57.5071) requires multiple operator samples. A commenter also observed that a single sample is not ''statistically significant or representative and cannot determine if the mine is out of compliance.'' The same commenter argued that the requirements for documenting dpm control plan effectiveness were unnecessary, burdensome, and duplicated other MSHA requirements.

Triggering plan. Under the final rule, a single out-of-compliance dpm sample constitutes a citable violation of the applicable concentration limit and triggers the requirement to implement a diesel particulate matter control plan. As noted above, one commenter recommended that a diesel particulate matter control plan should not be required unless a mine has a significant history of non-compliance with the applicable dpm concentration limit. MSHA disagrees with the commenter's position because MSHA does consider a single sample to be a valid means of determining compliance (see discussion under § 57.5060 on single sample), and because a ''significant history of non-compliance'' at a given mine, would almost certainly be accompanied by significant, prolonged, and repeated exposure of miners to dpm levels in excess of the applicable concentration limit. Such exposures cannot be tolerated. When sampling indicates non-compliance, remedial action consisting of the implementation of a dpm control plan, or modification of an existing plan, must be initiated without delay. This will insure a timely reduction in dpm levels, and will help prevent dpm levels from rising above the applicable concentration limit in the future.

No advance approval of plans required. § 57.5062 will maintain the Agency's metal and nonmetal mine plan tradition by not invoking a formal plan approval process. That is, the plan would not require advance approval of the MSHA District Manager. As noted in the discussion of § 57.5060(c) and (d), MSHA is requiring advance approval for an operator to obtain a special extension of up to 2 years to meet the final concentration limit, and/or to allow miners performing inspection, maintenance or repair work to conduct such activities in areas that exceed the concentration limit. But a plan required because the limit has been exceeded need not obtain such advance approval.

In the preamble to the proposal for this Part, MSHA requested comment from the mining industry as to whether dpm control plans should require pre-approval by the Agency (p. 58119). The only comment received was in support of the Agency's proposal that such plans not require pre-approval.

A dpm control plan would, however, have to meet certain requirements set forth in the final rule, and as noted in the preamble to the proposed rule, it would be a violation of § 57.5062 if MSHA determines that the operator has failed to adequately address each of the plan's required elements.

Moreover, as discussed subsequently in connection with paragraph (f) of this section, once in place, a dpm control plan becomes law for that mine, and an operator must comply with it.

Elements of plan. Under § 57.5062(b), a dpm control plan must describe the controls the operator will utilize to maintain the concentration of diesel particulate matter to the applicable limit specified by § 57.5060. The plan must also include a list of diesel-powered units maintained by the mine operator, together with information about any unit's emission control device and the parameters of any other methods used to control the concentration of diesel particulate matter.

Relationship to ventilation plan. At the discretion of the operator, the dpm control plan may be consolidated with the ventilation plan required by § 57.8520.

Demonstration of plan effectiveness. The final rule would require monitoring to verify that the dpm control plans are actually effective in reducing dpm concentrations in the mine to the applicable concentration limit. Because the dpm control plan was initiated as a result of a compliance action, the final rule would require the use of the same measurement method used by MSHA in compliance determinations—total carbon using NIOSH method 5040—to conduct verification sampling. As a result, mine operators who are required to establish a dpm control plan would need to acquire the necessary sampling equipment to conduct the verification sampling, or arrange for such sampling

to be conducted for them. As noted in Part II, the necessary sampling equipment is commercially available.

MSHA recognizes concerns about the commercial availability of the sampling equipment for NIOSH Method 5040. It is important that operators know whether they are in compliance with the standard. MSHA understands that the equipment will be available before this standard is in effect. MSHA will not use any equipment for sampling for compliance with this standard that is not commercially available. If the equipment is not commercially available by the effective date of the standard it is MSHA's intention not to enforce the dpm levels in the standard until the sampling equipment is available.

Effectiveness must be demonstrated by ''sufficient'' monitoring to confirm that the plan or amended plan will control the concentration of diesel particulate to the applicable limit under conditions that can be ''reasonably anticipated'' in the mine.

The final rule, like the proposed rule, does not specify that any defined number of samples must be taken—the intent is that the sampling provide a fair picture of whether the plan or amended plan is working. Instead, as indicated in the preamble to the proposed rule, MSHA will determine compliance with this obligation based on a review of the situation involved. While an MSHA compliance sample may be an indicator that the operator has not fulfilled the obligation under this section to undertake monitoring ''sufficient'' to verify plan effectiveness, it would not be conclusive on that point.

One commenter questioned the fairness of holding operators responsible for verifying plan effectiveness, the need for documentation to verify that plans will control dpm to the applicable limit, and for the requirement that such documentation must be provided upon request by MSHA. This commenter suggested that mine operators are already required to show compliance with air quality standards under § 57.5002, and that further documentation relating to the diesel particulate matter control plan therefore duplicates existing requirements.

While it is true that § 57.5002 requires mine operators to conduct ''dust, gas, mist, and fume surveys'' as frequently as necessary to determine the adequacy of control measures, this regulation does not specifically address diesel particulate matter, nor does it specify that dpm concentrations must be determined using the NIOSH Method 5040 (as is required in § 57.5062(c)). Thus, compliance with § 57.5002 will not insure compliance with the intent of § 57.5062. Section 57.5062(c) also requires that mine operators demonstrate that dpm concentrations will be controlled to applicable limits, not only under current conditions (*i.e.*, that a compliant sample be obtained), but also under reasonably anticipated conditions in the future.

MSHA disagrees with the commenter's suggestion that ''rigorous enforcement of existing TLV©'s and air quality rules, and * * * utilization of recommendations in the 'Diesel Toolbox''' will result in ''adequate safety levels.'' The 1973 Threshold Limit Values© or TLV©'s (the TLV©'s incorporated by reference in § 57.5001, and therefore currently enforceable in underground metal and nonmetal mines) do not include a limit of any kind for dpm. It is interesting to note that, as indicated in Table II–2 of Part II, section 5, the TLV©'s enforced by MSHA are derived from recommendations of the American Conference of Governmental Industrial Hygienists (ACGIH). That organization has recently proposed a limit for dpm (ACGIH Notice of Intended Changes for 1999) of $50_{DPM}\mu g/m^3$, well below what is being established by this rule. As noted in Part V of this preamble, MSHA has concluded that $50_{DPM}\mu g/m^3$ is an unreasonably low limit for dpm concentration in underground metal and nonmetal mines because MSHA's technological and economic feasibility assessment indicate that this level cannot be achieved using feasible control measures.

If a diesel particulate matter control plan is in effect, the final rule specifies that monitoring must be ''sufficient to verify that the plan will control the concentration of diesel particulate matter to the applicable limit under conditions that can be reasonably anticipated in the mine.'' Again, as conditions and circumstances in the mine change, the mine operator must demonstrate, on a continuing basis, through sampling results using NIOSH Method 5040, that compliance with the applicable concentration limit is consistently achieved.

MSHA believes that dpm control requires a holistic approach. A piecemeal solution to a dpm problem may result in shifting an overexposure from one area to another, but not eliminating the problem entirely. If an overexposure in one part of the mine is addressed by re-routing more ventilation air to that area, it means another part of the mine will have to give up some air, possibly causing an overexposure there. If an overexposure in one part of the mine is addressed by exchanging a dirty machine for a clean machine, it means the dirty machine is still polluting somewhere else. In these examples, the actions taken may simply move an overexposure to a different location, or they may result in overall compliance. The only way of knowing for sure whether the problem has actually been solved, is to consider the effects of a given action on the mine as a whole. That is what the regulation requires. MSHA does expect operators will focus their control plans on the areas of the mine in which dpm presents a hazard to miners.

The reason that MSHA can determine non-compliance based on a single sample whereas mine operators need multiple samples to demonstrate compliance is due to the fundamental difference between proving non-compliance versus proving compliance. For example, proving that at least one non-compliance condition exists somewhere in a mine requires only one non-compliant sample result. Proving conditions are fully compliant everywhere in a mine all the time requires more than one compliant sample result. The actual number of compliant samples necessary to prove that every location in the mine is fully compliant all the time would have to be determined, but it would rarely, if ever, be only one.

The differences between determining non-compliance versus determining compliance are incorporated into standard industrial hygiene practice. For example, regarding the evaluation of the exposure of a worker over a single day by means of a full-period measurement (which is MSHA's compliance sampling approach), *Patty's Industrial Hygiene and Toxicology* (3rd Edition, 1994) states, ''In that case, the error variance is determined by only the sampling and analytical error, and confidence limits tend to be quite narrow.'' By appropriately accounting for sampling and analytic errors, MSHA will assure, at the 95% confidence level, that an out-of-compliance sample accurately reflects an out-of-compliance condition in the mine.

This contrasts with the mine operator's need to verify compliance. *Patty's* states, ''Usually, however, our concern is with the totality of a workers exposure, and we wish to use the data collected to make inferences about other times not sampled. There is little choice; unless the universe of all exposure occasions is measured, we must ''sample,'' that is, make statements about, the whole based on measurement of some parts.''

''The American Industrial Hygiene Association has addressed the issue of

appropriate sample size (Hawkins et al., 1991) and recommends in the range of 6–10 random samples per homogeneous exposure group. Fewer than 6 leaves a lot of uncertainty and more than 10 results in only marginal improvement in accuracy. Also, it is usually possible to make a reasonable approximation of the exposure distribution with 10 samples although a rigorous goodness-of-fit test often requires 30 or more.'' Although a single sample is not adequate to demonstrate compliance, MSHA does not specify in the final rule, a minimum number of samples that will constitute adequate verification of compliance in all cases. It is the mine operator's responsibility to determine the appropriate level of sampling effort and explain the rationale in the diesel particulate matter control plan.

Like the final rule, the proposed rule provided that verification sampling would be conducted under conditions that can be ''reasonably anticipated'' in the mine. The Agency very specifically solicited comment on ''whether, and how, it should define the term 'reasonably anticipated.' '' (63 FR 58185) The agency noted that with respect to coal dust, the Dust Advisory Committee recommended that ''MSHA should define the range of production values which must be maintained during sampling to verify the plan. This value should be sufficiently close to maximum anticipated production.'' (MSHA, 1996) For dpm, the Agency suggested, the equivalent approach might be based on worst-case operating conditions of the diesel equipment—*e.g.,* all equipment is being operated simultaneously with the least ventilation. No comments were received on this point.

Recordkeeping retention and access. Pursuant to section 5062(b), a copy of the current dpm control plan is to be maintained at the mine site during the duration of the plan and for one year thereafter. Section 5062(c) requires that verification sample results be retained for 5 years. And, section 5062(d) provides that both the control plan and sampling records verifying effectiveness be made available for review, upon request, by the authorized representative of the Secretary, the Secretary of Health and Human Services, and/or the authorized representative of miners. Upon request of the District Manager or the authorized representative of miners, a copy of these records is to be provided by the operator.

Duration. The final rule requires the dpm control plan to remain in effect for three years from the date of the violation resulting in the establishment/modification of the plan. Section 57.5062(e)(1) and (e)(2). MSHA has concluded that operators have sufficient time under the final rule to come into compliance with the concentration limits; if a problem exists, maintaining a plan in effect long enough to ensure that daily mine practices really change is an important safeguard. MSHA noted its view in this regard in the preamble to the proposed rule; no comments were received on this point.

Modification during plan lifetime. If a diesel particulate matter control plan is already in effect at a mine, section 57.5062(a) requires the mine operator to modify the current plan upon a subsequent violation of section 57.5060, and to demonstrate the effectiveness of the modified plan.

Section 57.5062(e)(3) would require the mine operator to independently initiate the modification of an existing dpm control plan to reflect changes in mining equipment and/or the mine environment, and requires the operator to demonstrate the effectiveness of the modified plan.

It should also be noted that a mine operator, based on dpm sampling data or other information or analysis, may at any time, modify the provisions of a dpm control plan to make it less restrictive, provided sufficient sampling data confirm the plan's continuing effectiveness in controlling dpm to compliant levels. A modification made in this manner does not affect the 3-year duration of the plan (end date unaffected). These plans made by the operator do not require advance approval by MSHA.

Compliance with plan requirements. Section 57.5062(f) states that failure by a mine operator to comply with the provisions of a diesel particulate matter control plan is a violation of the rule, regardless of the concentration of dpm that may be present at any time. Once an underground metal or nonmetal mine operator adopts a dpm control plan, it is considered law for the mine. Section 57.5062(f) specifically provides that MSHA would not need to establish (by sampling) that an operator is currently in violation of the applicable concentration limit under § 57.5060 in order to determine (by observation) that an operator has failed to comply with any requirement of the mine's dpm control plan.

One commenter observed that, ''It does seem odd * * * that § 57.5062(f) contemplates that the mere failure to adhere to the [dpm control plan] itself is deemed a violation of the regulation—irrespective of the fact that the exposure to dpm may indeed be less than the [concentration limit].''

MSHA's rationale for making a mine's dpm control plan law for that mine derives from the rule's approach to setting control requirements. MSHA recognizes that every mine faces a unique set of conditions and circumstances relating to equipment, engines, emission controls, ventilation, etc. that would make uniform dpm control requirements across the entire underground metal and nonmetal mining industry unworkable, impractical, and ineffective. Hence, the final rule, with just a few exceptions, permits mine operators considerable freedom to select the mix of dpm control options they believe are necessary to comply with the applicable concentration limit. An operator can filter the emissions from diesel-powered equipment, install cleaner-burning engines, increase ventilation, improve fleet management, or use a variety of other readily available controls, all without consulting with, or seeking approval from MSHA.

However, if MSHA sampling indicates non-compliance with the applicable concentration limit, the rule requires the operator reduce to writing his or her specific plans for controlling dpm to the concentration limit and to adhere to that plan. MSHA considers miner exposure to dpm, a probable carcinogen, as a very serious matter, and has not established that exposures, even at the concentration limit, are safe. That is why a single non-compliant sample triggers the requirement for a compliance plan. The plan lays out the minimum steps the operator has determined must be followed in that mine to insure compliance. Failure to adhere to the requirements of the operator-developed plan must thus be viewed as a failure to take actions that are necessary for compliance with the concentration limit.

Because of the importance of adhering strictly to an effective dpm control plan, a means of enforcing such adherence is necessary. The plan is made law for that mine so that its provisions can be enforced by MSHA. The plan need not be approved by the MSHA District Manager, but it is, nonetheless, law for that mine, and any violation of the plan is therefore a violation of the regulation. As discussed above, an operator is free to modify a dpm control plan to make it less restrictive at any time during its life, and as often as desired, as long as sufficient sampling data confirm the plan's continuing effectiveness in controlling dpm to compliant levels. MSHA is of course concerned primarily with the health and safety of miners so the magnitude of any citation for a

violation of the plan will take into account the actual risk posed to miners.

With respect to the required diesel particulate matter control plan, the mine operator is essentially telling MSHA what steps are necessary for that mine to comply with the applicable concentration limit. If MSHA observes a violation of the plan, it is only reasonable and proper for MSHA to conclude that full compliance is therefore not possible. If enforcement of the provisions of the dpm control plan depended upon obtaining an out-of-compliance dpm sample, plan enforcement would be greatly diminished, both in terms of timeliness and effectiveness. If such a sample were taken, and found to be out of compliance, implementation of needed corrective measures would be delayed because MSHA could not require the mine operator to take remedial actions until the sample results were obtained from the analytic laboratory, which could involve several weeks of time. If such a sample were taken, and found to be in compliance, that fact would not constitute conclusive evidence that the plan as a whole was fully effective (see earlier discussion on the need for multiple samples to establish continuing compliance). Thus, while providing inconclusive information at best, such a sampling outcome would prevent MSHA from enforcing a provision of the plan. Regardless of sampling outcome, it is important to remember that a violation of the plan means the mine operator did not adhere to the very requirements that were represented to MSHA by the operator as being necessary for compliance.

It should also be noted that MSHA already has similar enforcement authority relative to various other plans that are required in the underground metal and nonmetal sector. Mine operators are required to prepare plans for such purposes as escape and evacuation, rock bursts, ventilation, and training. MSHA has the authority to enforce the provisions of these plans without first verifying that the observed violation has caused an immediate outcome which itself, is prohibited by regulation. There is also ample precedent for citing health-related violations without sampling, such as § 58.620 on drill dust control, and § 57.5005 on respiratory protection.

The mine operator is required to modify dpm control plans to reflect changes in mining equipment or circumstances. The mine operator is also required to modify dpm control plans if the plan proves to be inadequate, as evidenced by a subsequent non-compliance determination during the three year period that the plan is in effect. In either case, the modifications to the original plan become law for that mine, and violations are subject to enforcement action by MSHA regardless of dpm concentration.

It is also important to remember that dpm levels are determined by the complex interaction of numerous factors, such as equipment type, engine size, type, and horsepower, duty cycles, engine maintenance, equipment operator training and work practices, fuel and fuel additives, the characteristics and performance of exhaust filtering systems, mine ventilation flows, and many others. Effectively controlling dpm levels throughout a mine requires a systematic approach that acknowledges the interrelationships and interactions between these factors to produce the desired end result, which is compliance with the applicable concentration limit. A determination of non-compliance indicates that the system of controls has failed. Thus, an effective permanent solution requires a comprehensive approach which not only corrects the immediate cause of the non-compliance (an out-of-tune engine, for example), but also addresses the underlying system failure (deficient maintenance management, inadequate dpm monitoring, ineffective equipment operator training, failure to tag equipment believed to require maintenance, etc.).

The implementation of a dpm control plan avoids piecemeal solutions that result in a repetitive pattern of mines being in and out of compliance without ever coming to grips with underlying problems. The required elements of a dpm control plan force a comprehensive approach, and facilitate effective, permanent solutions to systemic failures. The three year duration of such plans insures that the necessary system changes become institutionalized and integrated into daily mine practices. This, in turn, will increase the chances that mines will be in compliance with the applicable concentration limit on a continuous, on-going basis.

MSHA recognizes that some operators may want to supplement the compliance plans required by the regulation with additional internal instructions that provide supplementary protection—i.e., to achieve concentration levels below those required. MSHA does not want to discourage such supplemental plans; indeed, it would like to encourage them. Accordingly, MSHA will, upon request, work closely with mine operators to help avoid confusion by mine and Agency personnel between required compliance plans that contain the minimum elements considered essential to achieve compliance (and whose provisions are therefore enforceable by MSHA) and non-required supplemental plans that contain elements the mine operator wishes to implement as a matter of company policy (but whose provisions are not enforceable by MSHA).

Section 57.5065 Fueling Practices

Summary. This section of the final rule establishes the requirements for fueling practices in underground metal and nonmetal mines. Unlike the proposed rule, the final rule has two subsections.

Subsection (a) limits the amount of sulfur that may be contained in diesel fuel used to power equipment in underground areas, and requires mine operators to maintain purchase records that verify the sulfur content of the fuel they use.

Subsection (b) requires that fuel additives used in underground diesel-powered equipment be restricted to those registered by the U.S. Environmental Protection Agency.

These subsections of the final rule have not been changed from the proposed rule.

The practices being required by these two subsections are accepted industry practices to reduce dpm emissions. They are among the methods for reducing dpm explicitly included in MSHA's toolbox publication, and were made requirements for underground coal mines as part of MSHA's diesel equipment rulemaking. They are among the ''best practices'' for reducing dpm emissions that MSHA has determined are technologically and economically feasible for all underground metal and nonmetal mines. Part II of this preamble contains some background information on these practices together with information about the rules currently applicable in underground coal mines.

Low-sulfur fuel. In the final rule, § 57.5065(a) would require underground metal and nonmetal mine operators to use only low-sulfur fuel having a sulfur content of no greater than 0.05 percent. This requirement is identical to that currently required for diesel equipment used in underground coal mines [30 CFR 75.1901(a)]. Both number 1 and number 2 diesel fuel meeting the sulfur content requirement of this rule are commercially available.

Sulfur content can have a significant effect on diesel emissions. Use of low-sulfur diesel fuel reduces the sulfate fraction of dpm matter emissions, and

reduces objectionable odors associated with diesel exhaust.

Another major benefit of using low-sulfur fuel is that the reduction of sulfur allows oxidation catalysts to perform properly. Some diesel emission aftertreatment devices, such as catalytic converters and catalyzed particulate traps, are ''poisoned'' with fuels having high-sulfur content (greater than 0.05 percent sulfur). MSHA believes the use of these aftertreatment devices is important to the mining industry because they will be necessary for many mines to meet the specified concentration limits. The requirement to use low-sulfur fuel will allow these devices to be used without additional adverse effects caused by the high-sulfur fuel.

Several commenters questioned why low-sulfur fuel was mandated, even for operators who could meet the applicable concentration limit using other means. MSHA responds by noting that the use of low-sulfur fuel is one of the ''best practices'' that MSHA requires all mines to follow, regardless of current dpm levels. Further elaboration on the rationale for mandating these ''best practices'' was included in the preamble to the proposed rule (63 FR 58119), and a summary was provided in this Part under the portion of § 57.5060 that discussed ''Meeting the concentration limit, operator choice of engineering controls.'' As noted in those discussions, MSHA is required by statute to reduce a significant risk to the extent feasible; the use of low-sulfur fuel is feasible, has not created any problems in the underground coal sector where it is required as a result of the diesel equipment rule, and its use will reduce dpm emissions from underground engines.

In the preamble to the proposal (63 FR 58186), MSHA indicated it did not believe a requirement mandating the use of low-sulfur fuel will add additional compliance costs. Several commenters contradicted this conclusion, arguing that the provision requiring low-sulfur fuel would have an adverse cost impact. One commenter supplied actual cost figures that showed their fuel costs increased over $18,000 per year after they switched to low-sulfur fuel. However, it is significant to note that this increase is quite small on both a cost per gallon of fuel basis (less than $0.03 per gallon), and a cost per ton basis (about $0.008 per ton), and that this mine had already made the switch to low-sulfur fuel, apparently because they perceived that the benefits justified the small additional expense.

As discussed in the Section IV of the PRIA, MSHA determined that the cost difference between high-sulfur and low-sulfur diesel fuel was less than $0.02 per gallon in many parts of the country, and in some areas, there was no difference at all, or a slight cost advantage to using low-sulfur fuel. Fuel used in over-the-road diesel engines is currently required by EPA regulations to meet the same 0.05% sulfur content limit that is being implemented for underground metal and nonmetal mines. Because over-the-road diesel engines represent the bulk of the diesel fuel market, such low-sulfur fuel is already readily available throughout the country. EPA has proposed regulations that would further reduce allowable fuel sulfur content to 0.0015% for over-the-road diesel engines. Current MSHA regulations limit the sulfur content of diesel fuel used in underground coal mines to 0.05%, and the availability of this fuel in remote coal mining areas has not been a problem for coal mine operators. As discussed above, MSHA has determined, based on extensive study of the metal and nonmetal mining industry, that compliance with the rule is economically feasible for the industry as a whole. Thus, although the provision requiring use of only low-sulfur fuel may, in some instances, result in a small cost increase for some operators, MSHA estimates that on average, the overall measurable impact is negligible. When they are measurable, it is because the mine is located in an area where heating fuel has relatively large market share compared to diesel fuel used for vehicles. This circumstance is unrelated to mine size. Most mines are not located in these regions and there is no evidence that small mines are disproportionately concentrated in these regions.

Fuel additives. Paragraph (b) of this section requires mine operators to use only diesel fuel additives that have been registered by the Environmental Protection Agency (40 CFR Part 79). Again, this rule is consistent with current requirements for diesel equipment used in underground coal mines [30 CFR 75.1901(c)], and is another of the ''best practices'' that MSHA considers to be feasible for all underground metal and nonmetal mines. The restricted use of additives would ensure that diesel particulate concentrations would not be inadvertently increased, while also protecting miners against the emission of other toxic contaminants. MSHA has published Program Information Bulletin No. P97–10, issued on May 5, 1997, that discusses the fuel additives list. The requirements of this paragraph do not place an undue burden on mine operators because operators need only verify with their fuel suppliers or distributors that the additive purchased is included on the EPA registration list. To assist mine operators in this regard, EPA's Internet site contains a current listing of additives registered with EPA. This site can be accessed at the following address: http://www.epa.gov/oms/regs/fuels/additive/web-dies.txt. No commenters objected to this requirement.

Idling practices. Proposed paragraph (c) of § 57.5021 would have prohibited idling of mobile diesel-powered equipment, except as required for normal mining operations. After further consideration of all comments received during the comment period, as well as testimony presented at the public hearings, MSHA has decided to delete this requirement from the final rule. Therefore, the final rule does not contain a restriction for operators on idling diesel-powered equipment. MSHA does, however, recommend as a best practice that mine operators do not allow miners to idle diesel-powered equipment unnecessarily.

Although commenters generally agreed with MSHA's statement in the proposal that this requirement would aid in the reduction of dpm concentrations at the mine, they pointed out that the total amount of diesel particulate matter emitted from this single source might have little effect on the levels of dpm in the overall mining environment. Also, several commenters questioned the need for an idling restriction in light of the proposed concentration limits established in the regulation. Additionally, another commenter indicated that the provision was not necessary because mine operators, in an effort to comply with the applicable concentration limits, would be forced to institute work rules to this effect anyway. Moreover, as pointed out by commenters, nothing in the regulatory language prohibits operators from voluntarily restricting idling at the mine, eliminating the need to include this provision. Accordingly, we have deleted proposed paragraph (c) from the final rule.

Section 57.5066 Maintenance standards.

Summary. This section of the final rule establishes maintenance standards for diesel-powered equipment operated in underground areas of metal and nonmetal mines. It has three subsections.

Subsection (a) addresses maintenance of diesel engines, emission related components, and emission or particulate control devices.

Subsection (b) institutes a mandatory procedure by which diesel equipment operators must be authorized and required to tag equipment they believe requires maintenance in order to comply with subsection (a) above, for mine operators to insure that equipment so tagged is promptly examined, and for mine operators to retain a log of tagged equipment and the corresponding equipment examinations.

Subsection (c) requires that persons maintaining diesel equipment in underground metal and nonmetal mines be appropriately qualified by virtue of training or experience, and that mine operators must retain evidence of the competence of such persons.

The provisions of this section in the final rule are unchanged from the proposal.

Maintain Approved engines in approved condition. § 57.5066(a)(1) requires that mine operators maintain any approved diesel engine in ''approved'' condition. Under MSHA's approval requirements, engine approval is tied to the use of certain parts and engine specifications. When these parts or specifications are changed (i.e., an incorrect part is used, or the engine timing is incorrectly set), the engine is no longer considered by MSHA to be in approved condition.

Often, engine exhaust emissions will deteriorate when this occurs. Maintaining approved engines in their approved condition will ensure near-original performance of an engine, and maximize vehicle productivity and engine life, while keeping exhaust emissions at approved levels. The maintenance requirements for approved engines in this rule are already applicable to underground coal mines. 30 CFR 75.1914.

Thus in practice, with respect to approved engines, mine maintenance personnel will have to maintain the following engine systems in near original condition: air intake, cooling, lubrication, fuel injection and exhaust. These systems shall be maintained on a regularly scheduled basis to keep the system in its ''approved'' condition and thus operating at its expected efficiency.

One of the best ways to ensure these standards are observed is to implement a proper maintenance program in the mine—but the final rule would not require operators to do this. A good program should include compliance with manufacturers' recommended maintenance schedules, maintenance of accurate records and the use of proper maintenance procedures. MSHA's diesel toolbox provides more information about the practices that should be followed in maintaining diesel engines in mines.

Maintain emissions related components of non-approved engines to manufacturer specifications. For any non-approved diesel engine, paragraph (a)(2) requires mine operators to maintain the emissions related components to manufacturer specifications.

The term ''emission related components,'' refers to the parts of the engine that directly affect the emission characteristics of the raw exhaust. These are basically the same components which MSHA examines for ''approved'' engines. They are the piston, intake and exhaust valves, cylinder head, injector, fuel injection pump, governor, turbo charger, after cooler, injection timing and fuel pump calibration.

Engine manufacturers are required to build engines in a manner that ensures continued compliance with EPA emissions levels and to establish specifications for adjusting and maintaining these engines to the engine manufacturer's specifications to ensure that the engines continue to perform properly and emit acceptable levels of emissions.

As it indicated in the preamble to the proposed rule, the Agency does not intend that this requirement could be misconstrued as establishing the basis for ''picky'' citations. It is not MSHA's intent that engines be torn down and the engine components be compared against the specifications in manufacturer maintenance manuals (63 FR 58187). Primarily, the Agency is interested in ensuring that engines are maintained in accordance with the schedule recommended by the manufacturer. However, if it becomes evident that the engines are not being maintained to the correct specifications or are being rebuilt in a configuration not in line with manufacturers' specifications or approval requirements, an inspector may ask to see the manuals to confirm that the right manuals are being used, or call in MSHA experts to examine an engine to confirm whether basic specifications are being properly observed.

This explanation of MSHA's intent relative to its enforcement of this provision was included in the Preamble to the proposed rule, accompanied by an invitation for comment from the mining industry to suggest alternative ways to rephrase this requirement so the Agency has a basis for ensuring compliance while minimizing the opportunity for overprescriptiveness (63 FR 58187). However, no such suggestions were received.

Maintain emission or Particulate Control Devices in effective operating condition. Paragraph (a)(3) requires that any emission or particulate control device installed on diesel-powered equipment be maintained in effective operating condition. Depending on the type of devices installed on an engine, this would involve having trained personnel perform such basic tasks as regularly cleaning aftertreatment filters, using methods recommended by the manufacturer for that purpose, or inserting appropriate replacement filters when required, checking for and repairing any exhaust system leaks, and other appropriate actions. This explanation of MSHA's intent relative to subsection (a)(3) was contained in the preamble to the proposed rule (63 FR 58187). One comment was received on this subsection from a commenter who submitted a complete regulatory alternative to MSHA's proposed dpm rule. The section of this regulatory alternative that corresponds to subsection (a)(3) of both the proposed and final rules reads as follows: ''Emission related components of diesel powered equipment shall be maintained in effective operating condition.'' This alternative language is functionally identical to both the proposed and final rules. It incorporates the phrase ''Emission related components of diesel powered equipment * * *,'' whereas the rules incorporate the phrase, ''Any emission or particulate control device installed on the equipment * * *,'' however, the requirement that such equipment, ''shall be maintained in effective operating condition,'' is identical. Therefore, MSHA concluded that no change from the proposal was necessary.

Ensuring equipment that may be out of compliance with maintenance standards is attended to—Tagging. Section 57.5066(b)(1) of the final rule requires underground metal and nonmetal mine operators to authorize and require miners operating diesel powered equipment to affix a visible and dated tag to the equipment at any time the equipment operator ''notes any evidence that the equipment may require maintenance in order to comply with the maintenance standards of paragraph (a) of this section.'' Moreover, § 57.5066 (b)(2) requires that the equipment be ''promptly'' examined by a person authorized by the mine operator to maintain diesel equipment, and prohibits removal of the tag until such examination has been completed. Section 57.5066 (b)(3) requires a log to be retained of all equipment tagged.

In proposing this approach, MSHA noted its view that tagging would

provide an effective and efficient method of alerting all mine personnel that a piece of equipment needs to be checked by qualified service personnel for possible emission problems, and that such a check is performed in a timely way (63 FR 58187).

The agency noted that the presence of a tag serves as a caution sign to miners working on or near the equipment, as well as a reminder to mine management, as the equipment moves from task to task throughout the mine. While the equipment is not barred from service, operators would be expected to use common sense and not use it in locations in which diesel particulate concentrations are known to be high.

The agency noted it was not requiring that equipment tagged for potential emission problems be automatically taken out of service. The rule is not, therefore, directly comparable to a ''tag-out'' requirement such as OSHA's requirement for automatic powered machinery, nor is it as stringent as MSHA's requirement to remove from service certain equipment ''when defects make continued operation hazardous to persons'' (see 30 CFR 57.14100). In the Preamble to the proposed rule, MSHA indicated that it did not think there was a need for something as stringent as these requirements because, although exposure to dpm emissions does pose a serious health hazard for miners, the existence or scope of an equipment problem cannot be determined until the equipment is examined or tested by a person competent to assess the situation. Moreover, the danger is not as immediate as, for example, an explosive hazard.

In the preamble to the proposed rule, MSHA also provided additional insights into how this approach would be implemented. It noted, for example, that the tag may be affixed because the equipment operator detects a problem through a visual exam conducted before the equipment is started, or because of a problem that comes to the attention of the equipment operator during mining operations, (i.e., black smoke while the equipment is under normal load, rough idling, unusual noises, backfiring, etc.) MSHA also noted it had not defined the term ''promptly'' with respect to how quickly tagged equipment must be examined by a qualified person, and sought comment on whether it should define this term—for example, by limiting the number of shifts it could operate before the required examination is performed (63 FR 58187).

The equipment tagging requirement was the subject of numerous comments. Most commenters were concerned that equipment operators would be authorized and required to make judgements about equipment function (and malfunction) for which they are unqualified, namely, to tag equipment they believe requires maintenance due to a problem related to dpm emissions. The commenters argued that, although equipment operators may be highly skilled in operating equipment, they are not necessarily qualified to make judgements concerning equipment maintenance requirements. Even though the regulation would not require tagged equipment to be removed from service, the commenters were concerned that such tags would cause unnecessary ''scurrying about of mechanics'' whose time could be more productively spent performing actual needed maintenance, rather than reacting to tags affixed for reasons that might be dubious, at best.

Commenters noted that, in addition to unnecessary maintenance inspections and the possibility of unnecessarily removing equipment from service, this requirement could result in a safety hazard if a tag affixed under § 57.14100(c) is mistaken for a tag affixed under § 57.5066(b)(1). The former addresses safety defects that ''make continued operation hazardous to persons,'' and it requires the equipment to be immediately removed from service. The latter relates to dpm emissions, and does not require the piece of equipment to be removed from service. If a tag under § 57.14100(c) is mistaken for a tag under § 57.5066(b)(1), the affected equipment would be allowed to remain in service, exposing the operator, and possibly others, to potentially dangerous conditions.

Some commenters suggested that the tagging requirement in the final rule was completely unnecessary because its intent is already satisfied by existing § 57.14100, and that for the sake of simplicity, § 57.5066(b)(1) should be eliminated. Another commenter noted that § 57.5066(b)(1) was unnecessary because mine operators already have effective mechanisms in place to identify and correct maintenance problems on diesel equipment, including emissions-related problems. Another commenter worried that a citation could be issued if an inspector believes an operator failed to tag a piece of diesel equipment with a ''smoky'' exhaust, even if the operator believes the exhaust is within the normal range. Several commenters speculated that disgruntled employees would deliberately shut down equipment by tagging it for an emissions check.

Several commenters suggested alternative requirements, including incorporating emissions checks into the pre-shift equipment inspection required under § 57.14100(a), requiring equipment operators to either inform their supervisors of any suspected emissions-related problems or note any suspected emissions-related problems in a log book provided in every piece of equipment for that purpose, and requiring the mine operator to insure that a qualified person examines any piece of equipment for which an emissions-related problem has been identified.

MSHA has considered these comments, and determined that the requirements contained in the proposal are both necessary, and more protective than the alternatives suggested by the commenters. For these reasons, the requirements contained in the proposal have been retained without change in the final rule.

MSHA believes that, since equipment operators spend more time running the equipment than other employees (such as mechanics), and are present when the equipment functions under the widest range of operating conditions, they are often better able to detect emissions-related problems than are mechanics. For this reason, the final rule requires that equipment operators be authorized and required to affix a visible and dated tag if they note any evidence that the equipment may need maintenance in order to comply with the rule's maintenance requirements. Even though equipment operators may not be trained or qualified as diesel mechanics, they often know the difference between normal and abnormal equipment performance, especially as it relates to diesel particulate matter generation, which is often plainly visible or apparent (i.e., black smoke while the equipment is under normal load, rough idling, unusual noises, backfiring, etc.).

MSHA acknowledges that an equipment operator's judgement should not necessarily be relied upon to remove a piece of diesel equipment from service, precisely because equipment operators are not specifically trained or qualified to make such a judgement. Accordingly, the final rule does not require equipment operators to be granted this authority; only that they be granted authority to visibly identify a potential problem machine by affixing a tag. It is then the responsibility of the mine operator to appropriately respond to the presence of a tag. Note that the response by the mine operator need not be immediate, nor does it necessarily require the affected equipment to be removed from service, as some commenters feared. Mine operators have the authority to establish work rules and procedures to prevent equipment from

being removed from service unnecessarily. Equipment operators and mechanics simply need to be trained as to their respective authority and responsibility under this section; namely, that equipment operators need to tag equipment suspected of requiring maintenance attention, and that qualified mechanics need to follow up to determine if a problem actually exists, and if so, what corrective maintenance work is needed.

It is highly unlikely that a tag intended to indicate a suspected emissions-related problems, if properly designed, would be confused with a tag intended to indicate a safety problem as per § 57.14100(c). Such tags could be differentiated by size, color, or other obvious visual characteristics so that mistaking one for the other would be virtually impossible. As noted below, the final rule allows mine operators the freedom to develop a design that suits their circumstances. In contrast, a design mandated by MSHA might be too similar to a given mine's existing § 57.14100(c) safety tag.

MSHA believes that the equipment tagging requirements of § 57.14100(c) and § 57.5066(b)(1) are inherently and significantly different, to the extent that the § 57.14100(c) requirement, even if modified to include health hazards, could not achieve the desired effect of § 57.5066(b)(1). The purpose of § 57.14100(c) is to immediately remove equipment from service if it poses a safety hazard, whereas the purpose of § 57.5066(b)(1) is to identify a potential emissions-related problem that might require maintenance, but does not justify immediate removal from service. Another important difference is that examinations under § 57.14100(c) occur before a piece of equipment is placed in operation on that shift, whereas § 57.5066(b)(1) applies throughout a work shift. These fundamental differences would make any attempt to combine the rules overly complicated, which would defeat the commenter's purpose of simplifying the rule.

As discussed above, MSHA believes that equipment operators should be authorized and required to note emissions-related deficiencies at all times during a work shift, and not be limited to making such observations during a pre-shift equipment inspection or before the equipment is placed into operation. Some emissions-related problems may not become apparent until after the equipment has been fully engaged for some time in heavy duty cycle activities. If the only time emissions-related deficiencies could be identified is before the equipment is placed into operation, the mine operator might never learn about such problems, or the corresponding notification might be unnecessarily delayed.

MSHA acknowledges that many underground metal and nonmetal mine operators utilize effective maintenance programs to identify and correct emissions-related problems in a timely manner. However, MSHA believes that §§ 57.5066(b)(1) and (2) are ''best practices'' that should be implemented at all mines. At mines that already have an effective program, this provision would serve as a complementary element. At mines that have no effective program, this provision would create an important safeguard. Further elaboration on the rationale for mandating these ''best practices'' was included in the preamble to the proposal (p. 58119), and a summary was provided in this Part under the portion of § 57.5060 that discussed ''Meeting the concentration limit, operator choice of engineering controls.''

The tagging provision of § 57.5066(b) requires judgement on the parts of both the equipment operator and the MSHA inspector. There is no absolute standard which precisely defines the physical proof that constitutes, ''evidence that the equipment may require maintenance in order to comply with the maintenance standards of paragraph (a) of this section.'' Thus, MSHA inspectors will be guided by a standard of reasonableness, based on an equipment operator's ability to differentiate normal emissions from grossly abnormal emissions. MSHA does not expect operators to tag equipment whenever there is a minor aberration or excursion from an optimum or perfect emissions condition, or that an inspector should make a fine distinction between emissions that are ''slightly too smoky'' versus ''barely acceptable.'' However, MSHA inspectors will not ignore an operator's failure to tag a piece of equipment suffering from a serious emissions-related problem that is so obvious as to suggest the mine operator is indifferent to, or even discourages such tagging.

MSHA believes that disgruntled employees' attempts to shut down equipment by affixing tags indicating possible emissions-related problems can be effectively controlled and prevented by mine operators through work rules and procedures, and employee discipline policies. Mine operators should treat the inappropriate exercise of this provision by a disgruntled employee no differently than any other disruptive or malicious behavior. In addition to being preventable, MSHA believes the inappropriate tagging of equipment would have minimal impact on mining operations because tagged equipment need not be immediately removed from service. The maintenance examination that is triggered by a tag might not take place until the next shift or the shift after, and if there is truly nothing wrong with the equipment, it would be obvious to the mechanic performing the examination, and would therefore only require a few minutes of a mechanic's time.

MSHA considers the provision for tagging equipment to be preferable to a system which permits equipment operators to simply notify their supervisor of a suspected emissions-related problem, because the presence of a tag serves as a caution sign to other miners working on or near the equipment, as well as a reminder to mine management that this piece of equipment needs to be examined. Simply informing the supervisor does not provide this ongoing visual indicator or reminder, and as miners and equipment are reassigned to different jobs in different parts of a mine, information that is communicated verbally can be easily forgotten. A major advantage of tagging is that the tag goes with the equipment throughout the mine, alerting all who come in contact with it of the potential dpm emissions problem. In this sense, tagging requirements are particularly valuable for mobile equipment that travels from place to place throughout the shift, and may have multiple operators over the course of several shifts.

Design of the tag. MSHA proposed that the design of the tag be left to the discretion of the mine operator, with the exception that the tag must be able to be marked with a date. MSHA sought comment on ''whether some or all elements of the tag should be standardized to ensure its purpose is met''.

Several commenters suggested that MSHA should design the tag to be used for indicating equipment suspected of needing emissions-related maintenance.

As noted above, the final rule leaves this decision to the discretion of the mine operator. Since the design of tags required under § 57.14100(c) is left to the discretion of the operator, it would be impossible for MSHA to insure that any mandated design for a tag under § 57.5066(b)(1) would be easily distinguishable from an existing § 57.14100(c) tag. However, MSHA strongly urges mine operators to adopt a design for their § 57.5066(b)(1) tags that is easily distinguishable from the design of their § 57.14100(c) tags, using, for example, different sizes, colors, or other obvious visual characteristics.

Time to inspect equipment. As noted above, MSHA sought specific comment on whether to define the term ''promptly.'' One commenter referred to ''promptly examined'' as, ''whatever that is,'' indicating they believed the term ''promptly examined'' is too vague. Another commenter suggested that a definite time period for examining equipment should be specified; namely, ''by the end of the next shift.'' However, another commenter agreed with MSHA that equipment tagged by an operator should be, ''promptly examined'' by an authorized diesel maintenance person. Another commenter proposed that, ''the required examination be conducted during normally scheduled maintenance cycles.''

The final rule, like the proposal, does not define the term ''promptly''. Operating and maintenance practices vary from mine to mine to such an extent that a proscriptive requirement mandating a specific time period within which an examination must be completed may be infeasibly short for some operators and unnecessarily long for other operators. However, MSHA's intent is that mine operators will insure such examinations are performed without undue delay. If a tag is affixed during a given shift, it would not be unreasonable to complete that shift before the maintenance examination. If no qualified mechanic is scheduled to work on the following shift, the equipment could be operated during that shift as well. However, if a qualified mechanic was scheduled to work on the next shift, the examination would be required before the equipment was used.

Tagged Equipment Log. Section 57.5066(b)(3) requires a log to be retained of all equipment tagged. Moreover, the log must include the date the equipment is tagged, the date the tagged equipment is examined, the name of the person making the examination, and the action taken as a result of the examination. Records in the log about a particular incident must be retained for at least one year after the equipment is tagged.

MSHA does not expect the log to be burdensome to the mine operator or mechanic examining or testing the engine. Based on MSHA's experience, it is common practice to maintain a log when equipment is serviced or repaired, consistent with any good maintenance program. The records of the tagging and servicing, although basic, provide mine operators, miners and MSHA with a history that will help in determining whether a maintenance program is being effectively implemented, and whether emissions-related components on the equipment are being maintained in a proper and timely fashion.

Several comments addressing the equipment log were received. Proposed revisions generally retained the requirement for an equipment log, but varied as to who would maintain the log (equipment operators, mechanics or supervisors), and how long they should be kept (one year versus until the condition is examined and remedied). It was also suggested that all record keeping could be accomplished under ''existing mobile equipment examination standards and maintenance work order systems,'' and that additional standards were therefore not needed.

MSHA has concluded that the requirements in the proposal relative to tagged equipment logs are essential to effectively controlling dpm, and have therefore been retained in the final rule without change. They enable both the mine operator and MSHA to track emissions-related problems on equipment, and the actions taken by the mine operator to resolve the problems that occur. The logs are also important because they provide a written record documenting when equipment was tagged, and how the mine operator responded.

The log creates an accountability chain that clearly indicates the date the equipment was tagged, the date the tagged equipment was examined, the name of the person making the examination, and the action taken as a result of the examination. Without the written record, MSHA would be unable to ascertain the extent to which mine operators respond in a timely and appropriate manner to emissions-related problems on diesel equipment. The one-year record retention requirement is necessary so that MSHA can review the emissions-related maintenance history on a given piece of equipment over a meaningful time period. This will enable MSHA to judge the mine operator's on-going commitment to proper and timely maintenance of these components. If the log were kept only until a given maintenance operation was completed, MSHA's opportunity to assess the mine operator's on-going responsiveness to emissions-related problems would be limited to the few chance occasions where a piece of equipment is tagged during an MSHA inspection of the mine.

These requirements are protective to miners because they force mine operators to address dpm emissions problems through a systematic and effective program. The combination of equipment tagging and logging helps insure problems will be identified and resolved quickly. If either or both requirements were eliminated, mine operators would be less likely to receive timely notice of a potential problem, and once notified, would be less motivated to promptly initiate the required examination and corrective measures.

Persons qualified to perform maintenance. Section 57.5066(c) requires that persons who maintain diesel equipment in underground metal and nonmetal mines be ''qualified,'' by virtue of training or experience, to ensure the maintenance standards of § 57.5066(a) are observed. Paragraph (c) also requires that an operator retain appropriate evidence of ''the competence of any person to perform specific maintenance tasks'' in compliance with the requirement's maintenance standards for one year.

The requirements being established in this regard are not as stringent as those in effect for the maintenance of diesel powered equipment in underground coal mines. Operators of underground coal mines where diesel-powered equipment is used are required, as of November 25, 1997, to establish programs to ensure that persons who perform maintenance, tests, examinations and repairs on diesel-powered equipment are qualified (30 CFR 75.1915). The unique conditions in underground coal mines require the use of specialized equipment. Accordingly, the persons who maintain this equipment generally must be appropriately qualified.

If repairs and adjustments to diesel engines used in underground metal and nonmetal mines are to be done properly, personnel performing such tasks must be properly trained. MSHA does not believe, however, that the qualifications required to perform this work in underground metal and nonmetal mines necessarily require the same level of training as is required for similar work in underground coal mines. Under the final rule, the training required would be that which is commensurate with the maintenance task involved. If examining and, if necessary, changing a filter or air cleaner is all that is required, a miner who has been shown how to do these tasks would be qualified by virtue of training or experience to do those tasks. For more detailed work, specialized training or additional experience would be required. Training by a manufacturer's representative, completion of a general diesel engine maintenance course, or practical experience performing such repairs could also serve as evidence of having the qualifications to perform the service.

In practice, the appropriateness of the training or experience of the maintenance personnel will be revealed by the performance of the equipment, both the diesel engine itself and any emission aftertreatment devices. If MSHA finds a situation where maintenance appears to be shoddy, where the log indicates an engine has been in for repair with more frequency than should be required, or where repairs have damaged engine approval status or emission control effectiveness, MSHA would ask the operator to provide evidence that the person(s) who worked on the equipment was properly qualified by virtue of training or experience.

It is MSHA's intent that equipment sent off-site for maintenance and repair is also subject to the requirement that the personnel performing the work be qualified by virtue of training or experience for the task involved. It is not MSHA's intent that a mine operator have to examine the training and experience record of off-site mechanics, but a mine operator will be expected to observe the same kind of caution as one would observe with a personal vehicle—*e.g.,* selecting the proper kind of shop for the nature of the work involved, and considering prior direct experience with the quality of the shop's work.

One commenter objected to the requirement that mine operators must retain evidence of the competence of such workers for one year after any applicable maintenance task is completed. MSHA believes the provision is important because the evidence retained by the mine operator is the only means by which MSHA can judge compliance with the competency requirement.

Another commenter recommended this provision be dropped from the final rule because it is unnecessary. This commenter argued that it is in a mine operator's self interest to employ only qualified diesel mechanics to perform maintenance on equipment that is critical to the productive capacity of the mine. Another commenter stated that the rule is unnecessary because they already keep a file on mechanic training. MSHA believes this provision is important because not all mine operators are as careful in employing only qualified persons to maintain the emissions-related components of their diesel equipment. For mine operators that do, this requirement should not be burdensome. For mine operators that don't, this requirement will prevent unqualified persons from performing improper maintenance procedures on this equipment, thereby preventing this equipment from generating potentially excessive diesel emissions.

Another commenter recommended that the final rule should include minimum qualifications for persons responsible for ventilation at underground metal and nonmetal mines. The recommendation applied to mines employing greater than 20 miners, and suggested that the minimum qualification should be a mining engineering degree from an accredited university having a program that includes training in the theory and practice of underground metal and nonmetal mine ventilation, and that qualified persons should also have some minimum level of operating experience in this field. MSHA believes that its existing ventilation regulations and this final dpm rule are appropriately performance oriented regarding the use of mine ventilation as a dpm control measure. Mine operators who rely on ventilation will be judged by MSHA according to their success in complying with the final concentration limit. Therefore, the final rule has not been changed to require persons who are responsible for ventilation at mines employing more than 20 miners to meet any minimum qualifications.

Section 57.5067 Engines

The final rule requires that, with the exception of diesel engines used in ambulances and fire-fighting equipment, any diesel engines added to the fleet of an underground metal or nonmetal mine in the future have to either be engines approved by MSHA under part 7 or part 36 or engines that meet or exceed the applicable dpm emission requirements of the EPA explicitly incorporated into a table in the rule. This requirement takes effect 60 days after the date this rule is promulgated. Only engines approved by MSHA as permissible can be used in areas of the mine where permissible diesel equipment is required. The composition of the existing fleet in an underground metal and nonmetal mine is not impacted by this part of the final rule. However, after the rule's effective date, any engine introduced into the underground areas of the mine must be either MSHA approved or meet the applicable EPA requirements. The term ''introduced'' is explicitly defined in the final rule to eliminate uncertainty regarding MSHA's intent. Engines that are introduced means engines in newly purchased equipment, engines in used equipment brought into the mine, or replacement engines that have a different serial number than the engine it is replacing. The term introduced does not include engines that were previously part of the mine inventory and rebuilt.

The final rule reflects a change from the proposed rule. The proposed rule would have required that, with the exception of diesel engines used in ambulances and fire-fighting equipment, any diesel engines added to the fleet of an underground metal or nonmetal mine in the future would have to have been approved by MSHA under Part 7 or Part 36. As discussed below, after reviewing the comments on this topic, MSHA concluded that it could accomplish the same goal, while providing operators with considerable extra flexibility, by permitting engines compliant with applicable EPA standards as an alternative to MSHA approved engines.

Table § 57.5067–1 in the final rule lists the applicable EPA dpm standards for diesel engines. The EPA standards represent the dpm emission limits set by EPA for light duty vehicles, light duty trucks, heavy duty highway engines, and nonroad engines. MSHA believes that all engines used in underground M/NM mines would come from these categories. MSHA chose the current on-highway dpm standards that have been in effect since 1994 for any commercially available on-highway vehicle. For nonroad, MSHA mainly used the EPA tier 1 standards that have been in effect starting in 1996 through 2000.

MSHA did notice one gap in the EPA nonroad standards. For engines in the 50 to 175 horsepower range, EPA did not list a dpm standard for tier 1. A tier 2 standard is listed in the final rule table for this reason. Full EPA implementation of the tier 2 standard for this horsepower range will become effective in 2003 for engines from 50–100 horsepower and in 2004 for engines 100 to 175 horsepower. However, MSHA believes that engines in this horsepower range are available now to meet the standard. MSHA has approved many engines under part 7 in this horsepower range that would meet the standard, and engine manufacturers are also producing other engine models in this horsepower range that meet the standard. The dpm requirement is the same for this engine horsepower range as was specified for engines in light duty vehicles in the coal final rule. Therefore, MSHA does not believe that mine operators will have problems introducing engines that meet any of the requirements of this section.

Several commenters questioned the need for engine restrictions at all if the applicable concentration limit could be achieved through other means. The rationale for this requirement is to promote the gradual turnover of the

existing fleet to better, less-polluting engines, thereby reducing dpm concentrations and attendant health risks. Without this requirement, there would be no constraint on the introduction of engines that are inherently higher polluting into underground metal and nonmetal mines. Such engines, regardless of the level of maintenance they receive, produce significantly higher dpm emissions than the low polluting engines mandated in the final rule. MSHA acknowledges that older, high polluting engines will eventually be replaced with low polluting engines through the normal equipment turnover process, because EPA emission requirements (and similar requirements imposed by foreign regulatory bodies) will make high polluting engines increasingly difficult for manufacturers to sell for any application. Even if a mine operator wanted to continue using high polluting engines, such engines will become more and more scarce over time. But in light of the risks of dpm exposure to miners, and the history of the underground mining industry to bring old engines underground and keep them operating for a long period of time, MSHA has concluded that a rule is required to bring about the transition to newer engines more quickly than would otherwise be the case. MSHA considers the gradual introduction of cleaner engines to be one of the ''best practices'' that is feasible for all underground metal and nonmetal mines. Further elaboration on the rationale for mandating these ''best practices'' was included in the preamble to the proposal (63 FR 58119), and a summary was provided in this Part under the portion of § 57.5060 that discussed ''Meeting the concentration limit, operator choice of engineering controls.''

Other commenters recommended that EPA certification be an acceptable alternative to MSHA approval. As noted above, after considering the matter, MSHA agrees that engines certified as meeting applicable EPA standards would provide an acceptable level of protection to miner health comparable to that which can be achieved by requiring MSHA approved engines. (For detailed information about the various ''tiers'' of EPA engine requirements, and the various types of engine categories, please see Part II, section 5). Therefore, under the final rule, engines meeting or exceeding applicable particulate emission requirements of the Environmental Protection Agency (as listed in the table in § 57.5067(b)) are an acceptable alternative to engines approved by MSHA as nonpermissible under subpart E of Part 7 of this title. This change in the final rule will provide mine operators with a wider choice of acceptable engines, and may reduce compliance costs.

MSHA is developing a program that will streamline the procedures by which manufacturers of diesel engines intended for use in outby areas of underground coal mines can gain Agency approval. The program will draw on the EPA approval programs for engines used in off-road applications. MSHA will continue to issue approvals for mining engines, but the application process will be abbreviated. Many of the provisions of part 7 are intended to ensure that engines continue to be manufactured in the same configuration and with the same emissions as the engine tested by MSHA. Procedures within the EPA approval programs reach the same end. Additionally, EPA has the resources and the regulatory authority to conduct an extensive quality assurance program to monitor emissions from production engines. In addition to streamlining the application process, MSHA will establish a program under which the engine emission tests conducted for EPA approval will satisfy the part 7 testing requirements. The test cycles under which emissions are tested for both MSHA and EPA are identical, and the gaseous emission results from the EPA tests can be used to establish the ventilating air quantity that appears on the engine approval plate and is referenced in mine ventilation regulations. MSHA will announce the specifics of the program when it is finalized. A listing of MSHA approved nonpermissible engines has been provided on MSHA's Internet web site. This listing can be accessed at the following address: http://www.msha.gov/S&HINFO/DESLREG/1909a.HTM.

Many underground metal and nonmetal mines are accustomed to employing front end loaders, haulage trucks, and other production equipment that is developed for, and primarily marketed to the surface mining and construction industries. Likewise, where conditions permit, underground metal and nonmetal mines often employ support vehicles such as pickup trucks, sport utility vehicles, and other small to medium sized trucks that are developed for, and primarily marketed to the surface over-the-road market. Mine operators employ this equipment because it is significantly less costly than purpose-built underground mining equipment, which has special mine-duty features and is produced in relatively low volume.

The engines in newly manufactured surface off-road equipment and over-the-road vehicles are already required to comply with EPA dpm emission regulations. EPA regulations are fashioned in a Tier structure whereby engines in designated horsepower ranges are required to meet increasingly stringent emissions levels. By changing the final rule as indicated above to accept engines meeting or exceeding applicable particulate emission requirements of the EPA, MSHA is, in essence, allowing mine operators to continue the long-standing and cost-effective practice of employing standard off-road equipment and over-the-road vehicles underground (if they are equipped with engines meeting the appropriate EPA requirements), without requiring potentially costly retrofits of approved engines. This change will enable mine operators and mine workers to gain the added benefits of engines that incorporate the most recent emission reducing technology.

Laboratory testing to certify that an engine meets the applicable EPA particulate matter limit or MSHA approval requirements is not the responsibility of the mine operator. MSHA approved engines carry an approval plate so they are easy to distinguish. Engines produced after the date indicated in the Table incorporated into 5067(b) will meet the EPA requirements for the listed category of engines.

Engines in diesel-powered ambulances and fire-fighting equipment are exempted from these requirements. This exemption is identical with that in the rule for diesel-powered equipment in underground coal mines. The rationale for this exemption is that the usage of these vehicles and equipment is so limited that their contribution to overall dpm levels in a mine is negligible. MSHA wishes to caution mine operators, however, that this exemption is intended to apply only to equipment that is used exclusively as an ambulance or fire fighting equipment. This exemption does not apply to vehicles and equipment that are normally used for other purposes, but serve as an ambulance or fire fighting equipment in the event of an accident or mine emergency.

Section 57.5070 Miner Training

Section 57.5070 requires any miner ''who can reasonably be expected to be exposed to diesel emissions'' be trained annually in: (a) The health risks associated with dpm exposure; (b) the methods used in the mine to control dpm concentrations; (c) identification of the personnel responsible for

maintaining those controls; and (d) actions miners must take to ensure the controls operate as intended. The final rule is the same as that proposed, and is identical to the rule being established for underground coal miners through MSHA's rulemaking limiting dpm concentrations in underground coal mines.

The purpose of these requirements is to promote miner awareness. Exposure to diesel particulate is associated with a number of harmful effects as discussed in Part III of this preamble, and the safe level is unknown. Miners who work in mines where they are exposed to this risk ought to be reminded of the hazard often enough to make them active and committed partners in implementing actions that will reduce that risk.

The training need only be provided to miners who can reasonably be expected to be exposed at the mine. The training is to be provided by operators; hence, it is to be without fee to the miner.

The rule places no constraints on the operator as to how to accomplish this training. MSHA believes that the required training can be provided at minimal cost and minimal disruption. The proposal would not require any special qualifications for instructors, nor would it specify the hours of instruction.

Instruction could take place at safety meetings before the shift begins. Devoting one of those meetings to the topic of dpm would be a very easy way to convey the necessary information. Simply providing miners with a copy of MSHA's ''Toolbox'' and, a copy of the plan, if a control plan is in effect for the mine, and reviewing these documents, can cover several of the training requirements. One-on-one discussions that cover the required topics are another approach that can be used.

Operators could also choose to include a discussion on diesel particulate matter emissions in their Part 48 training, provided the plan is approved by MSHA. There is no existing requirement that Part 48 training include a discussion of the hazards and control of diesel emissions. While mine operators are free to cover additional topics during the Part 48 training sessions, the topics that must be covered during the required time frame may make it impracticable to cover the additional material on dpm. Where adequate time is available at mines using diesel-powered equipment, operators would be free to include the dpm instruction in their Part 48 training plans. Since inclusion of dpm-related training in Part 48 training plans is not explicitly prohibited in the final rule, MSHA does not believe special language is required to permit this practice.

The final rule does not require the mine operator to separately certify the completion of the dpm training, but some evidence that the training took place would have to be produced upon request. A serial log with the employee's signature is an acceptable practice. To assist mine operators with this training requirement, it is MSHA's intent to develop an instructor's guide and corresponding training materials.

A few comments were received on § 57.5070, including the suggestion that such training be included under Part 48, and the opposing view that such training be independent of Part 48. Arguments in favor of including the training under Part 48 focused on the need to simplify the rule by not requiring separate diesel particulate emissions training and training recordkeeping. Arguments opposed focused on the difficulty of including more subject matter into a Part 48 training plan that is already overfilled. It was also noted that Part 48 training requires MSHA-certified instructors. By separating Part 48 training from the training required under § 57.5070, mine operators would have greater flexibility in choosing instructors.

MSHA believes the final rule satisfies both positions because inclusion of the specified diesel particulate emissions training topics under Part 48 training is neither required nor prohibited. Mine operators wishing to incorporate diesel emissions training in their Part 48 training plan are free to do so, whereas those wishing to conduct diesel emissions training separate from Part 48 training are equally free to choose that option. MSHA believes it is significant that none of the commenters discounted the importance of providing dpm-exposed miners with such training; their comments only addressed the mechanics of how such training should be delivered.

In its preamble to the proposed rule, MSHA specifically invited comment as to whether special language should be included in the final rule that would expressly permit required dpm training to be incorporated into Part 48 training. Only one commenter responded, expressing the view that special language was not necessary. Therefore, MSHA did not change this provision in the final rule.

Another commenter suggested that training required under § 57.5070 incorporate mandatory coverage of underground metal and nonmetal mine ventilation, that such training address auxiliary ventilation and the use of elementary ventilation measurement instruments, and that similar training be mandatory for first and second line supervisors.

MSHA agrees that ventilation is an important topic and that ventilation can have a significant effect on dpm concentrations underground. However, MSHA believes it would be inappropriate to specify the content of dpm-related miner training to the level of detail suggested by the commenter. Since MSHA allows mine operators considerable freedom to choose dpm control measures, MSHA expects significant variability from mine to mine in the mix of controls selected. For example, some mines may rely heavily on ventilation to comply with the applicable concentration limit, but other mines may rely more on enclosed cabs or diesel particulate filters. As a result, the most important training subject or subjects at one mine could be quite different at another mine.

By requiring training in the health risks associated with dpm exposure, the methods used in the mine to control dpm concentrations, identification of the personnel responsible for maintaining those controls, and the actions miners must take to ensure the controls operate as intended, MSHA believes it has established performance-based training requirements that are applicable to all mines.

As with the proposed rule, the final rule does not require the mine operator to separately certify the completion of dpm training, but some evidence that the training took place will have to be produced upon MSHA request. In this regard, as noted in the preamble to the proposed rule, a serial log with the employee's signature is an acceptable practice. Nevertheless, some commenters complained that the recordkeeping requirements in the training provisions are burdensome, and don't reduce diesel emissions. MSHA believes that dpm training is an essential element of a comprehensive dpm control program because miners who are fully informed are more apt to become active and committed partners in implementing an effective dpm control strategy. In this way, training can have an indirect, yet substantive and positive influence on reducing dpm exposure. The corresponding recordkeeping requirements are important, because the records are the means by which MSHA can insure that the mine operator is complying with the training requirements.

As noted in the preamble to the proposed rule, to assist mine operators with this training requirement, it is MSHA's intent to develop an instruction outline that mine operators can use as

a guide for training personnel. Instruction materials will be provided with the outline.

Section 57.5071 Environmental Monitoring

The final rule requires mine operators to monitor as often as necessary to effectively evaluate, under conditions that can be reasonably anticipated in the mine—(1) whether the concentration of dpm in an area where miners normally work or travel exceeds the applicable concentration limit; and (2) the average full shift airborne concentration at any position or on any person designated by the Secretary. This section also requires operators to provide affected miners and their representatives with notice and an opportunity to observe monitoring, to initiate corrective action by the next work shift should monitoring reveal a violation and to promptly complete such action, and requires certain posting and recordkeeping. The final rule is the same as the proposed rule.

Operator's Monitoring Responsibility. Section 57.5071(a) requires mine operators to monitor the underground mine environment to insure dpm concentrations are within compliance limits wherever the limits apply. Sampling, which could be area sampling, personal sampling, or occupational sampling, is required as often as necessary to ''effectively determine''—under conditions that can be reasonably anticipated in the mine—(1) whether the dpm concentration in any area of the mine where miners normally work or travel exceeds the applicable limit; and (2) the average full shift airborne concentration at any position or on any person designated by the Secretary.

This requirement is similar to existing § 57.5002 which requires mine operators to conduct dust, gas, mist, and fume surveys as frequently as necessary to determine the adequacy of control measures, and to existing § 62.110(a) and (b) which requires mine operators to measure each miner's noise dose sufficient to determine continuing compliance with the established noise limits. Under § 57.5071(a), mine operators are required to monitor dpm concentrations in much the same way they are already required to monitor dust, gas, mist, fume, and noise.

There are three important aspects of this operator monitoring requirement.

First, the responsibility for dpm monitoring rests with the mine operator, not with MSHA. Mine operators cannot rely on MSHA inspectors to conduct dpm monitoring whenever and wherever necessary to ensure compliance with the applicable dpm concentration limit. The purpose of operator monitoring is to determine continuing compliance, whereas the purpose of MSHA sampling is to identify non-compliance. MSHA sampling is neither intended for, nor capable of determining continued compliance.

Second, the information gathered through operator monitoring is to be used by the operator to determine whether action is necessary to maintain compliance anywhere the applicable concentration limits apply in the mine. Gathering dpm concentration data, though necessary, is not the final goal in itself. The reason for gathering this information is so it can be used by the mine operator to assess the effectiveness of dpm control measures. Sampling results which indicate non-compliance should prompt the mine operator to initiate whatever actions are required (i.e., implementation of appropriate engineering controls and work practices) to achieve compliance wherever the applicable concentration limits apply.

Third, this requirement ensures special attention will be focused on locations or persons known to MSHA to have a significant potential for overexposure to dpm.

The obligation of operators to ''effectively determine'' dpm concentrations in a mine is a separate obligation from that to keep dpm levels below the established limit, and can be the basis of a separate citation from MSHA. The final rule is performance-oriented in that the regularity and methodology used to make this evaluation are not specified. However, MSHA expects mine operators to sample with such frequency that they and the miners working at the mine site are aware of dpm levels in their work environment. In this regard, MSHA's own measurements will assist the Agency in verifying the effectiveness of an operator's monitoring program. If an operator is ''effectively determining'' the concentration of dpm at designated positions, for example, MSHA would not expect to regularly record concentrations above the limit when it samples at that location. If MSHA does find such a problem, it will investigate to determine how frequently an operator is sampling, where the operator is sampling, and what methodology is being used, so as to determine whether the obligation in this section is being fulfilled. (See previous discussion in this Part in the portion of § 57.5062 that addressed ''Demonstration of plan effectiveness'' for further information on the number of samples required to demonstrate continuing compliance.)

Operator Monitoring Methods. The final rule requires that full-shift diesel particulate concentrations be determined during periods of normal production or normal work activity in areas where miners work or travel. The rule does not specify a particular monitoring method or frequency; rather, the rule is performance-oriented. Operators may, at their discretion, conduct their monitoring using the same sampling and analytical method as MSHA, or they may use any other method that enables that mine to ''effectively determine'' the concentrations of dpm.

As required by § 57.5061, MSHA will collect samples using a respirable dust sampler equipped with a submicrometer impactor, and use NIOSH Method 5040, the sampling and analytical method that NIOSH has developed for accurately determining the concentration of total carbon, to determine compliance. Operators who must comply with the terms of a diesel particulate control plan pursuant to § 57.5062 must, as noted in the requirements of that section, use the same sampling and analytical method as MSHA to verify plan effectiveness; monitoring performed for that purpose would probably meet the obligation under § 5071 if it is done with enough sufficiency to meet the obligation under § 57.5062(c). But the method may not be necessary to effectively determine dpm in some mines for purposes of § 57.5071(a). For example, dpm measurements in limestone, potash and salt mines could be determined using the RCD method, since there are no large carbonaceous particles present that would interfere with the analysis. For hydrated minerals such as gypsum and trona, a two-step RCD method would be necessary, wherein the first step would elevate the temperature of the sample sufficient to cause dehydration (105 °C). The sample is then reweighed, and the conventional RCD analysis procedure is followed. Such estimates can be useful in determining the effectiveness of controls and where more refined measurements may be required.

Of course, mine operators using the RCD or size-selective methods to monitor their diesel particulate concentrations would have to convert the results to a TC equivalent to ascertain their compliance status. At the present time, MSHA has no conversion tables for this purpose, however a simple conversion approach would be to adjust the sampling result to the corresponding estimated whole dpm concentration, then multiply that value by 0.8. In most cases, the other methods will provide a good indication of

whether controls are working and whether further action is required.

Part II of this preamble provides information on monitoring methods and their constraints, and on laboratory and sampler availability.

One commenter observed that area sampling outside of an enclosed cab would defeat the purpose of installing the cab, and would diminish the status of such a cab, which is a recognized engineering control, to that of personal protective equipment, which is prohibited under the rule. MSHA agrees that area sampling is inappropriate where miners are protected by enclosed cabs with filtered breathing air and no other miners are required to work in the area outside of the cab. As discussed under section 5061(c)(3), area sampling by MSHA for compliance purposes would not be conducted outside of an enclosed cab unless miners are working in the area outside of such cabs, and MSHA would urge operators to follow the same approach. Also, as noted in discussing that section, personal sampling within cabs operated by smokers should only be conducted if the equipment operator agrees not to smoke during the sampling period.

Observation of Monitoring. Section 103(c) of the Mine Act requires that:

> The Secretary, in cooperation with the Secretary of Health, Education, and Welfare, shall issue regulations requiring operators to maintain accurate records of employee exposures to potentially toxic materials or harmful physical agents which are required to be monitored or measured under any applicable mandatory health or safety standard promulgated under this Act. Such regulations shall provide miners or their representatives with an opportunity to observe such monitoring or measuring, and to have access to the records thereof.

In accordance with this legal requirement, § 57.5071(b) of the final rule requires a mine operator to provide affected miners and their representatives with an opportunity to observe exposure monitoring required by this section. Mine operators must give prior notice of the date and time of intended monitoring so that affected miners and their representatives can exercise their right to observe the monitoring if they so choose.

Comments addressing § 57.5071(b) questioned the meaning of the terms ''miner's representative'' and ''affected miners,'' and objected to paying miners to observe dpm monitoring.

MSHA intends for miner's representative to mean any authorized representative of the miners. A representative of the miners could, but does not necessarily have to be, a representative of a certified union. Limiting representatives of miners to certified unions is a violation of the Mine Act and departs from previous MSHA practice.

MSHA intends for affected miners to mean the miners that are potentially exposed to the diesel particulate matter being monitored. The commenter suggested that this provision ''* * * leaves too much for interpretation. How many employees may observe? For how long?'' Consistent with the Mine Act, MSHA does not intend to limit the number of miners who may observe dpm monitoring, however, such miners need not be paid if, as a result of observing the monitoring, they are not performing their jobs.

Corrective Action if Concentration Is Exceeded. Section 57.5071(c) provides that if any monitoring performed under this section indicates that the applicable dpm concentration limit has been exceeded, an operator shall initiate corrective action by the next work shift, promptly post a notice of the corrective action being taken and promptly complete such corrective action.

The Agency wishes to emphasize that operator monitoring of dpm concentrations would not take the place of MSHA sampling for compliance purposes; rather, this requirement is designed to ensure the operator checks dpm concentrations on a more regular basis than is possible for MSHA to do. Paragraph (c) provides that if sampling results indicate the concentration limit has been exceeded in an area of a mine, an operator would initiate corrective action by the next work shift and promptly complete such action. Paragraph (c) does not require an operator to establish a dpm control plan. The establishment of a dpm control plan is triggered by a non-compliance determination based on sampling conducted by the Secretary.

In certain types of cases (*e.g.,* 30 CFR 75.323), MSHA has required that when monitoring detects a hazardous level of a substance, miners must be immediately withdrawn from an area until abatement action has been completed. Although MSHA did not include such a requirement in the final rule, MSHA in its proposal did solicit comment from the mining industry concerning this practice, especially in light of the evidence presented on the various risks posed by exposure to diesel particulate, including material presented in the preamble to the proposal that acute short-term increases in exposure can pose significant risks to miner health. The comments that were received in response to this solicitation were opposed to a provision requiring immediate withdrawal.

The agency also specifically asked for comments on three other points (63 FR 58189, 58190). First, the agency noted that it welcomed comments as to what guidance to provide with respect to corrective actions required where an operator is not using the total carbon analytical method. Second, the agency noted it welcomed comment as to whether personal notice of corrective action would be more appropriate than posting, given the health risks involved. Third, the agency solicited comment on whether clarification of the proposed requirement was needed in light of the fact that operators using more complex analytical procedures (*e.g.,* the total carbon method) may not receive the results for some time period after the posting has taken place.

No comments addressing these points were received.

Posting of Sample Results. Section 57.5071(d)(1) requires that monitoring results be posted on the mine bulletin board within 15 days of receipt, and remain posted for 30 days. A copy of the results must also be provided to the authorized miners' representative. Posting of the results will ensure that miners are kept aware of the hazard so they can actively participate in efforts to control dpm.

Comments that addressed this paragraph recommended that sampling results should not be given to the representative of the miners because this information is private, and recommended that mine operators should not be cited for posting sampling results that exceed the applicable concentration limit.

MSHA disagrees with the assertion that dpm sampling results are private, and therefore, such results should not be given the representative of the miners. The Mine Act clearly states that miners or their representatives have a legal right to access to exposure monitoring information.

Regarding the question of MSHA issuing a citation based on a mine operator posting sampling results that exceed the applicable concentration limit, it is not MSHA's intent to issue a citation under these circumstances. If such sampling indicates that dpm levels exceed the applicable concentration limit, a citation may be issued if the mine operator fails to initiate corrective action by the next work shift, as required under § 57.5071(c). However, mine operator sampling results that exceed the applicable limit is not, by itself, a violation.

MSHA recognizes that this is an important point, and reiterates that, as indicated in § 57.5061, MSHA itself is to conduct compliance sampling.

Retention of Sample Results. Section 57.5071(d)(2) requires that records of the sampling method and the sample results themselves be retained by mine operators for five years. This is because the results from a monitoring program can provide insight as to the effectiveness of controls over time, and provide a history of occupational exposures at the mine.

In the preamble to the proposed rule, MSHA welcomed comments on the sample retention period appropriate for the risks involved. None were received.

In the preamble to the proposed rule, MSHA also asked for comments regarding the advisability of instituting a system of medical surveillance of miners exposed to dpm to identify miners suffering ill effects of dpm exposure, and the subsequent medical removal of miners who are determined to be suffering such ill effects. The comments received in response to this request suggested that medical surveillance for excessive dpm exposure is not feasible at this time because the appropriate biological tests or markers do not exist. One commenter observed that they were, ''* * * unaware of any recognized or generally accepted examinations or tests for detecting whether miners are suffering from ill effects as a result of diesel particulate or exhaust exposure. This view is supported by EPA's Health Assessment Document for Diesel Emissions which states, 'There is no single medical test to determine if DP exposure has occurred. Many symptoms of episodic DP exposure are similar to symptoms caused by other agents or, in some cases, onset of a common cold. Invasive sampling of particle deposits in the upper respiratory tract or lung could be done, yet such particles may not be readily distinguishable from particulate matter from other sources' [EPA, 1998].'' MSHA agrees with these commenters that appropriate medical testing protocols are not currently available. Therefore, provision for neither medical surveillance nor medical removal protections have been incorporated into the final rule.

Section 57.5075 Diesel Particulate Records

Various recordkeeping requirements are set forth in the provisions of the final rule. For the convenience of the mining community, these requirements are also listed in a table entitled ''Diesel Particulate Recordkeeping Requirements,'' which can be found in § 57.5075(a). Each row involves a record that must be kept. The section requiring the record be kept is noted, along with the retention time.

This approach—having a summary table of recordkeeping requirements included in various sections of the rule—is identical to that taken in the proposed rule. MSHA indicated in the preamble to the proposed rule that it would welcome input from the mining community as to whether it liked this approach or found it duplicative or confusing, however, no comments were received.

Location of Records. Section 57.5075(b)(1) provides that any record which is required to be retained at the mine site may be retained elsewhere if it is immediately accessible from the mine site by electronic transmission. Compliance records need to be accessible to an inspector so they can be viewed during the course of an inspection, as the information in the records may determine how the inspection proceeds. If the mine site has a fax machine or computer terminal, there is no reason why the records cannot be maintained elsewhere. MSHA's approach in this regard is consistent with Office of Management and Budget Circular A–130.

One commenter, though supporting the concept of off-site electronic records storage, questioned MSHA's intent relative to the term ''immediately accessible.'' As noted above, MSHA intends that records maintained off-site be made available to an MSHA inspector so the information can be used to guide inspection decisions. Thus, undue delay in retrieving this information from off site electronic storage would impede an inspection, and would not be permitted. If the records are maintained in hardcopy form at an off-site location, and considering the time required to contact off-site personnel to request the records, for those personnel to locate and remove the records from the files, and to fax the records to the mine site, a delay of one or two hours would not be unreasonable. If records are maintained in an off-site electronic database, it is reasonable to assume they could be electronically transmitted to the mine site even faster; perhaps one hour or less.

These time frames are in contrast to the requirement in MSHA's new noise regulation for noise records to be accessible to the MSHA inspector, but not ''immediately accessible.'' The guideline established in the Preamble to the final noise rule states that records must be provided to the MSHA inspector within one business day or less (p. 49625).

The commenter notes further that, ''Even with Y2K compliant systems, computer and electronic transmission equipment is not 100% reliable, especially in remote mining environments.'' MSHA agrees that an insistence on 100% reliability of computer and electronic transmission equipment is unreasonable. However, MSHA will not accept chronic computer or electronic transmission problems as a justification for the repeated denial of timely access to the required records. If chronic computer or electronic transmission problems make ''immediate'' access to records problematic, such records would have to be kept at the mine site.

Records Access. Section 57.5075(b) also covers records access. Consistent with the statute, upon request from an authorized representative of the Secretary of Labor, the Secretary of Health and Human Services, or from the authorized representative of miners, mine operators are to promptly provide access to any record listed in the table in this section. A miner, former miner, or, with the miner's or former miner's written consent, a personal representative of a miner, is to have access to any exposure record required to be maintained pursuant to § 57.5071 to the extent the information pertains to the miner or former miner. Upon request, the operator must provide the first copy of such record at no cost. Whenever an operator ceases to do business, that operator would be required to transfer all records required to be maintained by this part to any successor operator.

General Effective Date of Part 57. The rule provides that unless otherwise specified, its provisions take effect 60 days after the date of promulgation of the final rule. Thus, for example, the requirements to implement certain work practice controls (*e.g.,* fuel type) go into effect 60 days after the final rule is published.

A number of provisions of the final rule contain separate effective dates that provide more time for technical support. For example, the initial concentration limit for underground metal and nonmetal mines would be delayed for 18 months.

A general outline of effective dates is summarized in Part I of this preamble.

Additionally, the paperwork provisions will not become effective until approved by the Office of Management and Budget.

V. Adequacy of Protection and Feasibility of Final Rule; Alternatives Considered

The Mine Act requires that in promulgating a standard, the Secretary, based on the best available evidence, shall attain the highest degree of health

and safety protection for the miner with feasibility a consideration.

Overview. This part begins with a summary of the pertinent legal requirements, followed by a general profile of the economic health and prospects of the metal and nonmetal mining industry.

The final rule establishes a concentration limit for dpm, supplemented by monitoring and training requirements. An operator in the metal and nonmetal sector would have the flexibility to choose any type or combination of engineering controls to keep dpm levels at or below the concentration limit. This part evaluates the final rule to ascertain if, as required by the statute, it achieves the highest degree of protection for underground metal and nonmetal miners that is feasible, both technologically and economically, for underground metal and nonmetal mine operators to provide.

Several regulatory alternatives to the final rule were also reviewed by MSHA in light of the record. The Agency has concluded that compliance with these alternatives either provide less protection than the feasible approach being adopted, or are not technologically or economically feasible for the underground metal and nonmetal industry as a whole at this time.

Pertinent Legal Requirements. Section 101(a)(6)(A) of the Federal Mine Safety and Health Act of 1977 (Mine Act) states that MSHA's promulgation of health standards must:

> * * * [A]dequately assure, on the basis of the best available evidence, that no miner will suffer material impairment of health or functional capacity even if such miner has regular exposure to the hazards dealt with by such standard for the period of his working life.

The Mine Act also specifies that the Secretary of Labor (Secretary), in promulgating mandatory standards pertaining to toxic materials or harmful physical agents, base such standards upon:

> * * * [R]esearch, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the miner, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws. Whenever practicable, the mandatory health or safety standard promulgated shall be expressed in terms of objective criteria and of the performance desired. [Section 101(a)(6)(A)].

Thus, the Mine Act requires that the Secretary, in promulgating a standard, based on the best available evidence, attain the highest degree of health and safety protection for the miner with feasibility a consideration.

In relation to feasibility, the legislative history of the Mine Act states that:

> * * *Section further provides that ''other considerations'' in the setting of health standards are ''the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws.'' While feasibility of the standard may be taken into consideration with respect to engineering controls, this factor should have a substantially less significant role. Thus, the Secretary may appropriately consider the state of the engineering art in industry at the time the standard is promulgated. However, as the circuit courts of appeal have recognized, occupational safety and health statutes should be viewed as ''technology-forcing'' legislation, and a proposed health standard should not be rejected as infeasible when the necessary technology looms in today's horizon. *AFL-CIO* v. *Brennan,* 530 F.2d 109 (1975); *Society of the Plastics Industry* v. *OSHA,* 509 F.2d 1301, *cert. denied,* 427 U.S. 992 (1975).

Similarly, information on the economic impact of a health standard which is provided to the Secretary of Labor at a hearing or during the public comment period, may be given weight by the Secretary. In adopting the language of [this section], the Committee wishes to emphasize that it rejects the view that cost benefit ratios alone may be the basis for depriving miners of the health protection which the law was intended to insure. S. Rep. No. 95–181, 95th Cong., 1st Sess. 21 (1977).

Court decisions have clarified the meaning of feasibility. The Supreme Court, in *American Textile Manufacturers' Institute* v. *Donovan* (OSHA Cotton Dust), 452 U.S. 490, 101 S.Ct. 2478 (1981), defined the word ''feasible'' as ''capable of being done, executed, or effected.'' The Court stated that a standard would not be considered economically feasible if an entire industry's competitive structure was threatened. According to the Court, the appropriate inquiry into a standard's economic feasibility is whether the standard is capable of being achieved.

Courts do not expect hard and precise predictions from agencies regarding feasibility. Congress intended for the ''arbitrary and capricious standard'' to be applied in judicial review of MSHA rulemaking (S.Rep. No. 95–181, at 21.) Under this standard, MSHA need only base its predictions on reasonable inferences drawn from the existing facts. MSHA is required to produce reasonable assessment of the likely range of costs that a new standard will have on an industry. The agency must also show that a reasonable probability exists that the typical firm in an industry will be able to develop and install controls that will meet the standard. See, *Citizens to Preserve Overton Park* v. *Volpe*, 401 U.S. 402, 91 S.Ct. 814 (1971); *Baltimore Gas & Electric Co.* v. *NRDC*, 462 U.S. 87 103 S.Ct. 2246, (1983); *Motor Vehicle Manufacturers Assn.* v. *State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29, 103 S.Ct. 2856 (1983); *International Ladies' Garment Workers' Union* v. *Donovan*, 722 F.2d 795, 232 U.S. App. D.C. 309 (1983), *cert. denied*, 469 U.S. 820 (1984); *Bowen* v. *American Hospital Assn.*, 476 U.S. 610, 106 S.Ct. 2101 (1986).

In developing a health standard, MSHA must also show that modern technology has at least conceived some industrial strategies or devices that are likely to be capable of meeting the standard, and which industry is generally capable of adopting. *United Steelworkers of America* v. *Marshall*, 647 F.2d 1189, 1272 (1980). If only the most technologically advanced companies in an industry are capable of meeting the standard, then that would be sufficient demonstration of feasibility (this would be true even if only some of the operations met the standard for some of the time). *American Iron and Steel Institute* v. *OSHA*, 577 F.2d 825, (3d Cir. 1978); see also, *Industrial Union Department, AFL-CIO* v. *Hodgson*, 499 F.2d 467 (1974).

Industry Profile. This industry profile provides background information about the structure and economic characteristics of the mining industry. It provides data on the number of mines, their size, the number of employees, and the diesel powered equipment used.

The Structure of the Metal/Nonmetal Mining Industry. MSHA divides the mining industry into two major segments based on commodity: (1) Coal mines and (2) metal and nonmetal (M/NM) mines. These segments are further divided based on type of operation (*e.g.,* underground mines or surface mines). MSHA maintains its own data on mine type, size, and employment, and the Agency also collects data on the number of independent contractors and contractor employees by major industry segment.

MSHA categorizes mines by size based on employment. For the past 20 years, for rulemaking purposes, MSHA has consistently defined a small mine to be one that employs fewer than 20 workers and a large mine to be one that employs 20 or more workers. To comply with the requirements of the Small

Business Regulatory Enforcement Fairness Act (SBREFA) amendments to the Regulatory Flexibility Act (RFA), however, an agency must use the Small Business Administration's (SBA's) criteria for a small entity-¾ for mining, 500 or fewer employees ¾ when determining a rule's economic impact.

Table V–1 presents the total number of small and large mines and the corresponding number of miners, excluding contractors, for the M/NM mining segment. The M/NM mining segment consists of metal mines (copper, iron ore, gold, silver, etc.) and nonmetal mines (stone including granite, limestone, dolomite, sandstone, slate, and marble; sand and gravel; and others such as clays, potash, soda ash, salt, talc, and pyrophyllite.) As Table II–1 indicates, 98 percent of all M/NM mines are surface mines, and these mines employ some 90 percent of all M/NM miners, excluding office workers. Table V–2 presents corresponding data on the number of independent contractors and their employees working in the M/NM mining segment.

TABLE V–1.—DISTRIBUTION OF M/NM MINE OPERATIONS AND EMPLOYMENT (EXCLUDING CONTRACTORS) BY MINE TYPE AND SIZE [a]

Size of M/NM mine [b]	Mine type			
	Underground	Surface	Office workers	Total M/NM
Fewer than 20 employees:				
Mines	134	9,635	.....	9,769
Employees	1,054	54,356	9,160	64,570
20 to 500 employees:				
Mines	124	1,419	.....	1,543
Employees	11,299	79,675	15,040	106,014
Over 500 employees:				
Mines	7	18	.....	25
Employees	4,594	16,836	3,543	24,973
All M/NM mines:				
Mines	265	11,072	.....	11,337
Employees	16,947	150,867	27,743	195,557

[a] Source: U.S. Department of Labor, Mine Safety and Health Administration, Office of Standards, Regulations, and Variances based on 1998 MS data, CM441/CM935LA cycle 1998/198. Data for Total Office workers from Mine Injury and Worktime Quarterly (1997 Closeout Edition) Table 2, p. 6.

[b] Based on MSHA's traditional definition, large mines include all mines with 20 or more employees. Based on SBA's definition, as required by SBREFA, large mines include only mines with over 500 employees.

TABLE V–2.—DISTRIBUTION OF M/NM CONTRACTORS AND CONTRACTOR EMPLOYMENT BY SIZE OF OPERATION [a]

Size of contractors [b]	Contractors			
	Underground	Surface	Office workers	Total
Fewer than 20 employees:				
Mines	399	2,783	.....	3,182
Employees	1,717	14,155	649	16,521
20 to 500 employees:				
Mines	36	349	.....	384
Employees	1,639	17,979	802	20,420
Over 500 employees:				
Mines	.....	3	.....	3
Employees	.....	2,560	105	2,665
Total contractors:				
Mines	434	3,135	.....	3,569
Employees	3,356	34,694	1,556	39,606

[a] Source: U.S. Department of Labor, Mine Safety and Health Administration, Office of Standards, Regulations, and Variances based on 1998 MS data, CT441/CT935LA cycle 1998/198. Data for total office workers from Mine Injury and Worktime Quarterly (1998 Closeout Edition) Table 6, p. 21.

[b] Based on MSHA's traditional definition, large mines include all mines with 20 or more employees. Based on SBA's definition, as required by SBREFA, large mines include only mines with over 500 employees.

The M/NM mining sector consists of about 80 different commodities including industrial minerals. There were 11,337 M/NM mines in the U.S. in 1998, of which 9,769 (86%) were small mines and 1,568 (14%) were large mines, using MSHA's traditional definition of small and large mines. Based on SBA's definition, however, only 25 M/NM mines (0.2%) were large mines.[1]

The data in Table V–1 indicate that employment at M/NM mines in 1998 was 195,557, of which 64,570 workers (33%) were employed by small mines and 130,987 miners (67%) were employed by large mines, using MSHA's definition. Based on SBA's definition, however, 170,584 workers (87%) were employed by small mines and 24,973 workers (13%) were employed by large mines. Using MSHA's definition, the average employment is 7 workers at a small M/NM mine and 84 workers at a

[1] U.S. Department of Labor, MSHA, 1998 Final MIS data CM441 cycle 1998/198.

large M/NM mine.[2] Using SBA's definition, there are an average of 15 workers in each small M/NM mine and 888 workers in each large M/NM mine.

Metal Mining. There are about 24 metal commodities mined in the U.S. Underground metal mines use a few basic mining methods, such as room and pillar and block caving. The larger mines rely more heavily on hydraulic drills and track-mounted haulage, and the smaller underground metal mines rely more heavily on hand-held pneumatic drills

Surface metal mines normally include drilling, blasting, and hauling; such processes are typical in all surface mines, irrespective of commodity types. Surface metal mines in the U.S. rank among some of the largest mines in the world.

Metal mines constitute 3 percent of all M/NM mines and employ 23 percent of all M/NM miners. Under MSHA's traditional definition of a small mine, 45 percent of metal mines are small, and these mines employ 2 percent of all miners working in metal mines. Using SBA's definition, 94 percent of metal mines are small, and they employ 53 percent of all miners working in metal mines.[3]

Stone Mining. In the stone mining subsector, there are eight different stone commodities, of which seven are further classified as either dimension stone or crushed and broken stone. Stone mining in the U.S. is predominantly by quarrying, with only a few slight variations. Crushed stone mines typically drill and blast, while dimension stone mines generally use channel burners, drills, or wire saws. Diesel powered-haulage is used to transfer the broken rock from the quarry to the mill where crushing and sizing are done.

Stone mines constitute 33 percent of all M/NM mines, and they employ 41 percent of all M/NM miners. Using MSHA's definition of a small mine, 71 percent of stone mines are small, and these mines employ 29 percent of all miners working in stone mines. Using SBA's definition, 99.9 percent of stone mines are small, and they employ 99 percent of all miners working in stone mines.[4]

Sand & Gravel Mining. Sand and gravel, for construction, is generally extracted from surface deposits using dredges or draglines. Further preparation involves washing and screening. As in other surface mining operations, sand and gravel uses diesel-driven machines, such as front-end loaders, trucks, and bulldozers, for haulage. The preparation of industrial sand and silica flour involves the use of crushers, ball mills, vibrating screens, and classifiers.

The sand and gravel subsector represents the single largest commodity group in the U.S. mining industry when the number of mining operations is being considered. Sand and gravel mines comprise 57 percent of all M/NM mines, and they employ 22 percent of all M/NM miners. Using MSHA's definition of a small mine, 95 percent of sand and gravel mines are small, and these mines employ 76 percent of all miners working in sand and gravel mines. Using SBA's definition, almost 100 percent of sand and gravel mines are small, and they employ approximately 42,800 miners.[5]

Other Nonmetal Mining. For enforcement and statistical purposes, MSHA separates stone and sand and gravel mining from other nonmetal mining. There are about 35 other nonmetal commodities, not including stone, and sand and gravel. Nonmetal mining uses a wide variety of underground mining methods such as continuous mining (similar to coal mining), in-situ retorting, block caving, and room and pillar. The mining method is dependent on the geologic characteristics of the ore and host rock. Some nonmetal operations use kilns and dryers in ore processing. Ore crushing and milling are processes common to both nonmetal and metal mining.

As with underground mining, there is a wide range of mining methods utilized in extracting minerals by surface mining. In addition to drilling and blasting, other mining methods, such as evaporation and dredging, are also utilized, depending on the ore formation.

''Other'' nonmetal mines comprise 7 percent of all M/NM mines, and they employ 14 percent of all M/NM miners. Using MSHA's definition of a small mine, 66 percent of other nonmetal mines are small, and they employ 12 percent of all miners working in these nonmetal mines. Using SBA's definition, 99 percent of other nonmetal mines are small, and they employ 92 percent of all miners working in these nonmetal mines.[6]

Economic Characteristics of the Metal/nonmetal Mining Industry. The value of all M/NM mining output in 1998 was estimated at $40 billion.[7] Metal mines, which include copper, gold, iron, lead, silver, tin, and zinc mines, contributed $17.8 billion. Nonmetal production was valued at $22.2 billion: $9.0 billion from stone mining, $5.2 billion from sand and gravel, and $8 billion from other nonmetals such as potash, clay, and salt.

The end uses of M/NM mining output are diverse. For example, iron and aluminum are used to produce vehicles and other heavy duty equipment, as well as consumer goods such as household equipment and soft drink cans. Other metals, such as uranium and titanium, have more limited uses. Nonmetals, like cement, are used in construction while salt is used as a food additive and for road deicing in the winter. Soda ash, phosphate rock, and potash also have a wide variety of commercial uses. Stone and sand and gravel are used in numerous industries and extensively in the construction industry.

A detailed economic picture of the M/NM mining industry is difficult to develop because most mines are either privately held corporations or sole proprietorships, or subsidiaries of publicly owned companies. Privately held corporations and sole proprietorships are not required to make their financial data available to the public. Parent companies are not required to separate financial data for subsidiaries in their reports to the Securities and Exchange Commission. As a result, financial data are available for only a few M/NM companies, and these data are not representative of the entire industry.

Adequacy of Miner Protection Provided by the Final Rule in Underground Metal and Nonmetal Mines. In evaluating the rule for this purpose, it should be remembered that MSHA has measured dpm concentrations in this sector as high as $5{,}570_{DPM}$ μg/m^3—a mean of 808_{DPM} μg/m^3. See Table III–1 and Figure III–2 in part III of the preamble. As discussed in detail in part III of the preamble, these concentrations place underground metal and nonmetal miners at significant risk of material impairment of their health,

[2] U.S. Department of Labor, MSHA, 1998 final MIS data CM441 cycle 1998/198.

[3] U.S. Department of Labor, Mine Safety and Health Administration, Office of Program Policy Evaluation, Mine Employment Size-Average Employment 1998.

[4] U.S. Department of Labor, Mine Safety and Health Administration, Office of Program Policy Evaluation, Mine Employment Size-Average Employment 1998.

[5] U.S. Department of Labor, Mine Safety and Health Administration, Office of Program Policy Evaluation, Mine Employment Size-Average Employment 1998.

[6] U.S. Department of Labor, Mine Safety and Health Administration, Office of Program Policy Evaluation, Mine Employment Size-Average Employment 1998.

[7] U.S. Department of Energy, Energy Information Administration, *Annual Energy Review 1998,* July 1999, pp. 3, 6, 142, 158, and 160.

and it does not appear there is any lower boundary to the risk. Accordingly, in accordance with the statute, the Agency has to set a standard which reduces these concentrations as much as is both technologically and economically feasible for this sector as a whole.

Specifically, the standard establishes a concentration limit on dpm. The concentration limit is the equivalent of about 200_{DPM} μg/m³ (as explained in Part IV, in the rule the concentration limit is expressed in terms of a restriction on the amount of total carbon because of the measurement system which MSHA will utilize for compliance sampling).

Alternatives considered. In order to ensure that the maximum protection that is feasible for the underground mining industry as a whole is being provided, the Agency has considered three alternatives that would provide greater protection: a lower concentration limit, a significantly shorter implementation period, and requiring certain categories of metal and nonmetal equipment to be filtered in addition to observing a concentration limit. In addition, the agency has considered whether the approach it is taking in underground coal mines would be feasible in this sector. Specific alternatives and approaches suggested by industry and labor are discussed in detail in part IV.

(1) *Establish a lower concentration limit for underground metal/nonmetal mines.* Based on the Agency's risk assessment, a lower concentration limit would provide more miner protection. The Agency has concluded, however, that at this time it would not be feasible for the underground metal and nonmetal sector to reach a lower concentration limit. The problem is not technological feasibility, but rather economic feasibility.

Technological feasibility of lower limit. In evaluating whether a lower concentration limit is technologically feasible for this sector, MSHA considered several examples of real-world situations. These examples, and a detailed description of the methodology by which they were developed, were published in the preamble to the proposed rule (65 FR 58198 *et seq.*). The examples were based on data about equipment and ventilation from several actual underground metal and nonmetal mines: a salt mine; an underground limestone mine that operates two completely different shifts, one for production, and one for support; and a multi-level underground gold mine. The data was placed into a computer model to estimate the ambient dpm that would remain in a mine section after the application of a particular combination of control technologies. The details of this computer model, referred to as ''The Estimator'', has subsequently been published in the literature (Haney and Saseen, *Mining Engineering,* April 2000). The results for the salt and limestone mines were written up in detail and placed into MSHA's record, with actual mine identifiers removed; the study of the underground gold mine is based on information supplied by inspectors, and all available data was presented in the preamble to the proposed rule.

MSHA had picked these mines because the Agency originally thought the conditions there were such that these mines would have great difficulty in controlling dpm concentrations. As the results indicated, however, even in these apparently difficult situations the concentration of dpm could be lowered to well below 200_{DPM} μg/m³ with readily available control techniques. Moreover as noted above, MSHA can adopt a rule which is not feasible for every mine; the standard is that the rule be feasible for the industry as a whole.

MSHA did receive comments on the Estimator. However, no specific examples of its application were received nor comments taking issue with the examples discussed above. Specific comments received on the Estimator are addressed in part IV.

Economic feasibility of lower concentration limit. MSHA estimates that it will cost the underground metal and nonmetal industry about $25.1 million a year to comply with a concentration limit of 160_{TC} μg/m³ (200_{DPM} μg/m³). For an average underground metal and nonmetal dieselized mine that uses diesel powered equipment, this amounts to about $128,000 per year.

The assumptions used in preparing the cost estimates for the final review are discussed in detail in the Agency's REA. They are based on a careful review of the evidence on the capabilities of various controls, and a careful review of an economic analysis submitted on behalf of several industry associations. That analysis estimated costs to be three times as high as MSHA's initial estimate. MSHA's analysis and the industry analysis agree on many of their assumptions; however, MSHA believes the industry analysis to be an overestimation primarily because it failed to properly optimize.

In general, MSHA has concluded that:

- The interim standard of 400_{TC} μg/m³ (500_{DPM} μg/m³) will be met primarily through the use of filters, but with cabs and ventilation in certain instances; and
- The final standard of 160_{TC} μg/m³ (200_{DPM} μg/m³) will be met through the use of more filters, ventilation changes, and the turnover in equipment and engines to less polluting models that will have occurred by the time the final standard goes into effect.

Based on its cost estimates, the Agency has concluded that this sector would not find it economically feasible to reduce dpm concentrations to a lower limit at this time. The incremental cost of additional controls would rise sharply if the industry were required to reach a substantially lower concentration level. It would begin to be necessary to retrofit cabs on equipment that was not designed with cabs and/or did not have off-the-shelf parts—at a cost per unit nearly three times as great as the costs for more limited retrofitting of suitably designed equipment. Additional ventilation improvements (*e.g.,* new shafts) could easily run into the millions of dollars—compared with the $300,000 estimate for more limited ''major system improvements'' used in the cost analysis. Additional replacement of engines beyond the natural turnover included in the baseline could run as high as $27,500 for the engine itself, with additional costs possibly as high as $65,000 for equipment modifications and installation.

(2) *Significantly shorten the phase-in time to reach the final concentration limit in underground metal/nonmetal mines.* Under the rule, there is a phase-in period for a dpm concentration limit. Operators have 18 months to reduce dpm concentrations in areas of the mine where miners work or travel to 400_{TC} μg/m³ (500_{DPM} μg/m³), and up to 60 months in all to reduce dpm concentrations in those areas to 160_{TC} μg/m³ (200_{DPM} μg/m³).

MSHA has established this phase-in period because it has concluded that it is economically infeasible for the underground metal and nonmetal mining industry as a whole to implement the requirements sooner. The costs of the rule would increase significantly were the final concentration limit to become effective significantly sooner. For example, the turnover of the fleet to less polluting engines would not be as complete by the time the final limit goes into effect; hence, operators would be required to purchase new engines ahead of schedule. Moreover, a substantial portion of the costs to implement these provisions were calculated using a 5-year discounting process to reflect the phase-in schedule.

Technological feasibility problems might also be more frequent with a quicker implementation schedule. The rule includes a provision for a special time extension to deal with unique situations; shortening the normal time frame available to this sector would tend to increase the frequency upon which operators would have to apply for such extensions.

Accordingly, MSHA has concluded that, for the underground metal and nonmetal sector as a whole, a significantly accelerated approach would not be feasible.

(3) *In addition to a concentration limit, require certain types of equipment to utilize an 80% efficiency filter.* This approach would help reduce dpm concentrations in localized areas of a mine, and ensure that problems with ventilation controls will have less of an impact on miner exposures. Most filters can meet the 80% requirement. The requirement could be applied: (a) just to loading and hauling equipment (*e.g.,* trucks and loaders); (b) to the equipment in (a) plus equipment used in the production process (*e.g.,* drills, powered trucks); (c) to the equipment in (a) and (b) and also direct support equipment (*e.g.,* scalers, lube trucks, generators, compressors and pumps); or (d) to all equipment except personnel carriers and supply trucks.

Such an approach would limit operator flexibility on controls—the broader the requirement, the less the flexibility. And it would increase expense, since the most efficient way to achieve compliance with the concentration limit might well be another type of control (*e.g.,* new engine, cab, ventilation, etc.). Accordingly, MSHA has determined that this approach would be infeasible for this sector at this time.

(4) *In lieu of a concentration limit, require certain types of equipment to reach tailpipe limits.* In the underground coal sector, MSHA is requiring various categories of equipment to meet specific tailpipe limits. Compliance with these limits is determined through laboratory tests of engines and control devices. This approach avoids questions about MSHA in-mine compliance sampling which have been the focus of much discussion in coal mining. Accordingly, MSHA considered requiring a similar approach in underground metal and nonmetal mines. However, the agency determined that this would not be practical, because the engines in the current fleet are not approved; hence, the agency lacks information on their emission rates, a key piece of information needed to implement a tailpipe standard. Moreover, in many cases a cab or ventilation change might be a more effective solution to a localized dpm concentration in an underground metal and nonmetal mine than a change in the engine or emission control device—and perhaps less expensive for equipment of this size. One of the advantages of a concentration limit is the flexibility of controls that the operator can apply to meet the limit.

Feasibility of the final rule for underground metal and nonmetal mining sector. The Agency has carefully considered both the technological and economic feasibility of the rule being promulgated for the underground metal and nonmetal mining sector as a whole.

Technological feasibility of final rule. There are arguably two separate issues with respect to technological feasibility—(a) the existence of technology that can accurately and reliably measure dpm concentration levels in all types of underground metal and nonmetal mines; and (b) the existence of control mechanisms that can bring dpm concentrations down to the proposed limit in all types of underground metal and nonmetal mines. Both have been addressed elsewhere in this preamble.

The first of these questions, concerning measurement, is reviewed in considerable detail in section 3 of Part II and in the discussion of section 57.5061 of the rule in Part IV. For the reasons set forth in those discussions, MSHA has concluded that with the use of a submicrometer sampler as required by the final rule, and with a sampling strategy that avoids the inteferences which can compromise individual samples in certain situations, it does have a technologically feasible measurement method that operators and the agency can use to determine if the limits established by the standard are in fact being met.

The second of these questions, concerning controls, is discussed earlier in this part [See ''(1) *Establish a lower concentration limit for underground metal/nonmetal mines*'']. MSHA has performed various studies which suggest that even in the most difficult situations, it is technologically feasible for operators to meet the rule's final concentration limit. In fact, these studies suggest it is technologically feasible for operators in this sector to reduce their dpm concentrations to an even lower concentration limit. In addition, as discussed in section 6 of Part II of this preamble, considerable progress has been made in recent years on the effectiveness of filters and cabs. MSHA very carefully reviewed this information with reference to the kinds of engines and equipment found in underground metal and nonmetal mines, and their ventilation, and is confident that the final rule is technologically feasible.

Although the agency has reached this conclusion, and moreover knows of no mine that cannot accomplish the required reductions in the permitted time, it has nevertheless retained in the final rule a provision that any underground metal or nonmetal mine may have up to an additional two years to install the required controls should it find that there are unforseen technological barriers to timely completion. A detailed discussion of the requirements for obtaining approval for such an extension of time to comply is provided in part IV of the preamble.

Economic Feasibility. MSHA estimates that the rule would cost the underground metal and nonmetal sector about $25.1 million a year even with the extended phase-in time. The costs per underground dieselized metal or nonmetal mine are estimated to be about $128,000 annually. The yearly cost of the final rule represents about 0.67 percent of yearly industry revenue. MSHA uses a one-percent ''screen'' of costs relative to revenues as a presumptive benchmark of economic feasibility. Therefore, since the cost of the rule is less than one percent of revenues, MSHA anticipates that (subject to contrary evidence) the rule is economically feasible for the dieselized underground M/NM mining sector as a whole. Note, however, that the costs are sufficiently close to one percent of revenues that the rule could threaten the economic viability of affected mines on the economic margin and that more costly regulatory alternative could conceivably threaten the economic viability of a substantial fraction of this mining sector.

As explained in the REA, nearly all ($24.1 million) of the anticipated yearly costs would be investments in equipment to meet the interim and final concentration limits. While operators have complete flexibility as to what controls to use to meet the concentration limits, the Agency based its cost estimates on the assumption that operators will ultimately need the following to get to the final concentration limit: (a) Fifty percent of the fleet will have new engines (these new engines do not impact cost of the rule). It is expected that the new engines will be more expensive and technologically superior to the ones that they replace. One aspect of this technological superiority will be substantially lower DPM emissions. It does not follow, however, that the

greater expense of these engines is an impact of this rule. Mine operators will not replace existing engines with the same type or model of engine. New engine technology makes engines much more efficient and productive than existing older engines. Particularly on larger equipment, greater productivity makes new engines an attractive investment that will pay back the greater costs. Moreover, due to EPA regulations which will limit DPM emissions from engines used in surface construction, surface mining, and over-the-road trucks (the major markets for heavy duty diesel engines), the market for low tech, ''dirtier'' engines will dry up. Underground mine operators will thus purchase high tech, cleaner engines because they will be the only engines available for purchase.

(b) One hundred percent of the production equipment and about fifty percent of the support equipment will be equipped with filters; (c) about thirty percent of all equipment will need to be equipped with environmentally controlled cabs; (d) twenty three percent of the mines will need new ventilation systems (fans and motors): (e) forty percent of the mines will need new motors on these fans; and (f) thirty two percent of the mines will need major ventilation upgrades.

The Agency is taking a number of steps to mitigate the impact of the rule for the underground metal and nonmetal sector, particularly on the smallest mines in this sector. These are described in detail in the Agency's Regulatory Flexibility Analysis, which the Agency is required to prepare under the Regulatory Flexibility Act in connection with the impact of the rule on small entities. (The regulatory flexibility analysis can be found in part VI of this preamble, or packaged with the Agency's REA.)

Based on its cost estimates, the Agency has concluded that this sector would not find it economically feasible to reduce dpm concentrations to a lower limit at this time. These assumptions and the rationale behind them are discussed in greater detail in the beginning of Chapter IV of the Regulatory Economic Analysis.

After a careful review of the information about this sector available from the industry economic profile, and the other obligations of this sector under the Mine Act, MSHA has concluded that a reasonable probability exists that the typical firm in this sector will be able at this time to afford the controls that will be necessary to meet the proposed standard.

Conclusion: metal and nonmetal mining sector. Based on the best evidence available at this time, the Agency has concluded that the final rule for the underground metal and nonmetal sector meets the statutory requirement that the Secretary attain the highest degree of health and safety protection for the miners in that sector, with feasibility a consideration.

VI. Regulatory Impact Analyses

This part of the preamble reviews several impact analyses which the Agency is required to provide in connection with its final rulemaking. The full text of these analyses can be found in the Agency's Regulatory Economic Analysis (REA).

(A) Costs and Benefits: Executive Order 12866

In accordance with Executive Order 12866, MSHA has prepared a Regulatory Economic Analysis (REA) of the estimated costs and benefits associated with the final rule for the underground metal and nonmetal mining sector.

The key conclusions of the REA are summarized, together with cost tables, in part I of this preamble (see Item number 7). The complete REA is part of the record of this rulemaking, and is available from MSHA.

The Agency considers this rulemaking ''significant'' under section 3(f) of Executive Order 12866, and has so designated the rule in its semiannual regulatory agenda (RIN 1219–AA74). However, based upon the REA, MSHA has determined that the final rule does not constitute an ''economically significant'' regulatory action pursuant to section 3(f)(1) of Executive Order 12866.

(B) Regulatory Flexibility Act (RFA)

Introduction

In accordance with section 605 of the Regulatory Flexibility Act of 1980 as amended, MSHA has analyzed the impact of the final rule on small businesses. Further, MSHA has made a determination with respect to whether or not it can certify that this final rule will not have a significant economic impact on a substantial number of small entities that are affected by this rulemaking. Under the Small Business Regulatory Enforcement Fairness Act (SBREFA) amendments to the Regulatory Flexibility Act (RFA), MSHA must include a factual basis for this certification. If the final rule does have a significant economic impact on a substantial number of small entities, then the Agency must develop a final regulatory flexibility analysis.

The Agency has, as required by law (5 U.S.C. 605), developed a final regulatory flexibility analysis which is set forth Chapter V of the REA. In addition to a succinct statement of the objectives of the final rule and other information required by the Regulatory Flexibility Act, the analysis reviews alternatives considered by the Agency with an eye toward minimizing the economic impact on small business entities.

Definition of a Small Mine

Under the RFA, in analyzing the impact of a rule on small entities, MSHA must use the Small Business Administration (SBA) definition for a small entity or, after consultation with the SBA Office of Advocacy, establish an alternative definition for the mining industry by publishing that definition in the **Federal Register** for notice and comment. MSHA has not taken such an action, and hence is required to use the SBA definition.

The SBA defines a small entity in the mining industry as an establishment with 500 or fewer employees (13 CFR 121.201). Of the 196 underground M/NM mines that use diesel powered equipment and are therefore affected by this rulemaking, 189 (or all but 7) fall into this category and hence can be viewed as sharing the special regulatory concerns that the RFA was designed to address.

Traditionally, the Agency has also looked at the impacts of its rules on a subset of mines with 500 or fewer employees ¾ those with fewer than 20 employees, which the mining community refers to as ''small mines.'' The way these small mines perform mining operations is generally recognized as being different from the way larger mines operate. These small mines differ from larger mines not only in the number of employees, but also, among other things, in economies of scale in material produced, in the type and amount of production equipment, and in supply inventory. Therefore, their costs of complying with MSHA rules and the impact of MSHA rules on them will also tend to be different. It is for this reason that ''small mines,'' as traditionally defined by the mining community, are of special concern to MSHA.

This analysis complies with the legal requirements of the RFA for an analysis of the impacts on ''small entities'' while continuing MSHA's traditional look at ''small mines.'' MSHA concludes that the final rule would not have a significant economic impact on small entities, as defined by SBA, *when considered as a group.* However, MSHA has determined that the final rule arguably would have a significant economic impact on a subset of small entities that are covered by this

rulemaking. That subset is small underground M/NM mines as traditionally defined by MSHA, those mines with fewer than 20 employees. This subset of affected mines constitutes a substantial number of small entities.

Screening Analysis

General Approach. The Agency's analysis of impacts on ''small entities'' begins with a ''screening'' analysis. The screening compares the estimated compliance costs of a rule for small entities in the sector affected by the rule to the estimated revenues for those small entities. When estimated compliance costs are less than 1 percent of the estimated revenues (for the size categories considered), the Agency believes it is generally appropriate to conclude that there is no significant economic impact on a substantial number of small entities. When estimated compliance costs exceed 1 percent of revenues, it tends to indicate that further analysis may be warranted.

Derivation of Costs and Revenues. The compliance costs presented here were previously introduced in Chapter IV of the REA along with an explanation of how they were derived. Table VI–1 summarizes the total yearly cost of the final rule by mine size.

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TABLE VI-1: Total Yearly Compliance Costs for M/NM Mine Operators by Mine Size Class

Requirement	Total Yearly Industry Cost By Mine Size Class		
	Under 20 Employees	20 to 500 Employees	Over 500 Employees
Section 57.5060(a)&(b) DPM Concentration Limits	$3,909,865	$17,068,073	$3,215,869
Section 57.5067 Newly Introduced Engines	$ -	$ 2,848	$ 712
Section 57.5060(c) Extension Application	$ 148	$ 401	$ 36
Section 57.5060(d) Respirator Protection	$ 67,247	$ 285,690	$ 17,855
Section 57.5062 DPM Control Plans	$ 1,408	$ 6,336	$ 704
Section 57.5066(c) Maintenance Training	$ 894	$ 2,384	$ 468
Section 57.5066(b) Tagging and Examination	$ 1,769	$ 6,178	$ 1,948
Section 57.5070 Miner Health Training	$ 5,226	$ 74,189	$ 42,005
Section 57.5071 Environmental Monitoring	$ 106,425	$ 297,213	$ 31,008
Section 57.5075 Diesel Particulate Records	$ 204	$ 1,639	$ 943
TOTAL COST	$4,093,186	$17,744,951	$3,311,548
COST PER MINE	$ 53,158	$ 158,437	$ 473,078

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Data on underground M/NM mines published by the U.S. Geological Survey [1] were used for tonnage and value of underground M/NM mines. These data, however, are not disaggregated by mine size class. MSHA collects data, by mine size, on both average employees and employee hours.[2] MSHA has used these data to estimate revenues by mine size class.

MSHA has assumed that tonnage is proportional to employee hours. This assumption (rather than proportionality with employees) implicitly adjusts for different shift lengths associated with different sizes of mines. MSHA has also assumed that all underground M/NM mines use diesel powered equipment.[3] Using these assumptions, MSHA has computed the percentages of employee hours of all underground M/NM mines that are accounted for by each size class. MSHA estimates that these percentages of total revenues are accounted for by the different mine size classes.

Results of the Screening Analysis. The final rule applies to underground M/NM mines that use diesel-powered equipment. Table VI–1 shows that the estimated yearly cost of the final rule as a percentage of yearly revenues is about 0.8 percent for the affected underground M/NM mines with 500 or fewer employees.

However, for a subset of affected underground M/NM mines, those with fewer than 20 employees, estimated yearly costs are equal to about 2.16 percent of yearly revenues for this subset of mines. The economic impact on these small mines, which constitute a substantial number of small entities affected by the final rule, is larger than one percent of their revenues. MSHA therefore cannot certify that the final rule would not have a significant impact on a substantial number of small entities.

The Agency has prepared a final regulatory flexibility analysis, as required by law, which explains the steps MSHA has taken to minimize the burden on these small entities and justifies the costs placed on them.

TABLE VI–2.—ESTIMATED YEARLY COSTS OF FINAL RULE RELATIVE TO YEARLY REVENUES FOR UNDERGROUND COAL MINES THAT USE DIESEL-POWERED EQUIPMENT

Mine size	Final rule yearly costs (In thousands)	Revenues[a] (In thousands)	Costs as Percentage of revenues
<20 emp.	$4,093	$189,305	2.16
≤500 emp.	21,837	2,745,137	0.80

[a] Source: Mine Safety and Health Administration, Office of Injury and Employment Information, Denver, Colorado. 1999, and U.S. Department of Energy, Energy Information Agency, *Annual Energy Review 1998,* DOE/EIA0384(98), July 1999, p.203.

Final Regulatory Flexibility Analysis

As indicated above, the estimated yearly cost of the final rule on a subset of small entities, those with fewer than 20 employees, is 2.16 percent of yearly revenue. This percentage is just over twice the value (1.0 percent) below which MSHA could say with reasonable confidence that the final rule does not have a significant economic impact on a substantial number of small entities. Accordingly, MSHA has prepared a final regulatory flexibility analysis.

Need for, and Objectives of, the Rule

Need. The rule is needed because underground miners in mines that use diesel powered equipment are currently exposed to extremely high concentrations of diesel particulate matter (DPM). Based on MSHA field studies, median DPM concentrations to which underground miners are exposed range up to 200 times as high as average environmental exposures in the most heavily polluted urban areas and up to 10 times as high as median exposures estimated for the most heavily exposed workers in any occupational group other than underground miners.

The available scientific information indicates that miners exposed to the extremely high DPM concentrations found in underground mines are at significant excess risk of experiencing three kinds of material impairment to their health:

- Increased risk of lung cancer has been linked to chronic occupational DPM exposure.
- Increased acute risk of death from cardiovascular, cardiopulmonary, or respiratory causes has been linked to short or long term DPM exposures.
- Sensory irritations and respiratory symptoms can result from even short term DPM exposures. Besides being potentially debilitating, such effects can distract miners from their responsibilities in ways that could pose safety hazards for everyone in the mine.

Although definitive dose-response relationships have not yet been established (especially for the acute effects), the best available evidence indicates that the risks are substantial.

Objective. The objective of the rule is to lower DPM exposures in underground M/NM mines to concentrations similar to the worst levels to which other occupational groups are exposed. By doing so, the rule is designed substantially to lower the health risks associated with DPM. Expected benefits include an estimated minimum of 8.5 lung cancer deaths avoided per year.

Significant Issues Raised in Response to the Initial RFA

Comments. The principal issue raised in comments on the PREA was that, for a variety of reasons, MSHA had substantially understated the costs of controlling DPM. The implication of these comments was that the rule was economically infeasible. The most comprehensive comments along these lines were by Head,[4] who argued (among other things) that MSHA had made the following errors and omissions in its analysis:

- MSHA had (according to Head) understated the numbers of machines and mines affected, including:

[1] U.S. Geological Survey, ''Mineral Industry Surveys: Mining and Quarrying Trends, 1998 Annual Review, April 2000.

[2] U.S. Department of Labor, MSHA, 1998 Final MIS data CM441 cycle 1998/198.

[3] This assumption ignores the fact that some very small mines do not use diesel powered equipment. MSHA believes, however, that these mines are generally very small (even among the mines with fewer than 20 employees) and that many of them operate only intermittently. Thus they account for employee hours proportionately far less than their numbers. Accordingly, MSHA believes that the most accurate way to interpret the data is to disregard the fact that these mines do not use diesel powered equipment.

[4] H. John Head, Principal Mining Engineer, Harding Lawson Associates, ''Review of Economic and Technical Feasibility of Compliance Issues Related to: Department of Labor—MSHA, 30 CFR Part 57—Proposed Rule for Diesel Particulate Matter Exposure of Underground Metal and Nonmetal Miners,'' Report prepared under contract with the National Mining Association, July 21, 1999.

• Understatement of the number of diesel units in underground M/NM mines by more than 50 percent, and

• Understatement of the number of ventilation upgrades needed by 20 percent to 40 percent

• MSHA had understated a number of costs, including:

• Understatement of the cost of replacement engines by up to one third,

• Understatement of the costs of filters on larger engines by 20 percent, and

• Understatement of the costs of vehicle cabs by about 60 percent.

• MSHA had omitted some costs entirely, including:

• Installation costs of retrofitting new engines in old equipment, which ran as high as three times the costs of the engines themselves, and

• Major ventilation improvements needed by about one third of the mines.

Based on his own numbers, Head estimated compliance costs to be three times as high as MSHA's estimate of the cost of the proposed rule of $19.2 million.

Analytical Assessment of Issues. MSHA considered the comments and reviewed its assessment of costs very carefully. The assessment focused on Head's comments, since his exposition was detailed enough for analysis of the basis of his estimates. MSHA responded in a variety of ways, which are summarized below.

The key to the issue of the number of diesel units affected by the rule was how one interpreted the number. MSHA resolved this issue by recognizing that not all diesel powered equipment would be affected in the same manner. In fact, the machines in Head's total count should be grouped into three categories: active, spares, and disused. Active diesel powered equipment (essentially MSHA's original count) needs to be fitted for everyday use. Spare equipment needs to be controlled for occasional use as back-up. Disused equipment is essentially not affected by the rule. A shift in the principal control strategy from engine replacement to ceramic filters (discussed further below) made these distinctions operational. With ceramic filters, both active and spare equipment can be fitted with filters (a relatively inexpensive operation), but filters need to be regenerated and changed (which encompasses most of the costs) only to the extent that the equipment is actually used.

MSHA believes that Head was simply wrong about the number of mines needing upgrades to their ventilation systems. Head appeared to believe that MSHA's count was arbitrary, and the basis for his proposed number was obscure. In fact, MSHA has based its count on mine-specific data on the existence and rate of air flow of ventilation systems. Thus, MSHA retained its original count.

MSHA's review of comments on costs produced different conclusions for different specific costs:

• MSHA accepted and used Head's estimate of costs of ceramic filters.

• MSHA does not entirely agree with Head's estimates of costs of new engines. Moreover, expensive new engines are technologically advanced and tend to produce substantial gains in productivity and savings in operating costs, which Head did not consider. The issue of engine costs became irrelevant, however, under a strategy of filters as the first-used control device.

• MSHA's re-examination of the costs of cabs indicated that MSHA's cost estimate is appropriate for equipment for which equipment manufacturers can provide off-the-shelf kits for retrofitting equipment, and Head's cost estimate is appropriate for equipment for which cabs have to be custom designed and retrofitted. Since the rule does not mandate cabs and MSHA expects cabs to be used on a relatively small proportion of equipment, however, MSHA believes that mine operators will not retrofit equipment for which cabs would need to be custom designed. Accordingly, MSHA has retained its original cost estimate.

• Head concurred with MSHA on the costs of ventilation improvements. While these costs appear to be an appropriate average estimate for M/NM mines as a whole, there is a distinct possibility that they may be too high for very small M/NM mines.[5] In the context of regulatory flexibility analysis, MSHA considers these cost estimates to be fairly conservative.

MSHA agrees that certain costs were omitted, but the conclusions of MSHA's reconsideration of these costs also vary with the cost:

• MSHA has accepted Head's estimates for major ventilation improvements and has included them in the analysis of costs.

• Head's comment that MSHA had omitted the costs of retrofitting new engines in old equipment is correct, although MSHA does not agree with the size of Head's cost estimates. The key issue, however, is that the strategy of relying primarily on filters does not entail retrofitting engines. Thus Head's comment is not germane.

Concentration Limits and the Toolbox. This standard for underground M/NM mines is a performance standard, with an interim DPM concentration limit of 500 micrograms/m^3, followed by a final DPM concentration limit of 200 micrograms/m^3. The rule encourages mine operators to use any combination of a ''toolbox'' of measures to meet these concentration limits. For cost estimation purposes, however, it is necessary to assume a specific set and sequence of control measures. Specifically, in the PREA MSHA assumed that:

• The interim standard would be met by replacing engines, installing oxidation catalytic converters, and improving ventilation; and

• The final standard would be met by adding cabs and filters.

Both the general strategy and the specific proportions of diesel powered equipment to be controlled by each measure were based on an optimizing approach, in which the most cost-effective additional measures were selected for additional DPM reductions at each stage.

In his comments, Head exactly replicated MSHA's assumptions about how many pieces of each kind of diesel equipment would be controlled, how they would be controlled, and the sequence in which controls would be used. Although his cost estimates differed substantially from MSHA's, Head made no attempt to optimize the use of DPM control ''tools'' from the toolbox.

Substantially the most important of Head's changes is to make filters much cheaper, relative to engine replacement. At the same time, data collected by MSHA since publication of the PREA indicate that filters are more effective than was previously understood. This finding has further enhanced the cost-effectiveness of filters, relative to engine replacement. These changes in information have caused MSHA to go back to the toolbox and rethink the optimized compliance strategy. The revised compliance strategy, upon which MSHA bases the revised estimates of compliance costs, reverses the two most widely used measures from the toolbox. MSHA now anticipates that:

• The interim DPM standard of 500 micrograms/m^3 will be met with filters, cabs, and ventilation; and

• The final DPM standard of 200 micrograms/m^3 will be met with more filters, ventilation, and such turnover in

[5] The issue is further complicated by the fact that mines that are ''small'' in terms of employment vary considerably among commodities and mining techniques in their physical size and ventilation requirements. Accordingly, MSHA has not attempted to make a separate cost estimate of ventilation improvement costs for ''small'' M/NM minas as a group.

equipment and engines as will have occurred in the baseline.

This new approach uses the same toolbox and optimization strategy that was used in the PREA. Since relative costs are different, however, the tools used and costs estimated are quite different. The effects on costs is substantial. Most of the difference between Head's cost estimate and the cost estimate in the REA is attributable to this change in strategy.

Changes in the Rule. Because the rule is a performance standard that uses a tool-box approach, most modifications that MSHA made in response to comments involved changes in the mix of tools within the framework of the rule, rather than changes in the rule per se. MSHA did make one significant change in the rule itself, however, by allowing compliance with listed EPA standards as a substitute for MSHA approval of new engines. Because most engines used in underground M/NM mining equipment are essentially the same engines used on the surface, which fall under EPA regulations, MSHA believes that virtually all new engines used in mining equipment will meet EPA standards. Therefore, this change resulted in eliminating a cost of approval that was estimated in the PREA to average $2,500 per new engine.

Small Entities to Which the Rule Will Apply

For the purposes of this regulatory flexibility analysis, the working definition of ''small'' is MSHA's definition of fewer than 20 employees. (Although SBREFA requires use of the SBA's definition, the impacts on mines with 500 or fewer employees as a whole are not economically significant.) Correspondingly, one element of a regulatory flexibility analysis involves developing a more focused definition of ''small.''

There are 77 M/NM mines that are ''small'' by this definition. These mines fall in four commodity groups:

- Stone is the largest group, accounting for 54 small underground M/NM mines that use diesel equipment (70 percent). These mines include limestone (46 mines), marble (5 mines), lime (2 mines), and granite (1 mine).
- Precious metals account for 10 small underground M/NM mines that use diesel equipment (13 percent). Most of these (9 mines) are gold mines; one mines both gold and silver.
- Other metals account for 4 small underground M/NM mines that use diesel equipment (5 percent). These mines include zinc (2 mines), copper (1 mine), and a combination of copper and zinc (1 mine).
- The other 9 small underground M/NM mines that use diesel equipment (12 percent) are a miscellany that includes shale (3 mines) as well as calcite, clay, gemstone, perlite, sand (industrial), and talc (1 mine each).

Collectively, these 77 mines have estimated revenues of $189.3 million, or an average of $2.46 million per mine. The estimated total costs of the rule are $4.1 million, or an average of $53,160 per mine. Estimated costs of the rule are 2.16 percent of estimated revenues.

Costs by Commodity Group and Mine Size. Table VI–3 shows the estimated yearly cost by size class for each commodity group in M/NM mines. Costs for Section 57.5060(a) and Section 57.5060(b) were recalculated for each commodity group, based on the diesel powered equipment and air flow of the mines in each commodity group. All other costs were very small, probabilistically distributed among mines, and/or essentially constant for all mines or for all mines in a size class. For these costs, the average cost per mine in each size class (from Table VI–1) was used, as very little precision was lost through this simpler estimation procedure. Table VI–3 shows a fair degree of variation among commodity groups.

- For mines with fewer than 20 employees, the average cost per mine is estimated to be $53,158, and estimated costs per mine for commodity groups range from $31,500 to $60,500, with:
- Costs above average for stone mines ($60,500) and base metal ($54,400), and
- Costs below average for other M/NM mines ($31,500) and gold mines ($34,600).
- For mines with 20 to 500 employees, the average cost per mine is estimated to be $158,437, and estimated costs per mine for commodity groups range from $102,100 to $201,700, with:
- Costs above average for base metal mines ($201,700) and gold mines ($171,900),
- Costs roughly average for stone mines ($150,900) and evaporates mines ($149,100), and
- Costs below average for other M/NM mines ($102,100).
- For mines with over 500 employees, the average cost per mine is estimated to be $473,078, and estimated costs per mine for commodity groups range from $291,800 to $660,300, with:
- Costs above average for gold mines ($660,300) and base metal mines ($592,300), and
- Costs below average for evaporates mines ($291,800) and stone mines ($298,000).

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Table VI-3: Yearly Compliance Costs by Commodity Group and Mine Size

Commodity Group	Mine Size	Total Yearly Industry Cost	Yearly Cost per Mine
Stone[a]	Under 20	$ 3,258,360	$ 60,340
	20 to 500	$ 6,330,996	$ 150,738
	Over 500	$ 297,691	$ 297,691
	All Mines	$ 9,887,047	$ 101,928
Precious Metals[b]	Under 20	$ 345,240	$ 34,524
	20 to 500	$ 3,263,782	$ 171,778
	Over 500	$ 659,978	$ 659,987
	All Mines	$ 4,269,000	$ 142,300
Other Metals[c]	Under 20	$ 217,104	$ 54,276
	20 to 500	$ 5,039,700	$ 201,588
	Over 500	$ 1,775,991	$ 591,997
	All Mines	$ 7,032,795	$ 219,775
Evaporates[d]	20 to 500	$ 3,724,100	$ 148,964
	Over 500	$ 582,990	$ 291,495
	All Mines	$ 4,307,090	$ 159,522
Other[e]	Under 20	$ 282,357	$ 31,373
	20 to 500	$ 101,950	$ 101,950
	All Mines	$ 384,307	$ 38,431

[a] Granite, lime, limestone, marble, and sandstone.

[b] Gold, Platinum, and silver.

[c] Copper, iron ore, lead, molybdenum, uranium, and zinc.

[d] Gypsum, potash, salt, and trona.

[e] Borate, calcite, clay, gemstones, perlite, sand (industrial), shale, and talc.

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Thus by overall commodity group:

- Compliance costs are relatively high in gold mines (except for small mines) and base metal mines,
- Compliance costs are relatively low in evaporates mines and other M/NM mines, and
- Compliance costs of stone mines show no consistent pattern relative to average costs for all M/NM mines.

The differences in cost per mine appear to be attributable to the interaction of three characteristics of the mines, which are included in Table VI–4:

- The percentage of mines that need new ventilation systems;
- The number of diesel powered machines per mine; and
- The proportion of diesel powered equipment that is large production equipment.

Table VI-4: Factors Contributing to Variability of Yearly Compliance Costs Across Commodity Groups

Commodity Group	Mine Size	Machines per Mine				Percent Needing Ventilation Improvements	
		Production		Sup.	Total		
		>150 h.p.	≤150 h.p.			New System	New Motor
Stone	Under 20	4.3	0.5	4.4	9.2	44%	30%
	20 to 500	8.5	1.0	7.6	17.1	33%	31%
	Over 500	16.0	1.0	23.0	40.0	0%	100%
	All Mines	6.3	0.7	6.0	12.9	39%	31%
Gold	Under 20	0.4	1.2	0.8	2.4	40%	40%
	20 to 500	6.6	5.8	11.7	24.1	0%	68%
	Over 500	26.0	12.0	95.0	133.0	0%	0%
	All Mines	5.2	4.5	10.9	20.5	13%	57%
Base Metal	Under 20	3.5	1.0	6.2	10.7	25%	50%
	20 to 500	10.3	2.8	16.6	29.8	0%	48%
	Over 500	17.3	29.3	68.0	114.7	0%	33%
	All Mines	10.1	5.1	20.2	35.3	3%	47%
Evaporate	20 to 500	5.2	4.6	21.1	30.9	4%	40%
	Over 500	1.5	11.5	80.0	93.0	0%	0%
	All Mines	4.9	5.1	25.5	35.5	4%	41%
Other	Under 20	1.2	0.8	0.2	2.2	11%	67%
	20 to 500	0.0	15.0	0.0	15.0	0%	100%
	All Mines	1.1	2.2	0.2	3.5	10%	70%

These three characteristics interact in somewhat different ways in the different mine size classes:

• For mines with fewer than 20 employees, the cost per mine is:

• Relatively high (or just above average) in commodity groups where two or all three of these factors have relatively high values, and

• Relatively low when two of these factors have relatively low values.

• For mines with 20 to 500 employees, the cost per mine is:

• Relatively high in commodity groups where the number of machines per mine and the proportion of machines that are large production equipment are both relatively large,

• Average when one of these two factors is relatively high and the other is relatively small, and

• Relatively low when all three of the factors have relatively low values.

• For mines with over 500 employees (none of which need new ventilation systems), the cost per mine is:

• Relatively high in commodity groups where the number of machines per mine is relatively large, and

• Relatively low when the number of machines per mine or the proportion of machines that are large production equipment is relatively small.

Impacts on Small Mines by Commodity Group. The available data are not adequate to support a realistic estimate of impacts on small underground M/NM mines by commodity group, since revenues of individual commodities cannot be allocated to different size classes of mine. The analysis of costs per mine suggests, however, that stone is the only commodity group with impacts much above average. The costs per small stone mine are 13.6 percent higher than the average for all small underground M/NM mines. Impacts on small underground mines in other M/NM commodity groups appear to be about average or less.

Projected Reporting, Recordkeeping, and Other Requirements of the Rule

The rule requires several types of records and reports. Plans are required in conjunction with respirator use and DPM control if the concentration levels are violated, and these must be posted and provided to various parties. An extension may be applied for. Maintenance training, miner health training, and respirator training must be logged. Environmental monitoring results must be recorded and provided to miners upon request. While there are a number of reporting and recordkeeping requirements, however, each one is straightforward, and most are no more than the simplest form of documentation. Thus the total cost of recordkeeping is only about 0.35 percent of the compliance costs for small mines.

The principal source of costs of the rule is controls to reduce the DPM concentrations in underground mines. MSHA has adopted a flexible ''toolbox'' approach that allows mine operators to select the controls that will be most cost-effective for their mines. MSHA has based its cost estimates on extensive use of ceramic filters, less widespread use of cabs on equipment, and ventilation upgrades. MSHA also assumes that new diesel engines introduced into the mines as part of the baseline turnover of the fleet and its engines will be relatively clean and will contribute to reduced DPM levels. These control costs account for an estimated 95.6 percent of the yearly compliance costs of small mines. Of these costs, ventilation costs (47.1 percent) and filter costs (46.3 percent) account for nearly half each, while the cost of cabs (6.6 percent) is relatively minor.

Only two other requirements impose costs of any size. Environmental monitoring accounts for about 2.6 percent of the estimated compliance costs of small mines. Occasional use of respirators (equipment, training, inspection, etc.) accounts for about 1.6 percent of estimated compliance costs. Maintenance training and miner health training account for less than 0.2 percent of compliance costs. The non-control requirements of the rule are quite modest.

Steps Taken to Minimize Impacts on Small Entities

Constraints of the Mine Safety and Health Act. The Federal Mine Safety and Health Act of 1977 was enacted to protect miners. MSHA has always read the Act to prohibit discriminating among miners by providing different degrees of protection that varied systematically with the size of the mine in which they worked. Accordingly, the Mine Safety and Health Act rules out certain classes of regulatory flexibility alternatives, particularly exemption of small mines, but also any alternative that would result in systematically higher allowable DPM concentration levels in small mines. Because over 95 percent of the yearly costs to be incurred by small mines are directly related to protection, there is little scope for distinct provisions for small mines.

Built-In Flexibility. To minimize impacts on small entities, MSHA has taken steps to build as much flexibility into the rule itself as possible. The rule itself is a performance standard that allows mine operators to meet the DPM concentration limits with their own choice of ''tools.'' While MSHA has selected a specific set of tools for the cost analysis, MSHA expects that operators of specific mines probably will often be able to come into compliance at lower costs by using a mix of techniques tailored to that specific mine.

Other parts of the rule provide similar flexibility. Training and recordkeeping requirements indicate the information to be imparted or retained, for example, but they do not spell out how this is to be done. Much of the reporting is required only upon request, rather than routinely. Where a requirement (*e.g.,* MSHA approval of new engines) appeared to be relatively expensive, MSHA added an alternative (compliance with listed EPA standards).

Phasing in over five years is another element that MSHA has incorporated to minimize impacts (albeit for all mines, not just for small ones). This not only defers costs, it allows impacts to be reduced in a number of ways. Mine operators can spread major expenses out to avoid a capital crunch. To a great degree, mine operators will be able to take advantage of the natural turnover of their fleets, rather than doing extensive (and more expensive) retrofitting. In extreme cases, if a mine is quite marginal and/or is likely to shut down in a few years anyway, the five-year phase-in allows an orderly closure that minimizes impacts.

Low Risk of Short-Term Closures. Ultimately, the issue of concern related to impacts whether mines may be forced to close. When costs are a significant but relatively small fraction of revenues (or profits), however, it is especially difficult to determine whether closure is an impact resulting from the rule or a baseline event that would have happened anyway. Given the fact that profits fluctuate widely over time, even the presence of losses is not necessarily a good indicator of whether businesses will recover or fail. In many cases where a business does fail, the true impact of a regulation is not causing its failure but rather hastening its failure. Because of the phasing of this rule, it affords an opportunity to consider the potential for hastening the failure of a small mine.

If a mine is likely to close within five to seven years without the regulation, the impacts of the rule are different from the above analysis. In order to stay open for five years, a mine need only comply with the interim DPM concentration level. To this end, it needs to incur the costs of:

• Control costs necessary for Section 57.5060(a); [6]
• Respirator protection costs of Section 57.5060(d); [7]
• DPM control plan costs of Section 57.5062; [8]
• Maintenance training, tagging, and examination costs of Section 57.5066(b) and Section 57.5066(c);[9]
• Miner Health Training costs of Section 57.5071; [10]
• Environmental monitoring costs of Section 57.5071; [11] and
• DPM record costs of Section 57.5075. [12]

Thus the yearly costs for small mines, amortized over 5 years at an annual discount rate of 7.0 percent, would be $1,554,086, or an average of $20,183 per mine. This is 0.82 percent of annual revenue, which is below the threshold for a significant economic impact. This is not the type of impact that would force a mine to close sooner rather than later. The conclusion is that any closure impacts would be mild and would occur foreseeably over time, rather than abruptly.

Compliance Assistance

The Agency plans to provide extensive compliance assistance to the mining community. MSHA intends to focus these efforts on smaller metal and nonmetal operators, including training them to measure DPM concentrations, providing technical assistance on available controls, and establishing a system for addressing compliance inquiries from small businesses. The Agency will also issue a compliance guide, continue its current efforts to disseminate educational materials and software, and hold workshops to inform the mining community.

In conclusion, MSHA believes that it has taken all of the steps consistent with the Mine Safety and Health Act that could substantially reduce the impacts of this rule on small entities.

(C) Alternatives Considered

MSHA did explore a variety of alternatives in its Initial Regulatory Flexibility Analysis. See 63 FR 58212. For example, it looked at a regulatory approach that would have focused on limiting workers exposure rather than limiting particulate concentration. Under such an approach, operators would have been able to use administrative controls and respiratory protection equipment to reduce diesel particulate exposure. For the reasons explained in that Initial Analysis, the Agency declined to take such an approach. For MSHA's response to comments on the specific topics of administrative controls and respiratory protection equipment, see Part IV's discussion of 57.5060(e) and 57.5060(f).

(D) Unfunded Mandates Reform Act of 1995

For purposes of the Unfunded Mandates Reform Act of 1995, the final rule does not include any Federal mandate that may result in increased expenditures by State, local, or tribal governments, or increased expenditures by the private sector of more than $100 million.

(E) Paperwork Reduction Act of 1995

The final rule contains information collections which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA95). The final rule will impose two types of paperwork burden hours on underground M/NM mine operators that use diesel powered equipment. First, there are burden hours that will occur *only* in the first year the rule is in effect (hereafter known as first year burden hours). Second, there are burden hours that will occur *every* year that the rule is in effect, starting with the first year (hereafter known as ''annual'' burden hours).

In the first year, mine operators will incur 3,571 burden hours and associated burden costs of about $171,926. After the first year, mine operators will incur 526 burden hours annually and associated costs of about $21,871.

We have submitted a copy of this final rule to OMB for its review and approval of these information collections. Interested persons are requested to send comments regarding this information collection, including suggestions for reducing this burden, to the Office of Information and Regulatory Affairs, OMB New Executive Office Building, 725 17th St., NW, Rm. 10235, Washington, DC 20503, Attn: Desk Officer for MSHA. Submit written comments on the information collection not later than 60 days after date of publication in the **Federal Register**.

Our paperwork submission summarized above is explained in detail in the REA. The REA includes the estimated costs and assumptions for each final paperwork requirement related to this final rule. A copy of the REA is available from us. These paperwork requirements have been submitted to the Office of Management and Budget for review under section 3504(h) of the Paperwork Reduction Act of 1995. Respondents are not required to respond to any collection of information unless it displays a current valid OMB control number.

(F) National Environmental Protection Act

The National Environmental Policy Act (NEPA) of 1969 requires each Federal agency to consider the environmental effects of final actions and to prepare an Environmental Impact Statement on major actions significantly affecting the quality of the environment. MSHA has reviewed the final rule in accordance with NEPA requirements (42 U.S.C. 4321 et. seq.), the regulations of the Council of Environmental Quality (40 CFR Part 1500), and the Department of Labor's NEPA procedures (29 CFR Part 11). As a result of this review, MSHA has determined that this rule will have no significant environmental impact.

(G) Executive Order 12360 Governmental Actions and Interference With Constitutionally Protected Property Rights

This final rule is not subject to Executive Order 12360, Governmental Actions and Interference with Constitutionally Protected Property Rights, because it does not involve implementation of a policy with takings implications.

(H) Executive Order 13045 Protection of Children From Environmental Health Risks and Safety Risks

In accordance with Executive Order 13045, MSHA has evaluated the environmental health and safety effects of the final rule on children. The Agency has determined that the rule will not have an adverse impact on children.

(I) Executive Order 12988 (Civil Justice)

The Agency has reviewed Executive Order 12988, Civil Justice Reform, and determined that the final rule will not unduly burden the Federal court system. The rule has been written so as to provide a clear legal standard for affected conduct, and has been reviewed carefully to eliminate drafting errors and ambiguities.

[6] These controls include ceramic filters and cabs, but not ventilation (which MSHA did not estimate to be necessary for the interim DPM level. These costs, amortized over 5 years at an annual discount rate of 7.0 percent, are $1,119,800 for filters and $150,437 for cabs.

[7] These costs, amortized over 5 years at an annual discount rate of 7.0 percent, are $164,845.

[8] Annual costs are $1,408.

[9] These costs, amortized over 5 years at an annual discount rate of 7.0 percent, are $5,681.

[10] Annual costs are $5,226.

[11] Annual costs are $106,425.

[12] Annual costs are $204.

(J) Executive Order 13084 Consultation and Coordination With Indian Tribal Governments

MSHA certifies that the final rule will not impose substantial direct compliance costs on Indian tribal governments.

(K) Executive Order 13132 (Federalism)

MSHA has reviewed the final rule in accordance with Executive Order 13132 regarding federalism and has determined that it does not have ''federalism implications.'' The final rule does not ''have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

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Supplementary References

Below is a list of supplemental references that MSHA reviewed and considered in the development of the proposed rule. These documents are not specifically cited in the preamble discussion, but are applicable to MSHA's findings:

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List of Subjects in 30 CFR Part 57

Metal and nonmetal, Mine safety and health, Underground mines, Diesel particulate matter.

Dated: January 8, 2001.

Robert A. Elam,

Acting Assistant Secretary for Mine Safety and Health.

Chapter I of Title 30 of the Code of Federal Regulations is hereby amended as follows:

PART 57—[AMENDED]

1. The authority citation for Part 57 continues to read as follows:

Authority: 30 U.S.C. 811, 957, 961.

2. The heading of Subpart D of Part 57 is revised to read as follows:

Subpart D—Air Quality, Radiation, Physical Agents, and Diesel Particulate Matter

3. A new undesignated center heading and §§ 57.5060 through 56.5075 are added to subpart D.

DIESEL PARTICULATE MATTER—UNDERGROUND ONLY

Sec.
57.5060 Limit on concentration of diesel particulate matter.
57.5061 Compliance determinations.
57.5062 Diesel particulate matter control plan.
57.5065 Fueling and idling practices.
57.5066 Maintenance standards.
57.5067 Engines.
57.5070 Miner training.
57.5071 Environmental monitoring.
57.5075 Diesel particulate records.

DIESEL PARTICULATE MATTER—UNDERGROUND ONLY

§ 57.5060 Limit on concentration of diesel particulate matter.

(a) After July 19, 2002 and until January 19, 2006, any mine operator covered by this part must limit the concentration of diesel particulate matter to which miners are exposed in underground areas of a mine by restricting the average eight-hour equivalent full shift airborne concentration of total carbon, where miners normally work or travel, to 400 micrograms per cubic meter of air (400_{TC} μg/m^3).

(b) After January 19, 2006, any mine operator covered by this part must limit the concentration of diesel particulate matter to which miners are exposed in underground areas of a mine by restricting the average eight-hour equivalent full shift airborne concentration of total carbon, where miners normally work or travel, to 160 micrograms per cubic meter of air (160_{TC} μg/m^3).

(c)(1) If, as a result of technological constraints, a mine requires additional time to come into compliance with the limit specified in paragraph (b) of this section, the operator of the mine may file an application with the Secretary for a special extension.

(2) No mine may be granted more than one special extension, nor may the time otherwise available under this section to a mine to comply with the limit specified in paragraph (b) be extended by more than two years.

(3) The application for a special extension may be approved, and the additional time authorized, only if the application includes information adequate for the Secretary to ascertain:

(i) That diesel-powered equipment was used in the mine prior to October 29, 1998;

(ii) That there is no combination of controls that can, due to technological constraints, bring the mine into full compliance with the limit specified in paragraph (b) within the time otherwise specified in this section;

(iii) The lowest achievable concentration of diesel particulate, as demonstrated by data collected under conditions that are representative of mine conditions using the method specified in § 57.5061; and

(iv) The actions the operator will take during the duration of the extension to:

(A) Maintain the lowest concentration of diesel particulate; and

(B) Minimize the exposure of miners to diesel particulate.

(4) The Secretary may approve an application for a special extension only if:

(i) The mine operator files, the application at least 180 days prior to the date the mine must be in full compliance with the limit established by paragraph (b) of this section; and

(ii) The application certifies that the operator has posted one copy of the application, at the mine site for 30 days prior to the date of application, and has provided another copy to the authorized representative of miners.

(5) A mine operator must comply with the terms of any approved application for a special extension, and post a copy of an approved application for a special extension at the mine site for the duration of the special extension period.

(d)(1) Mine operators may permit miners engaged in inspection, maintenance, or repair activities, and only in such activities, with the advance approval of the Secretary under the circumstances and conditions defined in paragraphs (d)(2) through (d)(4) of this section, to work in concentrations of diesel particulate matter exceeding the applicable concentration limit under paragraph (a) or (b) of this section.

(2) The Secretary will only provide advance approval:

(i) For inspection, maintenance or repair activities to be conducted:

(A) In areas where miners work or travel infrequently or for brief periods of time;

(B) In areas where miners otherwise work exclusively inside of enclosed and environmentally controlled cabs, booths and similar structures with filtered breathing air; or

(C) In shafts, inclines, slopes, adits, tunnels and similar workings that the operator designates as return or exhaust air courses and that miners use for access into the mine or egress from the mine;

(ii) When the Secretary determines that it is not feasible to reduce the concentration of dpm in the areas where the inspection, maintenance or repair activities are to be conducted to those otherwise applicable under paragraph (a) or (b) of this section; and

(iii) When the Secretary determines that the mine operator will employ adequate safeguards to minimize the dpm exposure of the miners.

(3) The Secretary's determinations under paragraph (d)(2) of this section will be based on evaluating a plan prepared and submitted by the operator no less than 60 days before the commencement of any inspection, maintenance or repair activities. The mine operator must certify in the plan that one copy of the application has been posted at the mine site for 30 days prior to the date of submission, and another copy has been provided to the authorized representative of miners. The plan must identify, at a minimum, the types of anticipated inspection, maintenance, and repair activities that must be performed for which engineering controls sufficient to comply with the concentration limit are not feasible, the locations where such activities could take place, the concentration of dpm in these locations, the reasons why engineering controls are not feasible, the anticipated frequency and duration of such activities, the anticipated number of miners involved in such activities, and the safeguards that the operator will employ to limit miner exposure to dpm, including, but not limited to the use of respiratory protective equipment. The approved plan must include a program for selection, maintenance, training, fitting, supervision, cleaning and use of personal protective equipment and must meet the minimum requirements established in § 57.5005 (a) and (b).

(4) An advance approval by the Secretary for employees to engage in inspection, maintenance, or repair activities will be valid for no more than one year. A mine operator must comply with the conditions of the approved plan [which was the basis of the approval], and must post a copy of the approved plan at the mine site for the duration of its applicability.

(e) Other than pursuant to the conditions required in paragraphs (c) or (d) of this section, an operator must not

utilize personal protective equipment to comply with the requirements of either paragraph (a) or paragraph (b) of this section.

(f) An operator must not utilize administrative controls to comply with the requirements of this section.

§ 57.5061 Compliance determinations.

(a) A single sample collected and analyzed by the Secretary in accordance with the requirements of this section shall be an adequate basis for a determination of noncompliance with an applicable limit on the concentration of diesel particulate matter pursuant to § 57.5060.

(b) The Secretary will collect samples of diesel particulate matter by using a respirable dust sampler equipped with a submicrometer impactor and analyze the samples for the amount of total carbon using the method described in NIOSH Analytical Method 5040, except that the Secretary also may use any methods of collection and analysis subsequently determined by NIOSH to provide equal or improved accuracy for the measurement of diesel particulate matter. Copies of the NIOSH 5040 Analytical Method are available by contacting MSHA's, Pittsburgh Safety and Health Technology Center, P.O. Box 18233, Cochrans Mill Road, Pittsburgh, PA 15236.

(c) The Secretary will determine the appropriate sampling strategy for compliance determination, utilizing personal sampling, occupational sampling, and/or area sampling, based on the circumstances of the particular exposure.

§ 57.5062 Diesel particulate matter control plan.

(a) In the event of a violation by the operator of an underground metal or nonmetal mine of the applicable concentration limit established by § 57.5060, the operator, in accordance with the requirements of this section, must—

(1) Establish a diesel particulate matter control plan for the mine if one is not already in effect, or modify the existing diesel particulate matter control plan, and

(2) Demonstrate that the new or modified diesel particulate matter control plan controls the concentration of diesel particulate matter to the applicable concentration limit specified in § 57.5060.

(b) A diesel particulate control plan must describe the controls the operator will utilize to maintain the concentration of diesel particulate matter to the applicable limit specified by § 57.5060. The plan also must include a list of diesel-powered units maintained by the mine operator, information about any unit's emission control device, and the parameters of any other methods used to control the concentration of diesel particulate matter. The operator may consolidate the plan with the ventilation plan required by § 57.8520. The operator must retain a copy of the current diesel particulate matter control plan at the mine site during its duration and for one year thereafter.

(c) An operator must demonstrate plan effectiveness by monitoring, using the measurement method specified by § 57.5061(b), sufficient to verify that the plan will control the concentration of diesel particulate matter to the applicable limit under conditions that can be reasonably anticipated in the mine. The operator must retain a copy of each verification sample result at the mine site for five years. The operator monitoring must be in addition to, and not in lieu of, any sampling by the Secretary pursuant to § 57.5061.

(d) The records required by paragraphs (b) and (c) of this section must be available for review upon request by the authorized representative of the Secretary, the authorized representative of the Secretary of Health and Human Services, or the authorized representative of miners. In addition, upon request by the District Manager or the authorized representative of miners, the operator must provide a copy of any records required to be maintained pursuant to paragraph (b) or (c) of this section.

(e)(1) A control plan established as a result of this section must remain in effect for 3 years from the date of the violation which caused it to be established, except as provided in paragraph (e)(3) of this section.

(2) A modified control plan established as a result of this section must remain in effect for 3 years from the date of the violation which caused the plan to be modified, except as provided in paragraph (e)(3) of this section.

(3) An operator must modify a diesel particulate matter control plan during its duration as required to reflect changes in mining equipment or circumstances. Upon request from the Secretary, an operator must demonstrate the effectiveness of the modified plan by monitoring, using the measurement method specified by § 57.5061, sufficient to verify that the plan will control the concentration of diesel particulate matter to the applicable limit under conditions that can be reasonably anticipated in the mine.

(f) The Secretary will consider an operator's failure to comply with the provisions of the diesel particulate matter control plan in effect at a mine or to conduct required verification sampling to be a violation of this part without regard for the concentration of diesel particulate matter that may be present at any time.

§ 57.5065 Fueling and idling practices.

(a) Diesel fuel used to power equipment in underground areas must not have a sulfur content greater than 0.05 percent. The operator must retain purchase records that demonstrate compliance with this requirement for one year after the date of purchase.

(b) The operator must only use fuel additives registered by the U.S. Environmental Protection Agency in diesel powered equipment operated in underground areas.

(c) Idling of mobile diesel-powered equipment in underground areas is prohibited except as required for normal mining operations.

§ 57.5066 Maintenance standards.

(a) Any diesel powered equipment operated at any time in underground areas must meet the following maintenance standards:

(1) The operator must maintain any approved engine in approved condition;

(2) The operator must maintain the emission related components of any non-approved engine to manufacturer specifications; and

(3) The operator must maintain any emission or particulate control device installed on the equipment in effective operating condition.

(b)(1) A mine operator must authorize and require each miner operating diesel powered equipment underground to affix a visible and dated tag to the equipment at any time the miner notes any evidence that the equipment may require maintenance in order to comply with the maintenance standards of paragraph (a) of this section.

(2) A mine operator must ensure that any equipment tagged pursuant to this section is promptly examined by a person authorized by the mine operator to maintain diesel equipment, and that the affixed tag not be removed until the examination has been completed.

(3) A mine operator must retain a log of any equipment tagged pursuant to this section. The log must include the date the equipment is tagged, the date the equipment is examined, the name of the person examining the equipment, and any action taken as a result of the examination. The operator must retain the information in the log for one year

after the date the tagged equipment was examined.

(c) Persons authorized by a mine operator to maintain diesel equipment covered by paragraph (a) of this section must be qualified, by virtue of training or experience, to ensure that the maintenance standards of paragraph (a) of this section are observed. An operator must retain appropriate evidence of the competence of any person to perform specific maintenance tasks in compliance with those standards for one year after the date of any maintenance, and upon request must provide the documentation to the authorized representative of the Secretary.

§ 57.5067 Engines.

(a) Any diesel engine introduced into an underground area of a mine covered by this part after March 20, 2001, other than an engine in an ambulance or fire fighting equipment which is utilized in accordance with mine fire fighting and evacuation plans, must either:

(1) Have affixed a plate evidencing approval of the engine pursuant to subpart E of Part 7 of this title or pursuant to Part 36 of this title; or

(2) Meet or exceed the applicable particulate matter emission requirements of the Environmental Protection Administration listed in Table 57.5067–1, as follows:

TABLE 57.5067–1

EPA requirement	EPA category	PM limit
40 CFR 86.094–8(a)(1)(i)(A)(2)	light duty vehicle	0.1 g/mile.
40 CFR 86.094–9(a)(1)(i)(A)(2)	light duty truck	0.1 g/mile.
40 CFR 86.094–11(a)(1)(iv)(B)	heavy duty highway engine	0.1 g/bhp-hr.
40 CFR 89.112(a)	nonroad (tier, power range)	varies by power range:
	tier 1 kW<8 (hp<11)	1.0 g/kW-hr (0.75 g/bhp-hr).
	tier 1 8≤kW<19 (11≤hp<25)	0.80 g/kW-hr (0.60 g/bhp-hr).
	tier 1 19≤kW<37 (25≤hp<50)	0.80 g/kW-hr (0.60 g/bhp-hr).
	tier 2 37≤kW<75 (50≤hp<100)	0.40 g/kW-hr (0.30 g/bhp-hr).
	tier 2 75≤kW<130 (100≤hp<175)	0.30 g/kW-hr (0.22 g/bhp-hr).
	tier 1 130≤kW<225 (175≤hp<300)	0.54 g/kW-hr (0.40 g/bhp-hr).
	tier 1 225≤kW<450 (300≤hp<600)	0.54 g/kW-hr (0.40 g/bhp-hr).
	tier 1 450≤kW<560 (600≤hp<750)	0.54 g/kW-hr (0.40 g/bhp-hr).
	tier 1 kW≥560 (hp≥750)	0.54 g/kW-hr (0.40 g/bhp-hr).

Notes:
"g" means grams.
"hp" means horsepower.
"g/bhp-hr" means grams/brake horsepower-hour.
"kW" means kilowatt.
"g/kW-hr" means grams/kilowatt-hour.

(b) For purposes of paragraph (a):

(1) The term ''introduced'' means any engine added to the underground inventory of engines of the mine in question, including:

(i) An engine in newly purchased equipment;

(ii) An engine in used equipment brought into the mine; and

(iii) A replacement engine that has a different serial number than the engine it is replacing; but

(2) The term ''introduced'' does not include engines that were previously part of the mine inventory and rebuilt.

§ 57.5070 Miner training.

(a) Mine operators must provide annual training to all miners at a mine covered by this part who can reasonably be expected to be exposed to diesel emissions on that property. The training must include—

(1) The health risks associated with exposure to diesel particulate matter;

(2) The methods used in the mine to control diesel particulate matter concentrations;

(3) Identification of the personnel responsible for maintaining those controls; and

(4) Actions miners must take to ensure the controls operate as intended.

(b) An operator must retain a record at the mine site of the training required by this section for one year after completion of the training.

§ 57.5071 Environmental monitoring.

(a) Mine operators must monitor as often as necessary to effectively determine, under conditions that can be reasonably anticipated in the mine—

(1) Whether the concentration of diesel particulate matter in any area of the mine where miners normally work or travel exceeds the applicable limit specified in § 57.5060; and

(2) The average full shift airborne concentration of diesel particulate matter at any position or on any person designated by the Secretary.

(b) The mine operator must provide affected miners and their representatives with an opportunity to observe exposure monitoring required by this section. Mine operators must give prior notice to affected miners and their representatives of the date and time of intended monitoring.

(c) If any monitoring performed under this section indicates that the applicable concentration limit established by § 57.5060 has been exceeded, an operator must promptly post notice of the corrective action being taken, initiate corrective action by the next work shift, and promptly complete such corrective action.

(d)(1) The results of monitoring for diesel particulate matter, including any results received by a mine operator from sampling performed by the Secretary, must be posted on the mine bulletin board within 15 days of receipt and must remain posted for 30 days. The operator must provide a copy of the results to the authorized representative of miners.

(2) The mine operator must retain for five years (from the date of sampling), the results of any samples the operator collected as a result of monitoring under this section, and information about the sampling method used for obtaining the samples.

§ 57.5075 Diesel particulate records.

(a) The table entitled ''Diesel Particulate Recordkeeping Requirements'' lists the records the operator must retain pursuant to §§ 57.5060 through 57.5071, and the duration for which particular records need to be retained. The table follows:

DIESEL PARTICULATE RECORDKEEPING REQUIREMENTS

Record	Section reference	Retention time
1. Approved application for extension of time to comply with final concentration limit.	§ 57.5060(c)	1 year beyond duration of extension.
2. Approved plan for miners to perform inspection, maintenance or repair actions in areas exceeding the concentration limit.	§ 57.5060(d)	For duration of plan.
3. Control plan	§ 57.5062(b)	1 year beyond duration of plan.
4. Compliance plan verification sample results	§ 57.5062(c)	5 years from sample date.
5. Purchase records noting sulfur content of diesel fuel.	§ 57.5065(a)	1 year beyond date of purchase.
6. Maintenance log	§ 57.5066(b)	1 year after date any equipment is tagged.
7. Evidence of competence to perform maintenance.	§ 57.5066(c)	1 year after date maintenance performed.
8. Annual training provided to potentially exposed miners.	§ 57.5070(b)	1 year beyond date training completed.
9. Sampling method used to effectively evaluate mine particulate concentration, and sample results.	§ 57.5071(d)	5 years from sample date.

(b)(1) Any record listed in this section which is required to be retained at the mine site may, notwithstanding such requirement, be retained elsewhere if the mine operator can immediately access the record from the mine site by electronic transmission.

(2) Upon request from an authorized representative of the Secretary of Labor, the Secretary of Health and Human Services, or from the authorized representative of miners, mine operators must promptly provide access to any record listed in the table in this section.

(3) An operator must provide access to a miner, former miner, or, with the miner's or former miner's written consent, a personal representative of a miner, to any record required to be maintained pursuant to § 57.5071 to the extent the information pertains to the miner or former miner. The operator must provide the first copy of a requested record at no cost, and any additional copies at reasonable cost.

(4) Whenever an operator ceases to do business, that operator must transfer all records required to be maintained by this part, or a copy thereof, to any successor operator who must maintain them for the required period.

[FR Doc. 01–996 Filed 1–18–01; 8:45 am]

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Federal Register

Friday,
January 19, 2001

Part III

Department of Housing and Urban Development

24 CFR Part 221

Discontinuation of the Section 221(d)(2) Mortgage Insurance Program; Final Rule

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 221

[Docket No. FR–4588–F–02]

RIN 2502–AH50

Discontinuation of the Section 221(d)(2) Mortgage Insurance Program

AGENCY: Office of the Assistant Secretary for Housing-Federal Housing Commissioner, HUD.

ACTION: Final rule.

SUMMARY: This final rule discontinues HUD's section 221(d)(2) mortgage insurance program. The section 221(d)(2) program is rarely used by homebuyers, primarily due to its low mortgage limits. Accordingly, HUD will no longer enter into new contracts for mortgage insurance under the program. The final rule removes those provisions of the section 221(d)(2) regulations concerning eligibility for participation in the program, and replaces them with a savings clause. The rule, however, retains those regulatory provisions regarding the contract rights and servicing responsibilities for existing program participants. This final rule follows publication of a September 28, 2000 proposed rule. There were no public comments on the proposed rule, and HUD is adopting the proposed regulatory amendments without change.

DATES: *Effective Date:* February 20, 2001.

FOR FURTHER INFORMATION CONTACT: Vance T. Morris, Director, Office of Single Family Program Development, Office of Insured Single Family Housing, Room 9266, U.S. Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410–8000; telephone (202) 708–2121 (this is not a toll-free number). Hearing- or speech-impaired individuals may access this number via TTY by calling the toll-free Federal Information Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION:

I. Background

Section 221(d)(2) of the National Housing Act (12 U.S.C. 1715l(d)(2)), authorizes HUD to insure private lenders against loss from default on mortgage loans made to finance the purchase, construction, or rehabilitation of low-cost, one- to four-family homes. HUD's regulations implementing the section 221(d)(2) program are located in 24 CFR part 221.

On September 28, 2000 (65 FR 58338), HUD published a proposed rule to discontinue the section 221(d)(2) mortgage insurance program. The program is rarely used by homebuyers, primarily due to its low mortgage limits. Moreover, the section 221(d)(2) program provides few homeownership opportunities not already made available by other HUD mortgage insurance programs, primarily the single family home mortgage insurance programs authorized by section 203 of the National Housing Act (12 U.S.C. 1709) (implemented by HUD in 24 CFR part 203), and the condominium mortgage insurance program authorized by section 234 of the National Housing Act (12 U.S.C. 1715y) (implemented by HUD in 24 CFR part 234). For these reasons, HUD has decided to discontinue the section 221(d)(2) program.

II. This Final Rule

This final rule adopts the policies and procedures of the September 28, 2000 proposed rule. The public comment period for the proposed rule closed on November 27, 2000. By close of business on that date, HUD had not received any public comments on the proposed rule. Accordingly, this final rule adopts the proposed regulatory amendments without change.

The final rule removes HUD's regulations establishing the eligibility requirements for section 221(d)(2) mortgage insurance in subpart A of 24 CFR part 221. A savings clause is retained in subpart A of the part 221 regulations, which provides that the authority to insure section 221(d)(2) mortgages is terminated, except that HUD will endorse for insurance validly processed mortgages under direct endorsement where the credit worksheet was signed by the mortgagee's underwriter before the effective date of the final rule. The savings clause also provides that subpart A, as it existed immediately before the termination date, will continue to govern the rights and obligations of insured mortgage lenders, mortgagors, and HUD with respect to section 221(d)(2) single family loans insured before the effective date of the final rule, and to the aforementioned direct endorsement loans.

III. Findings and Certifications

Environmental Impact

A Finding of No Significant Impact with respect to the environment was made at the proposed rule stage, in accordance with HUD regulations at 24 CFR part 50, which implement section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4223). That finding remains applicable to this final rule and is available for public inspection between the hours of 7:30 a.m. and 5:30 p.m. weekdays in the Office of the Rules Docket Clerk, Office of General Counsel, Room 10276, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC.

Regulatory Flexibility Act

The Secretary has reviewed this final rule before publication, and by approving it certifies, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), that this final rule will not have a significant economic impact on a substantial number of small entities. As noted above, the section 221(d)(2) program is rarely used by homebuyers. Mortgage lenders eligible to participate in the section 221(d)(2) program are also generally eligible to participate in other, alternative, FHA single family mortgage insurance programs that are preferred by homebuyers (such as the section 203 and section 234(c) programs). Accordingly, HUD's decision to discontinue the section 221(d)(2) program is not anticipated to have a significant economic impact on a substantial number of mortgage lenders participating in these FHA programs.

Executive Order 13132, Federalism

Executive Order 13132 (entitled ''Federalism'') prohibits an agency from publishing any rule that has federalism implications if the rule either imposes substantial direct compliance costs on State and local governments and is not required by statute, or the rule preempts State law, unless the agency meets the consultation and funding requirements of section 6 of the Executive Order. This final rule would not have federalism implications and would not impose substantial direct compliance costs on State and local governments or preempt State law within the meaning of the Executive Order.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments, and on the private sector. This final rule would not impose any Federal mandates on any State, local, or tribal governments, or on the private sector, within the meaning of the Unfunded Mandates Reform Act of 1995.

Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance program number applicable to 24 CFR part 221 is 14.120: Mortgage Insurance—Homes for Low/Moderate Income Families.

List of Subjects in 24 CFR Part 221

Low and moderate income housing, Mortgage insurance, Reporting and recordkeeping requirements.

Accordingly, for the reasons described in the preamble, HUD amends 24 CFR part 221 to read as follows:

PART 221—LOW COST AND MODERATE INCOME MORTGAGE INSURANCE

1. The authority citation for part 221 is revised to read as follows:

Authority: 12 U.S.C. 1715b, 1715l; 42 U.S.C. 3535(d).

2. Subpart A is revised to read as follows:

Subpart A—Eligibility Requirements—Low Cost Homes—Savings Clause

§ 221.1 Savings clause.

(a) Effective February 20, 2001, the authority to insure mortgages under section 221(d)(2) of the National Housing Act (12 U.S.C. 1715l(d)(2)) for low cost and moderate income mortgage insurance is terminated, except that HUD will endorse for insurance validly processed mortgages under direct endorsement where the credit worksheet was signed by the mortgagee's underwriter before February 20, 2001.

(b) Subpart A of this part, as it existed immediately before February 20, 2001, will continue to govern the rights and obligations of insured mortgage lenders, mortgagors, and HUD with respect to section 221(d)(2) single family loans insured before February 20, 2001, or in accordance with paragraph (a) of this section, pursuant to the applicable provisions of this subpart.

Dated: January 9, 2001.

William C. Apgar,

Assistant Secretary for Housing-Federal Housing Commissioner.

[FR Doc. 01–1534 Filed 1–18–01; 8:45 am]

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Federal Register

Friday,
January 19, 2001

Part IV

Department of Labor

Occupational Safety and Health Administration

29 CFR Parts 1904 and 1952

Occupational Injury and Illness Recording and Reporting Requirements; Final Rule

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Parts 1904 and 1952

[Docket No. R–02]

RIN 1218–AB24

Occupational Injury and Illness Recording and Reporting Requirements

AGENCY: Occupational Safety and Health Administration (OSHA), U.S. Department of Labor.

ACTION: Final rule.

SUMMARY: The Occupational Safety and Health Administration (OSHA) is revising its rule addressing the recording and reporting of occupational injuries and illnesses (29 CFR parts 1904 and 1952), including the forms employers use to record those injuries and illnesses. The revisions to the final rule will produce more useful injury and illness records, collect better information about the incidence of occupational injuries and illnesses on a national basis, promote improved employee awareness and involvement in the recording and reporting of job-related injuries and illnesses, simplify the injury and illness recordkeeping system for employers, and permit increased use of computers and telecommunications technology for OSHA recordkeeping purposes.

This rulemaking completes a larger overall effort to revise Part 1904 of Title 29 of the Code of Federal Regulations. Two sections of Part 1904 have already been revised in earlier rulemakings. A rule titled Reporting fatalities and multiple hospitalization incidents to OSHA, became effective May 2, 1994 and has been incorporated into this final rule as § 1904.39. A second rule entitled Annual OSHA injury and illness survey of ten or more employers became effective on March 13, 1997 and has been incorporated into this final rule as § 1904.41.

The final rule being published today also revises 29 CFR 1952.4, Injury and Illness Recording and Reporting Requirements, which prescribes the recordkeeping and reporting requirements for States that have an occupational safety and health program approved by OSHA under § 18 of the Occupational Safety and Health Act (the ''Act'' or ''OSH Act'').

DATES: This final rule becomes effective January 1, 2002.

FOR FURTHER INFORMATION CONTACT: Jim Maddux, Occupational Safety and Health Administration, U.S. Department of Labor, Directorate of Safety Standards Programs, Room N–3609, 200 Constitution Ave., NW, Washington, DC 20210. Telephone (202) 693–2222.

SUPPLEMENTARY INFORMATION:

I. Table of Contents

The following is a table of contents for this preamble. The regulatory text and appendices follow the preamble. Documents and testimony submitted to the docket (Docket R–02) of this rulemaking are cited throughout this preamble by the number that has been assigned to each such docket entry, preceded by the abbreviation ''Ex.,'' for exhibit.

II. The Occupational Safety and Health Act and the Functions of the Recordkeeping System
III. Overview of the Former OSHA Recordkeeping System
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II. The Occupational Safety and Health Act and the Functions of the Recordkeeping System

Statutory Background

The Occupational Safety and Health Act (the ''OSH Act'' or ''Act'') requires the Secretary of Labor to adopt regulations pertaining to two areas of recordkeeping. First, section 8(c)(2) of the Act requires the Secretary to issue regulations requiring employers to ''maintain accurate records of, and to make periodic reports on, work-related deaths, injuries and illnesses other than minor injuries requiring only first aid treatment and which do not involve medical treatment, loss of consciousness, restriction of work or motion, or transfer to another job.'' Section 8(c)(1) of the Act also authorizes the Secretary of Labor to develop regulations requiring employers to keep and maintain records regarding the causes and prevention of occupational injuries and illnesses. Section (2)(b)(12) of the Act states Congress' findings with regard to achieving the goals of the Act and specifically notes that appropriate reporting procedures will help achieve the objectives of the Act.

Second, section 24(a) of the Act requires the Secretary to develop and maintain an effective program of collection, compilation, and analysis of occupational safety and health statistics. This section also directs the Secretary to ''compile accurate statistics on work injuries and illnesses which shall include all disabling, serious, or significant injuries and illnesses, whether or not involving loss of time from work, other than minor injuries requiring only first aid treatment and which do not involve medical treatment, loss of consciousness, restriction of work or motion, or transfer to another job.''

After passage of the Act, OSHA issued the required occupational injury and illness recording and reporting regulations as 29 CFR part 1904. Since 1971, OSHA and the Bureau of Labor Statistics (BLS) have operated the injury and illness recordkeeping system as a cooperative effort. Under a Memorandum of Understanding dated July 11, 1990 (Ex. 6), BLS is now responsible for conducting the nationwide statistical compilation of occupational illnesses and injuries (called the Annual Survey of Occupational Injuries and Illnesses), while OSHA administers the regulatory components of the recordkeeping system.

Functions of the Recordkeeping System

This revision of the Agency's recordkeeping rule is firmly rooted in the statutory requirements of the OSH Act (see the Legal Authority section of the preamble, below). OSHA's reasons for revising this regulation to better achieve the goals of the Act are discussed in the following paragraphs.

Occupational injury and illness records have several distinct functions or uses. One use is to provide information to employers whose employees are being injured or made ill by hazards in their workplace. The information in OSHA records makes employers more aware of the kinds of injuries and illnesses occurring in the workplace and the hazards that cause or contribute to them. When employers analyze and review the information in their records, they can identify and

correct hazardous workplace conditions on their own. Injury and illness records are also an essential tool to help employers manage their company safety and health programs effectively.

Employees who have information about the occupational injuries and illnesses occurring in their workplace are also better informed about the hazards they face. They are therefore more likely to follow safe work practices and to report workplace hazards to their employers. When employees are aware of workplace hazards and participate in the identification and control of those hazards, the overall level of safety and health in the workplace improves.

The records required by the recordkeeping rule are also an important source of information for OSHA. During the initial stages of an inspection, an OSHA representative reviews the injury and illness data for the establishment as an aid to focusing the inspection effort on the safety and health hazards suggested by the injury and illness records. OSHA also uses establishment-specific injury and illness information to help target its intervention efforts on the most dangerous worksites and the worst safety and health hazards. Injury and illness statistics help OSHA identify the scope of occupational safety and health problems and decide whether regulatory intervention, compliance assistance, or other measures are warranted.

Finally, the injury and illness records required by the OSHA recordkeeping rule are the source of the BLS-generated national statistics on workplace injuries and illnesses, as well as on the source, nature, and type of these injuries and illnesses. To obtain the data to develop national statistics, the BLS and participating State agencies conduct an annual survey of employers in almost all sectors of private industry. The BLS makes the aggregate survey results available both for research purposes and for public information. The BLS has published occupational safety and health statistics since 1971. These statistics chart the magnitude and nature of the occupational injury and illness problem across the country. Congress, OSHA, and safety and health policy makers in Federal, State and local governments use the BLS statistics to make decisions concerning safety and health legislation, programs, and standards. Employers and employees use them to compare their own injury and illness experience with the performance of other establishments within their industry and in other industries.

III. Overview of the Former OSHA Recordkeeping System

The OSH Act authorizes OSHA to require employers to keep records and to report the recorded information to OSHA. However, the Agency only requires some employers to create and maintain occupational injury and illness records. Those employers who are required to keep records must report on those records only when the government specifically asks for the information, which occurs exclusively under limited circumstances that are described below.

Employers covered by the recordkeeping regulations must keep records of the occupational injuries and illnesses that occur among their employees. To do so, covered employers must complete two forms. First, the employer must maintain a summary form (OSHA Form 200, commonly referred to as the ''OSHA Log,'' or an equivalent form) that lists each injury and illness that occurred in each establishment during the year. For each case on the Log, the employer also prepares a supplementary record (OSHA Form 101, or an equivalent), that provides additional details about the injury or illness. Most employers use a workers' compensation First Report of Injury in place of the 101 form. The Log is available to employees, former employees, and their representatives. A Summary of the Log is posted in the workplace from February 1 to March 1 of the year following the year to which the records pertain. The Log and summary, as well as the more detailed supplementary record, are available to OSHA inspectors who visit the establishment.

The employer is only obligated to record work-related injuries and illnesses that meet one or more of certain recording criteria. In accordance with the OSH Act, OSHA does not require employers to record cases that only involve ''minor'' injuries or illnesses, *i.e.,* do not involve death, loss of consciousness, days away from work, restriction of work or motion, transfer to another job, medical treatment other than first aid, or diagnosis of a significant injury or illness by a physician or other licensed health care professional.

The language of the OSH Act also limits the recording requirements to injuries or illnesses that are ''work-related.'' The Act uses, but does not define, this term. OSHA has interpreted the Act to mean that injuries and illnesses are work-related if events or exposures at work either caused or contributed to the problem. Work-related injuries or illnesses may (1) occur at the employer's premises, or (2) occur off the employer's premises when the employee was engaged in a work activity or was present as a condition of employment. Certain limited exceptions to this overriding geographic presumption were permitted by the former rule.

Although the Act gives OSHA the authority to require all employers covered by the OSH Act to keep records, two major classes of employers are not currently required regularly to keep records of the injuries and illnesses of their employees: employers with no more than 10 employees at any time during the previous calendar year, and employers in certain industries in the retail and service sectors.

Although the Act authorizes OSHA to require employers to submit reports on any or all injuries and illnesses occurring to their employees, there are currently only three situations where OSHA requires an employer to report occupational injury and illness records to the government. First, an employer must report to OSHA within eight hours any case involving a work-related fatality or the in-patient hospitalization of three or more employees as the result of a work-related incident (former 29 CFR 1904.8, final rule 1904.39). These provisions were revised in 1994 to reduce the reporting time for these incidents from 48 hours to 8 hours and reduce the number of hospitalized employees triggering a report from five workers to three workers (59 FR 15594 (April 1, 1994)). Changes made to this section in 1994 have largely been carried forward in the final rule being published today.

Second, an employer who receives an annual survey form from the Bureau of Labor Statistics must submit its annual injury and illness data to the BLS. The BLS conducts an annual survey of occupational injuries and illnesses under 29 CFR 1904.20–22 of the former rule (1904.41 of the final rule). Using a stratified sample, the BLS sends survey forms to randomly selected employers, including employers who, under Part 1904, would otherwise be exempt from the duty to keep the OSHA Log and Summary. These otherwise exempt employers are required to keep an annual record of the injuries and illnesses occurring among their employees that are recordable under Part 1904 if the BLS contacts them as part of the annual survey. At the end of the year, these employers must send the results of recordkeeping to the BLS. The BLS then tabulates the data and uses them to prepare national statistics on occupational injuries and illnesses. The

BLS survey thus ensures that the injury and illness experience of employers otherwise exempted from the requirement to keep OSHA records—such as employers with 10 or fewer employees in the previous year and employers in certain Standard Industrial Classification (SIC) codes—is reflected in the national statistics. In accordance with its statistical confidentiality policy, the BLS does not make public the identities of individual employers.

Finally, OSHA may require employers to send occupational injury and illness data directly to OSHA under a regulation issued in 1997. That section of this regulation is entitled Annual OSHA Injury and Illness Survey of Ten or More Employers. It allows OSHA or the National Institute for Occupational Safety and Health (NIOSH) to collect data directly from employers. This section was published in the **Federal Register** on February 11, 1997 (62 FR 6434) and became effective on March 13, 1997. It has been included in this final rule as section 1904.41 without substantive change; however, this section has been rewritten in plain language for consistency with the remainder of Part 1904.

IV. OSHA's Reasons for Revising the Recordkeeping Rule

OSHA had several interrelated reasons for revising its recordkeeping rule. The overarching goal of this rulemaking has been to improve the quality of workplace injury and illness records. The records have several important purposes, and higher quality records will better serve those purposes. OSHA also believes that an improved recordkeeping system will raise employer awareness of workplace hazards and help employers and employees use and analyze these records more effectively. In revising its recordkeeping rule, the Agency also hopes to reduce underreporting and to remove obstacles to complete and accurate reporting by employers and employees.

A major goal of the revision has been to make the system simpler and easier to use and understand and to update the data on which the system is based. For example, OSHA has updated the list of partially exempt industries to reflect the most recent data available. The revisions to the final rule will also create more consistent statistics from employer to employer. Further, by providing more details about the system in the regulation itself and writing the rule in plain language, fewer unintentional errors will be made and the records will be more consistent. More consistent records will improve the quality of analyses comparing the injury and illness experience of establishments and companies with industry and national averages and of analyses looking for trends over several years.

Another objective of the rulemaking has been to lessen the recordkeeping burden on employers, reduce unnecessary paperwork, and enhance the cost-effectiveness of the rule. The final rule achieves this objective in several ways. It updates the partially exempt industry list, reduces the requirement to keep track of lengthy employee absences and work restrictions caused by work-related injuries and illnesses and, above all, greatly simplifies the forms, regulatory requirements, and instructions to make the system easier for employers and employees to manage and use.

In this rulemaking, OSHA has also addressed some of the objections employers have raised in the years since OSHA first implemented the injury and illness recordkeeping system. For example, the final rule includes a number of changes that will allow employers to exclude certain cases, eliminate the recording of minor illness cases, and allow employers maximum flexibility to use computer equipment to meet their OSHA recordkeeping obligations.

OSHA is also complying with the President's Executive Memorandum on plain language (issued June 1, 1998) by writing the rule's requirements in plain language and using the question-and-answer format to speak directly to the user. OSHA believes that employers, employees and others who compile and maintain OSHA records will find that the plain language of the final rule helps compliance and understanding.

Many of OSHA's goals and objectives in developing this final rule work together and reinforce each other. For example, writing the regulation in plain language makes the rule easier for employers and employees to use and improves the quality of the records by reducing the number of errors caused by ambiguity. In some cases, however, one objective had to be balanced against another. For example, the enhanced certification requirements in the final rule will improve the quality of the records, but they also slightly increase employer burden. Nevertheless, OSHA is confident that the final rule generally achieves the Agency's goals and objectives for this rulemaking and will result in a substantially strengthened and simplified recordkeeping and reporting system.

The Need To Improve the Quality of the Records

The quality of the records OSHA requires employers to keep is of crucial importance for anyone who uses the resulting data. Problems with completeness, accuracy, or consistency can compromise the data and reduce the quality of the decisions made on the basis of those data. Several government studies, as well as OSHA's own enforcement history, have revealed problems with employers' injury and illness recordkeeping practices and with the validity of the data based on those records.

A study conducted by the National Institute for Occupational Safety and Health (NIOSH) between 1981 and 1983 revealed that 25 percent of the 4,185 employers surveyed did not keep OSHA injury and illness records at all, although they were required by regulation to do so (Ex. 15:407–P).

A study of 192 employers in Massachusetts and Missouri conducted by the BLS in 1987 reported that an estimated 10 percent of covered employers did not maintain OSHA records at all, total injuries were underrecorded by approximately 10 percent (even though both overrecording and underrecording were discovered), lost workday injuries were undercounted by 25 percent, and lost workdays were undercounted by nearly 25 percent. Approximately half of the uncounted lost workdays were days of restricted work activity, and the other half were days away from work. Some of the underrecording was due to employers entering lost time cases on their records as no-lost-time cases (Exs. 72–1, 72–2).

Through its inspections of workplaces, OSHA has also discovered that some employers seriously underrecord injuries and illnesses. In cases where the inspector has found evidence that the employer willfully understated the establishment's injury and illness experience, OSHA has levied large penalties and fines under its special citation policy for egregious violations. OSHA has issued 48 egregious injury and illness recordkeeping citations since 1986 (Ex. 74).

As part of the OSHA Data Initiative (ODI), a survey allowing OSHA to collect injury and illness data from employers to direct OSHA's program activities, the Agency conducts Part 1904 records audits of 250 establishments each year. The following table shows the results of the audits conducted to date.

1996 THROUGH 1998 OSHA RECORDKEEPING AUDIT RESULTS *

Error type	Data reference year (percent)		
	1996	1997	1998
Cases not entered on employers Log	13.56	10.49	12.91
Lost workday cases recorded as non-lost workday cases	8.39	6.53	6.21
Non-lost workday cases recorded as lost workday cases	(**)	2.10	1.94
Total major recording errors	21.95	19.11	21.07
Total cases recorded without major errors	78.05	80.89	78.93

* The results were tabulated using unweighted data and should not be used to draw broad conclusions about the recordkeeping universe.
** Data not calculated for 1996.
Source: OSHA Data Initiative Collection Quality Control: Analysis of Audits on 1996–1998 Employer Injury and Illness Recordkeeping.

Explicit Rules Are Needed To Ensure Consistent Recording

When OSHA's recordkeeping regulation was first promulgated in 1971, many industry safety experts were concerned that the regulations and the instructions on the forms did not provide adequate guidance for employers. They requested that the Department of Labor provide additional instructions on employers' recordkeeping obligations and clarify several recordkeeping issues. The BLS responded in 1972 by publishing supplemental instructions to the recordkeeping forms, BLS Report 412, What Every Employer Needs To Know About OSHA Recordkeeping (Ex. 1). These supplemental instructions were designed to help employers by providing detailed information on when and how to record injury and illness cases on the recordkeeping forms. The supplemental instructions clarified numerous aspects of the rule, including the important recordability criteria that outline which injuries and illnesses are work-related and thus recordable. This BLS Report was revised and reissued in 1973, 1975, and 1978.

In response to requests from labor and industry, and after publication in the **Federal Register** and a public comment period, the BLS 412 report series was replaced in April of 1986 by the *Recordkeeping Guidelines For Occupational Injuries And Illnesses* (the *Guidelines*) (Ex. 2). The *Guidelines* contained an expanded question-and-answer format similar to that of the BLS 412 report and provided additional information on the legal basis for the requirements for recordkeeping under Part 1904. The *Guidelines* provided clearer definitions of the types of cases to be recorded and discussed employer recordkeeping obligations in greater detail. The *Guidelines* also introduced a number of exceptions to the general geographic presumption that injuries and illnesses that occurred ''on-premises'' were work-related to cover situations where the application of the geographic presumption was considered inappropriate. Further, the *Guidelines* updated the lists that distinguished medical treatment from first aid and addressed new recordkeeping issues. The BLS also published a shortened version of the *Guidelines,* entitled A Brief Guide to Recordkeeping Requirements for Occupational Injuries and Illnesses (Ex. 7).

Although the 1986 edition of the *Guidelines* clarified many aspects of the recordkeeping regulation, concerns persisted about the quality and utility of the injury and illness data. In response to inquiries from employers, unions, employees, BLS, and OSHA staff, the Agency issued many letters of interpretation. These letters restated the former rule's regulatory requirements, interpreted the rules as they applied to specific injury and illness cases, and clarified the application of those requirements. A number of these letters of interpretation have been compiled and entered into the docket of this rulemaking (Ex. 70). OSHA has incorporated many of the prior interpretations directly into the implementation questions and answers in the regulatory text of the final rule, so that all affected employers will be aware of these provisions.

External Critiques of the Former Recordkeeping System

Because of concern about the injury and illness records and the statistics derived from them, several organizations outside OSHA have studied the recordkeeping system. The National Research Council (NRC), the Keystone Center, and the General Accounting Office (GAO) each published reports that evaluated the recordkeeping system and made recommendations for improvements. OSHA has relied on these studies extensively in developing this final rule.

The NRC Report

In response to concern over the underreporting of occupational injuries and illnesses and inconsistencies in the national data collected by the BLS, Congress appropriated funds in 1984 for the BLS to conduct a quality assurance study of its Annual Survey of Occupational Injuries and Illnesses. The BLS asked the National Research Council (NRC) to convene an expert panel to analyze the validity of employer records and the BLS annual survey, to address any problems related to determining and reporting occupational diseases, and to consider other issues related to the collection and use of data on health and safety in the workplace.

In 1987, NRC issued its report, Counting Injuries and Illnesses in the Workplace: Proposals for a Better System (Ex. 4). The report contained 24 specific recommendations (Ex. 4, Ch. 8). In sum, the NRC panel recommended that BLS take the following steps to improve the recordkeeping system: (1) Modify the BLS Annual Survey to provide more information about the injuries and illnesses recorded; (2) discontinue the Supplementary Data System, replace it with a grant program for States and individual researchers, and develop criteria for the detail and quality of the data collected by the replacement system; (3) conduct an ongoing quality assurance program for the Annual Survey to identify underreporting by comparing the information on employers' logs with data from independent sources; (4) implement a system of surveillance for occupational disease, including the collection of data on exposure to workplace hazards; (5) improve the collection of national occupational fatality data; (6) implement an administrative data system that would allow OSHA to obtain individual establishment data to conduct an ''effective program for the prevention of

workplace injuries and illnesses * * *''; and (7) thoroughly evaluate recordkeeping practices in individual establishments, using additional resources requested from Congress for that purpose to avoid diverting resources from OSHA inspections of workplace hazards (Ex. 4, p. 10).

The Keystone Report

In 1987, The Keystone Center convened 46 representatives from labor unions, corporations, the health professions, government agencies, Congressional staff, and academia for a year-long dialogue to discuss occupational injury and illness recordkeeping. Two years later, Keystone issued its final report, Keystone National Policy Dialogue on Work-related Illness and Injury Recordkeeping, 1989 (Ex. 5). The report focused on four major topics: (1) Recordkeeping criteria; (2) OSHA enforcement procedures; (3) injury and illness data systems; and (4) occupational illnesses. The Keystone report recommended that: (1) OSHA and the BLS should revise various aspects of the recording criteria; (2) OSHA should use injury and illness data to target enforcement efforts; (3) the BLS should revise the *Guidelines* to make them easily and uniformly understood; (4) the BLS should develop a national system to collect and disseminate occupational injury and illness information; and (5) OSHA and the BLS should broaden the type of information collected concerning occupational illness and make the information available to employees and government agencies for appropriate purposes such as research and study.

The General Accounting Office (GAO) Study

An August 1990 report by the GAO, Options for Improving Safety and Health in the Workplace (Ex. 3), discussed the importance of employer injury and illness records. The GAO noted that these records have several major uses. They help employers, employees and others understand the nature and extent of occupational safety and health problems. They help employers and employees identify safety and health problems in their workplaces so that they can correct the problems. They also enable OSHA to conduct research, evaluate programs, allocate resources, and set and enforce standards. The report focused on the use of the records in OSHA enforcement, particularly in targeting industries and worksites for inspections and determining the scope of inspections.

The GAO report found that there was ''possibly significant injury and illness underrecording and subsequent underreporting'' (Ex. 3, p. 3). The GAO report gave three main reasons for inaccurate recording and reporting: (1) Employers intentionally underrecord injuries and illnesses in response to OSHA inspection policies or management safety competitions; (2) employers unintentionally underrecord injuries and illnesses because they do not understand the recording and reporting system; and (3) employers record injuries and illnesses inaccurately because they do not place a high priority on recordkeeping and do not supervise their recordkeepers properly. The GAO report noted that OSHA's revised enforcement procedures, which included increasing its fines for recordkeeping violations and modifying its records-review procedures, would likely help to improve the accuracy of recordkeeping. The GAO recommended that the Department of Labor study the accuracy of employers' records using independent data sources, evaluate how well employers understand the revised *Guidelines,* and audit employers' records in selected enforcement activities.

OSHA's Strategy for Improving the Quality of Records

OSHA has developed a four-part strategy to improve the quality of the injury and illness records maintained by employers. The first component is to provide information, outreach and training to employers to make them more aware of the recordkeeping requirements, thereby improving their compliance with these requirements. For example, information on injury and illness recordkeeping is included in many of OSHA's publications and pamphlets, on the OSHA CD–ROM, and on OSHA's Internet site. OSHA personnel answer thousands of recordkeeping questions each year in response to phone calls and letters. OSHA also trains employers at the OSHA Training Institute in recordkeeping procedures and provides speakers on this topic for numerous safety and health events.

The second component is improved enforcement of the recordkeeping requirements. OSHA continues to review employer records during many of its workplace inspections. OSHA also audits the records of some employers who submit data to OSHA under former section 1904.17 (recodified as section 1904.41 Requests from OSHA for Data in the final rule). Although OSHA does not issue citations for minor reporting and recording violations, the Agency does cite and fine employers when it encounters serious or willful injury and illness recordkeeping problems.

The third component of OSHA's overall plan is this revision of the injury and illness recordkeeping rule. The revised final rule will streamline the recordkeeping system by simplifying the forms and the logic used to record an individual case. It will also consolidate the instructions that were formerly contained in the rule itself, in the *Guidelines,* and in many interpretative letters and memoranda. In addition, the final rule will improve the quality of the injury and illness records by changing several requirements to ensure that data are entered correctly. OSHA has simplified and streamlined the recordkeeping forms and processes to reduce errors. Other changes include: (1) Simplifying and clarifying the definitions of terms such as ''medical treatment,'' ''first aid,'' and ''restricted work'' to reduce recording errors; (2) providing specific recordkeeping guidance for specific types of injuries and illnesses; (3) including a detailed discussion of the process of determining whether an injury or illness is work-related; (4) giving employees greater involvement by improving their access to records and providing a longer posting period for the annual summary; (5) requiring higher level management officials to certify the records; (6) adding a falsification/penalty statement to the Summary; (7) adding a disclaimer to the Log to clarify that an employer who records an injury or illness is not admitting fault, negligence or liability for workers' compensation or insurance purposes; and (8) requiring the employer to establish a process for employees to report injuries and illnesses and to tell employees about it, and explicitly prohibiting the employer from discriminating against employees who report injuries and illnesses.

V. The Present Rulemaking

In 1995, the Keystone Center reassembled a group of business, labor, and government representatives to discuss draft proposed changes to the recordkeeping rule. OSHA shared its draft proposed revision of the rule with the participants and the public. The draft was also reprinted in several national safety and health publications. Written comments generated by the on-going dialogue were used to help develop the proposal and the final rule, and they are in the rulemaking record (Ex. 12).

OSHA consulted with the Advisory Committee on Construction Safety and Health (ACCSH) before issuing the

proposed rule. ACCSH made specific recommendations to OSHA for improving the recordkeeping system as it applied to the construction industry. OSHA gave the ACCSH recommendations careful consideration and responded by modifying the proposal in several areas. The ACCSH recommendations, OSHA's written briefing, and the relevant portions of the transcripts of the October and December 1994 ACCSH meetings are also part of the public record (Ex. 10).

OSHA published a Notice of Proposed Rulemaking (NPRM) on February 2, 1996 (61 FR 23), giving formal notice that the Agency proposed to revise the injury and illness recording and reporting regulations, forms, and supplemental instructions (Ex. 14). The proposed rule reflected a number of suggestions made by the Keystone participants and ACCSH.

The NPRM invited all interested parties to submit comments on the proposal to the docket by May 2, 1996. In response to requests from members of the public, OSHA held two public meetings during the comment period and extended the comment period to July 1, 1996.

OSHA received 449 written comments in response to the NPRM and compiled 1200 pages of transcripts from 60 presentations made at the public meeting. Comments and testimony were received from a broad range of interested parties, including corporations, small business entities, trade associations, unions, state and local governments, professional associations, citizens groups, and safety and health organizations. OSHA has carefully reviewed all of the comments and testimony in its preparation of the final rule.

As described in greater detail below, the final rule revises OSHA's regulation for the recording and reporting of work-related deaths, injuries and illnesses. The rule is part of a comprehensive revision of the OSHA injury and illness recordkeeping system.

The final rule becomes effective, on January 1, 2002. At that time, the following recordkeeping actions will occur:

(1) 29 CFR Part 1904, entitled Recording and Reporting Occupational Injuries and Illnesses, will be in effect.

(2) The State plan provisions in 29 CFR Part 1952, Section 1952.4, entitled Injury and Illness Recording and Reporting Requirements will be in effect.

(3) Three new recordkeeping forms will come into use:

(A) OSHA Form 300, OSHA Injury and Illness Log, and OSHA Form 300 A Summary, which will replace the former OSHA Form 200, Log and Summary of Occupational Injuries and Illnesses; and

(B) OSHA Form 301, OSHA Injury and Illness Incident Record, which will replace the former OSHA Form 101, Supplementary Record of Occupational Injuries and Illnesses.

(4) The following BLS/OSHA publications will be withdrawn:

(A) Recordkeeping Guidelines for Occupational Injuries and Illnesses, 1986; and

(B) A Brief Guide to Recordkeeping Requirements for Occupational Injuries and Illnesses, 1986.

(5) All letters of interpretation regarding the former rule's injury and illness recordkeeping requirements will be withdrawn and removed from the OSHA CD–ROM and the OSHA Internet site.

Provisions Not Carried Forward From the Proposal

Two proposed regulatory sections in OSHA's 1996 Notice of Proposed Rulemaking (NPRM) have not been carried forward in this rulemaking. They are: (1) Falsification of, or failure to keep records or provide reports (Proposed section 1904.16), and (2) Subcontractor records for major construction projects (Proposed section 1904.17).

Paragraphs (a) and (b) of proposed section 1904.16, ''Falsification of, or failure to keep records or provide reports,'' were included in the proposal because they had been included in the former rule. The proposed section included a provision stating that employers may be subject to criminal fines under section 17(g) of the Act for falsifying injury and illness logs and may be cited and fined under sections 9, 10, and 17 of the Act for failure to comply with the recordkeeping rule. Several commenters favored retention of this proposed provision in the final rule because, in their view, OSHA needs strong enforcement of the recordkeeping rule to make sure that employers keep accurate records (see, *e.g.*, Exs. 15: 11, 289). Others, however, objected to the proposed provision (see, *e.g.*, Exs. 15: 22, 335, 375). The views of this latter group were reflected in a comment from the American Petroleum Institute (Ex. 15: 375), which urged OSHA to delete this section from the rule in its entirety because nothing like it is found in any other OSHA regulation or standard. In the final rule, OSHA has decided that this section is not needed to enforce the final rule, and when need be, to issue citations and levy penalties.

The Keystone report recommended, and OSHA proposed, to require construction employers to maintain ''site logs,'' or comprehensive injury and illness records, for major construction projects. The Keystone report noted that construction sites are normally composed of multiple contractors and subcontractors, each of whom may be present at the site for a relatively short period of time, and that no records of the safety and health experience of the site are readily available, either to OSHA or to employers and employees.

In an attempt to address this problem, the proposed provision would have required site-controlling employers in the construction industry to maintain a separate record reflecting the overall injury and illness experience of employees working for sub-contract construction firms for any construction site having an initial construction contract value exceeding $1,000,000. The site-controlling employer would thus have been required to record the injuries and illnesses of subcontractor employees who were employed by construction employers with 11 or more employees working at the site at any time during the previous calendar year.

Many commenters strongly favored the addition of a construction site log provision to the final rule (see, *e.g.*, Exs. 20; 29; 35; 36; 45; 15: 48, 110, 113, 129, 136, 137, 141, 181, 224, 266, 278, 310, 350, 359, 369, 375, 394, 407, 413, 415, 418, 425, 438, 440). Several of these commenters urged OSHA to expand this ''multi-employer'' log concept to employers in other industries (see, *e.g.*, Exs. 35; 15: 48, 113, 129, 369, 415, 418, 438). For example, the AFL–CIO (Ex. 15: 418) encouraged OSHA to ''[e]xpand this recommendation to all industries. As the Agency is well aware, safety and health problems related to multi-employer worksites and contract work are a major concern in many industries beyond construction. Many of the major chemical explosions and fatalities at steel mills, power plants and paper mills have been related to contract work. With more and more businesses contracting out services for on-site activities, the safety and health concern associated with these practices is growing.''

Other commenters argued that the proposed site log provisions should be expanded to include injuries and illnesses to construction employees working for employers who would otherwise be exempt from OSHA recordkeeping requirements because they employ fewer than 11 workers (see, *e.g.*, Exs. 20; 15: 350, 359, 369, 407, 425). Two of these commenters recommended adding a requirement to the final rule requiring the site-controlling employer to assist smaller

employers with their records (Exs. 15: 350, 359).

Several commenters recommended adding provisions to the final rule that would provide greater access to the construction site log by employees (see, *e.g.*, Exs. 15: 129, 310, 394) and by other employers (see, *e.g.*, Ex. 15: 310). Others recommended that OSHA include in the final rule a requirement for the site-controlling employer to collect the number of hours worked by each subcontractor to make it easier to calculate each subcontractor's injury and illness rates (see, *e.g.*, Exs. 15: 310, 369, 394), and some commenters recommended that the final rule contain a requirement for subcontractors to report work-related injuries and illnesses to the site-controlling employer (see, *e.g.*, Exs. 15: 359, 369, 440).

The Building and Construction Trades Department (BCTD), AFL–CIO discussed many of these issues while commenting in favor of site logs:

On the project level, the fragmentation of employers on construction sites makes it impossible to assess fully safety and health on a particular project. Since the origins of OSHA, injury and illness recordkeeping has been the responsibility of each individual employer. Nevertheless, the hazards of construction activity are shared by employees across the site, and are not specific to a single employer. Employees are often injured or made ill by circumstances that are not under their own employer's full control. The balkanization of recordkeeping contributes to the failure of full and complete communication in construction.

What is needed, at a national and the project level, is a way to record and count the injuries and illnesses that occur on specific projects. We need to know about illnesses and injuries that are associated with distinct types of construction activity, with the various phases of construction, and with the methods, materials, and hazards that are common to those types of work. Furthermore, we need to develop a measure of injury and illness that spans employers, to get a picture of the aggregate outcomes affecting all actors on a common site. Only with such a tool can the construction industry establish and meet performance benchmarks for safety and health.

Site logs would be useful to all of the actors in the occupational safety and health arena. First, employers would benefit from the collection of this data. General contractors increasingly use safety and health information in selecting their subcontractors, and in evaluating projects. Site logs will give them a new tool for both self-evaluation and the evaluation of other contractors. Similarly, subcontractors are often ignorant of the safety and health performance of other contractors and the general contractor. Site logs will lead to better information for all contractors on the project.

Second, employees will benefit from site logs. The site log will focus employers' attentions upon the risks and hazards that are encountered across the worksite. By concretely illustrating that hazards are everyone's problems, the site log will prompt employers and employees to minimize those hazards and to maximize site safety and health.

Third, owners will benefit from site logs. Today, many owners are selecting contractors on the basis of the contractors' rates for lost work days and total recordables. In many cases, these rates are a poor measure for the owner's purpose. An owner's typical concern is with how well a general contractor manages safety and health on the entire site, not with how many injuries and illnesses occurred within that contractor's own workforce. Site logs can be used to measure the management performance of the general contractor, and will greatly assist the owners in their quest for construction safety.

Finally, OSHA will find the site logs to be enormously useful in its efforts to become a ''data-driven'' agency. First, a project-centric focus will allow OSHA to focus its enforcement and consultation resources. Site logs will be useful to OSHA in scheduling inspections during the phases of construction which appear, through this data, to present the most risks, and in focusing its inspections at construction sites, since the recent illness and injury history of the entire site can be assayed by examining a single document. By the same token, the information revealed by the logs will assist OSHA in reaching out to employers to provide consultative services. Site specific data will also aid OSHA in developing safety and health standards that are appropriately tailored to the risks and hazards of specific types of construction.

The BCTD is convinced that private actors will use site logs to improve safety and health performance. If OSHA establishes a requirement that site logs be kept, the private marketplace will use this new tool to the betterment of employee safety and health (Ex. 15: 394).

Other commenters opposed the addition of a site log provision to the final rule (see, *e.g.*, Exs. 43; 51; 15: 9, 17, 21, 38, 40, 43, 61, 67, 74, 77, 97, 111, 116, 119, 121, 126, 151, 155, 163, 170, 194, 195, 204, 213, 235, 242, 256, 260, 262, 263, 265, 269, 270, 281, 294, 298, 304, 305, 312, 314, 341, 342, 351, 356, 364, 377, 389, 395, 397, 401, 406, 412, 423, 433, 437, 443, 441). The most common argument presented by these commenters was that records should only be kept by the employer, and that one employer should not keep records for another employer's employees (see, *e.g.*, Exs. 15: 9, 116, 126, 163, 195, 204, 260, 262, 265, 281, 294, 304, 312, 314, 341, 342, 351, 364, 389, 395, 396, 397, 401, 406, 423, 433). The Jewell Coal and Coke Company (Ex. 15: 281) stated that:

[t]he sub-contractor should be responsible for keeping up with their own employee injury/illness records as they are the ultimate responsible party for their own employees under worker's compensation regulations and in all other legal issues. This proposal would appear to be trying to switch total responsibility to the site controlling employer for that record keeping purpose and taking the responsibility off the subcontractor with whom the responsibility should lie. It is, we feel, unfairly discriminatory against the site-controlling employer in this case and we are strongly opposed to the wording of this proposal. Even the alternative proposal in this section places the ultimate responsibility upon the project owner for collection of accident and illness information and send it to OSHA. Again we are strongly opposed to the wording of this proposal because it takes the responsibility for record keeping off the sub-contractor and places the ultimate responsibility on the project owner, a responsibility that we feel belongs to the sub-contractor irregardless of their size.

Brown & Root, Inc. (Ex. 15: 423) added ''A site controlling employer cannot be held responsible for determining which injuries and illnesses of a subcontractor's employees are recordable. A contractor cannot become involved in the medical records of employees who do not work for him or her. The subcontractor employer has to be held accountable and responsible for his own employees, this responsibility cannot be delegated to another contractor. The number of employees or the value of the construction project is irrelevant.''

Some of the commenters who generally opposed this provision agreed that site-specific data would be useful if it could be collected by a method that allowed each employer to keep its own records (see, *e.g.*, Exs. 15: 9, 116, 195, 260, 262, 265, 304, 364, 401). Other commenters pointed out that there would be problems in getting accurate data from subcontractors (see, *e.g.*, Exs. 15: 242, 263, 269, 270, 310, 314, 377, 395, 397, 406) or suggested that the site-controlling employer should not be held responsible for the quality of the records received from subcontractors (see, *e.g.*, Exs. 33; 15: 176, 195, 231, 273, 294, 301, 305, 312, 351).

The Alabama Branch of the Associated General Contractors of America, Inc. (AGC) cited difficulties associated with other regulatory requirements that could result from the proposed OSHA site log requirement:

This could place an undue hardship on the site controlling employer far beyond his ability to appoint and manage independent contractors and subcontractors without there being other entangling both federal and state obligations, which would lead to the subcontractor's employees being declared employees of the controlling contractor. Many states use the common law to make a determination of the employer/employee relationship, as well as the Internal Revenue Service. This employee/employer relationship under the common law usually

says if a controlling contractor exercises any control as to time, place, method or result of a person's work that they are in fact defacto employees of the controlling contractor, for social security purposes and other state purposes. Therefore, I think it is shallow thinking to believe that the general contractor with 100 subcontractors should have all 5,500 employees under their control and avoid other legal entanglements, without the ability to actually control the subcontractor.

The National Federation of Independent Business (NFIB) expressed concern about the proposed site log provision as it would relate to OSHA's multi-employer citation policy (Ex. 15: 304), and the Small Business Administration (Exs. 51: 67, 437) argued that the proposed requirement would require competing employers to share sensitive business information.

A number of commenters objected to the requirement because of the additional burden it would place on employers (see, *e.g.*, Exs. 51; 15: 40, 43, 67, 77, 97, 119, 121, 163, 194, 204, 235, 242, 256, 263, 269, 270, 294, 298, 304, 312, 314, 356, 377, 389, 395, 397, 406, 412, 437, 441), arguing that the proposed requirement would result in duplication (see, *e.g.*, Exs. 51; 15: 9, 38, 67, 77, 119, 155, 204, 304, 312, 351, 356, 364, 377, 395, 397, 437). For example, the American Iron and Steel Institute (Ex. 15: 395) stated that the proposed requirement would place a ''near impossible burden on the 'site controlling employer' '' to determine the size of each subcontractor to decide which subcontractors would be required to keep records.

A number of commenters also questioned the value of the statistical data that would be produced by a site log requirement (see, *e.g.*, Exs. 51; 15: 61, 62, 67, 74, 77, 97, 121, 151, 194, 312, 314, 351, 389, 395, 433, 437, 433), and several participants were concerned that the records would not be useful for accident prevention purposes (see, *e.g.*, Exs. 15: 121, 151, 312, 351, 389, 433) .

OSHA received many comments addressing miscellaneous points related to the proposed construction site log requirement. For example, some commenters suggested limiting the scope of the project records required to be maintained (see, *e.g.*, Exs. 15: 17, 21, 111, 116, 213, 155), while others argued that the proposed dollar threshold ($1 million) for a covered construction project was too low and should be raised (see, *e.g.*, Exs. 15: 17, 111, 116, 441). Others suggested that the site log requirement should be triggered by the time duration of the project (Ex. 15: 116); the number of construction workers at the site (Ex. 15: 111); or include only construction employers with more than 11 employees (see, *e.g.*, Exs. 15: 170, 213, 405). Some commenters urged the Agency not to expand the site log concept beyond the construction industry (see, *e.g.*, Exs. 33; 15: 176, 231, 273, 301, 397). Finally, several commenters urged OSHA to make any site log provision in the final rule compatible with the corresponding provisions of the Process Safety Management Standard (29 CFR 1910.119), especially if the site log requirement in the recordkeeping rule was expanded beyond construction (see, *e.g.*, Exs. 33; 15: 159, 176, 231, 273, 301, 335).

Based on a thorough review of the comments received, OSHA has decided not to include provisions in the final that require the site-controlling employer to keep a site log for all recordable injuries and illnesses occurring among employees on the site. OSHA has made this decision for several reasons. First, such a provision would not truly capture the site's injury and illness experience because many subcontractors employ 10 or fewer employees and are therefore exempt from keeping an OSHA Log. To require these very small employers to keep records under Part 1904 for the periods of time they worked on a construction site meeting the dollar threshold for this provision would be a new recordkeeping burden. This would create considerable complexity for these employers and for the site-controlling employer. Second, under the Data Initiative (section 1904.41 of the final rule), OSHA now has a means of targeting data requests for records of the safety and health experience of categories of employers and can therefore obtain the data it needs to establish inspection priorities in a less administratively complex and less burdensome way when the Agency needs such data. Third, OSHA was concerned with the utility of the data that would have been collected under the proposed site log approach, because of the time lag between collection of the data and its use in selecting employers for inspections or other interventions. In many cases work at the site would be complete before the data was collected and analyzed. Finally, a site log requirement is not necessary to enable general contractors to compare the safety records of potential subcontractors since they can require such information as a condition of their contractual arrangements without OSHA requirements. For these reasons, the final rule does not contain a site log provision.

The Use of Alternative Data Sources

Several commenters suggested that the Agency use data from existing data sources, such as state workers' compensation agencies, insurance companies, hospitals, or OSHA inspection files, instead of requiring separate data for OSHA recordkeeping purposes (see, *e.g.*, Exs. 15: 2, 28, 58, 63, 97, 184, 195, 289, 327, 341, 374, 444). For example, Alex F. Gimble observed:

Since similar data are readily available from other sources, such as the National Safety Council, insurance carriers, etc., why not use these statistics, rather than go through this duplication of effort at taxpayer expense? Another approach would be to utilize data collected by OSHA and State Plan compliance officers during site visits over the past 25 years (Ex. 15: 28).

Several commenters suggested that OSHA use injury and illness data from the workers' compensation systems in lieu of employer records. The comments of the American Health Care Association (AHCA) are representative of the views of these commenters:

AHCA encourages OSHA to consider the use of workers' compensation data in lieu of proposed OSHA 300 and 301 forms. Pursuing the enactment of legislation that would allow OSHA access to every state's workers' compensation data would eliminate the need for employers to maintain two sets of records, provide OSHA with necessary safety and health data, and ease administrative and cost burdens now associated with recordkeeping for employers in every industry across the country (Ex. 15: 341).

Ms. Diantha M. Goo recommended the use of injury and illness data obtained from treatment facilities rather than the OSHA records:

The accuracy and usefulness of OSHA's reporting system would be vastly improved if it were to shift responsibility from employers (who have a vested interest in concealment) to the emergency rooms of hospitals and clinics. Hospitals are accustomed to reporting requirements, use the correct terminology in describing the accident and its subsequent treatment and are computerized (Ex. 15: 327).

In response to these comments, OSHA notes that the injury and illness information compiled pursuant to Part 1904 is much more reliable, consistent and comprehensive than data from any available alternative data source, including those recommended by commenters. This is the case because, although some State workers' compensation programs voluntarily provide injury and illness data to OSHA for various purposes, others do not. Further, workers' compensation data vary widely from state to state. Differing state workers' compensation laws and administrative systems have resulted in

large variations in the content, format, accessibility, and computerization of that system's data. In addition, workers' compensation databases often do not include injury and illness data from employers who elect to self-insure.

Additionally, most workers' compensation databases do not include information on the number of workers employed or the number of hours worked by employees, which means that injury and illness incidence rates cannot be computed from the data. Workers' compensation data are also based on insurance accounts (i.e., filed claims), and not on the safety and health experience of individual workplaces. As a result, an individual account often reflects the experience of several corporate workplaces involved in differing business activities. Finally, as discussed below in the Legal Authority section of the preamble, the OSH Act specifically sets out the recordability criteria that must be included in the OSHA recordkeeping system envisioned by the Congress when the Act was passed. The Congress intended that all non-minor work-related injuries and illnesses be captured by the OSHA recordkeeping system, both so that individual establishments could evaluate their injury and illness experience and so that national statistics accurately reflecting the magnitude of the problem of occupational injury and illness would be available.

Although OSHA disagrees that any of the alternate sources of data are satisfactory substitutes for the information gathered under Part 1904, the Agency recognizes that data from these sources have value. To the extent that information from workers' compensation programs, the BLS statistics, insurance companies, trade associations, etc., are available and appropriate for OSHA's purposes, OSHA intends to continue to use them to supplement its own data systems and to assess the quality of its own data. However, consistent with the Congressional mandate of the OSH Act, OSHA must continue to maintain its own recordkeeping system and to gather data for this system through recording and reporting requirements applicable to covered employers.

Section 1952.4 Injury and Illness Recording and Reporting Requirements

The requirements of 29 CFR 1952.4 describe the duties of State-Plan states to implement the 29 CFR 1904 regulations. These requirements are discussed in Section IX of the preamble, State Plans, and in the preamble discussion for section 1904.37, State recordkeeping regulations.

General Issues Raised by Commenters

In addition to the issues discussed above, three issues concerning recordkeeping warrant discussion: analysis of the data, training and qualifications of recordkeepers, and recordkeeping software.

Analysis of the Data

During OSHA's public meetings, Eric Frumin of the Union of Needletrades, Industrial and Textile Employees, AFL–CIO (UNITE) urged OSHA to include a requirement for employers to analyze the OSHA 1904 data in depth to discover patterns and trends of occupational injury and illness, stating that:

> [y]ou're telling the employers to evaluate information that's coming to them, and I say that to stress the point that's a very logical, common sense requirement and you're not generally speaking asking them to do that once they compile a log. You stop short of asking employers to evaluate the log in toto, to look for the kinds of trends and comparisons and so forth that we've been discussing here. I think it's important for OSHA to consider some—making such a requirement, particularly in light of a fairly consistent pattern of testimony in this proceeding, wherein employers now do not analyze what's on the log in much depth. * * * But what has emerged at the end of the day is not a whole lot of use of the information on the log for—in terms of analyzing it for trends and various associations or conclusions about how to protect people, how to stop the injuries and illness (Ex. 58X, pp. 372—375).

In the final rule, OSHA has not included any requirement for employers to analyze the data to identify patterns or trends of occupational injury and illness. OSHA agrees with Mr. Frumin that analysis of the data is a logical outgrowth of maintaining records. Employers and employees can use such analyses to identify patterns and trends in occupational injuries and illnesses, and use that information to correct safety and health problems in the workplace. OSHA encourages both employers and employees to use the data for these purposes. However, a requirement of this type would go beyond the scope of the recording and reporting rule, which simply requires employers to keep records of work-related injuries and illnesses, and report the data under certain circumstances. OSHA believes that requirements of this type are better addressed through an OSHA standard, rather than the 1904 recordkeeping regulation.

Training of Recordkeepers

The American Federation of Labor and Congress of Industrial Organizations (AFL–CIO) suggested that OSHA add requirements for the training of the individual who maintains the 1904 records for the employer, stating that:

> [a]nother important issue relates to the qualifications and responsibilities of the individual filling out the 300 log and Form 301. Most workplaces generally have a non-safety and health professional entering this information in the 300 log after the decision of a recordable injury or illness has been made. In our view it is important that these individuals have proper training about the recordkeeping rule and the employer's recordkeeping system. In order to assure the most accurate and complete recording of work-related injuries and illnesses, we encourage the Agency to consider developing guidelines for the qualifications and training of these individuals (Ex. 15: 418).

OSHA has not included a training requirement for the person entering the information on the Part 1904 records in this final rule. The Agency believes that the Section 1904.32 provisions of the final rule calling for annual review of the records and certification of the annual summary by a company executive will ensure that employers assign qualified personnel to maintain the records and to see that they are trained in that task. Further, because OSHA did not include training requirements in its 1996 proposal, the Agency has not gathered sufficient information in the rulemaking docket about whether specific training provisions would have utility, as well as the appropriate qualifications and training levels that would assist in writing such provisions at this time.

As part of its outreach and training program accompanying this rule, OSHA will be providing speeches and seminars for employers to help them train their recordkeeping staff. OSHA will also be producing materials employers can use to help train their recordkeeping staff, including free software employers can use to keep records, training programs, presentations, course outlines, and a training video. All of these materials will be available through OSHA's Internet home page at www.osha.gov.

OSHA-Produced Recordkeeping Software

In its proposal (61 FR 4048), OSHA asked the public to comment on whether or not OSHA should develop computer software to make injury and illness recordkeeping easier for employers, and discussed the features that would be desirable for such software. Those features were:

—decision-making logic for determining if an injury or illness is recordable;

—automatic form(s) generation;

—the ability to assist the employer in evaluating the entered data through several preset analytical tools (*e.g.*, tables, charts, etc.); and

—computer based training tools to assist employers in training employees in proper recordkeeping procedures.

OSHA also suggested that any such software should be in the public domain and/or be available at cost to the public and asked the following questions: What percentage of employers have computers to assist them in their business? What percentage of employers currently use computers for tracking employee-related information (payroll, timekeeping, etc.)? Should the distribution be through the Government, public domain share-ware distribution, or other channels? Should OSHA develop the software or only provide specifications for its requirements?

Several commenters said that most business establishments had computers (see, *e.g.*, Exs. 15: 9, 95, 163, 281, 288, 375). The American Health Care Association (AHCA) estimated that 50% to 70% of their members used computers (Ex. 15: 341), and Raytheon Constructors, Inc. estimated that 60% of employers are using computers. OSHA agrees that computers are available in most businesses, although certainly not all of them. The agency also notes that these comments were made in 1996, and that businesses' computer usage has grown since that time.

A number of commenters urged OSHA to produce and distribute software to help employers keep the Part 1904 records (see, *e.g.*, Exs. 35; 36; 51; 15: 9, 26, 32, 34, 67, 68, 76, 87, 95, 105, 109, 111, 129, 154, 157, 170, 181, 182, 197, 225, 235, 239, 247, 272, 277, 281, 283, 288, 303, 313, 327, 341, 347, 350, 352, 353, 356, 394, 405, 406, 409, 418, 426, 437, 438). The commenters gave various reasons for favoring the provision of OSHA-provided software, including reducing the burden and cost of the rule for employers (see, *e.g.*, Exs. 15: 87, 95, 111, 170, 182, 197, 350), saving businesses programming costs (Ex. 15: 277), helping small businesses (Ex. 51; 15: 67), resulting in more uniform data (see, *e.g.*, Exs. 36; 15: 32, 153, 170, 181, 347, 409, 418), and facilitating analysis of the data (see, *e.g.*, Exs. 35; 15: 153, 418). For example, the Ford Motor Company stated that ''Ford feels that the development of recordkeeping software by OSHA, which will employ a decision-making logic, automatic form generation, the ability to assist the employer in evaluating the entered data, and a tutorial section to assist employers in training is necessary. This will enhance the uniformity of data collection amongst all users, which is currently lacking'' (Ex. 15: 347). The Muscatine Iowa Chamber of Commerce Safety Committee (Ex. 15: 87) added that:

> ''[e]very feature identified as a minimum requirement would be a great benefit to employers attempting to comply with the OSHA recordkeeping requirements. Prompts which would in any way aid in the determination of recordability would be appreciated by any person without a great deal of experience in filing OSHA reports. We feel these features are especially important now with the changes in forms and information to be collected.''

Several of the commenters who urged OSHA to provide computer software tempered their support by asking that the use of such software should be optional and not mandatory (see, *e.g.*, Exs. 15: 60, 109, 154, 198, 225, 247, 272, 303, 394), and several other commenters recommended that OSHA provide both software and specifications so employers could use the OSHA product to build their own data systems (see, *e.g.*, Exs. 15: 170, 247, 283).

A number of commenters told OSHA that the Agency should not produce software to help employers with their 1904 recordkeeping obligations (see, *e.g.*, Exs. 15: 78, 82, 85, 156, 163, 324, 348, 359, 363, 374, 375, 378, 402, 414). Several of these commenters suggested OSHA produce software performance specifications for the industry (see, *e.g.*, Exs. 15: 156, 163, 357, 387). The commenters had various reasons for opposing the production of software. Several stated that each employer wants different data in its own unique form (see, *e.g.*, Exs. 15: 78, 85, 375, 414). For example, the Central Vermont Public Service Corporation (Ex. 15: 85) stated that ''[b]usinesses using safety related software use programs that can perform OSHA recordkeeping and workers' compensation functions in one package. It is unlikely that software developed by OSHA will perform workers' compensation functions and therefore it will not be well received or utilized by business.'' Other commenters stated that OSHA should focus elsewhere, that the private sector could produce software more economically (see, *e.g.*, Exs. 15: 357, 375, 387), and that OSHA software is not needed (see, *e.g.*, Exs. 15: 363, 378). For example, the Synthetic Organic Chemical Manufacturers Association, Inc. (SOCMA) stated that ''[a]n outside organization with software development expertise should develop the software. OSHA's limited resources should go directly toward improving safety and health in the workplace'' (Ex. 15: 357). The Air Transport Association added: ''[m]ost major companies have developed their own software to support required OSHA recordkeeping, and others have taken advantage of commercially available programs. We see no need for OSHA to enter this market'' (Ex. 15: 378).

OSHA has decided that the Agency will produce software for employers to use for keeping their OSHA 1904 records. There is obviously a need for the Agency to provide outreach and assistance materials for employers, particularly small employers, to help them meet their obligations in the least burdensome way possible, and software will clearly help achieve this goal. In addition, computer software will improve the consistency of the records kept by employers, and will assist them with analysis of the data. At this time, OSHA has not developed the software or its specifications, but will make every effort to produce and distribute software to assist employers by the time this final rule becomes effective. Use of the OSHA produced software will be optional; employers are not required to use this software and may keep records using paper systems. Employers are also free to produce their own software, or to purchase software.

VI. Legal Authority

A. The Final Recordkeeping Rule Is a Regulation Authorized by Sections 8 and 24 of the Act

The Occupational Safety and Health Act authorizes the Secretary to issue two types of final rules, ''standards'' and ''regulations.'' Occupational safety and health standards, issued pursuant to section 6 of the Act, specify the measures to be taken to remedy known occupational hazards. 29 U.S.C. 652(8), 655. Regulations, issued pursuant to general rulemaking authority found, inter alia, in section 8 of the Act, are the means to effectuate other statutory purposes, including the collection and dissemination of records on occupational injuries and illnesses. 29 U.S.C. 657(c)(2).

OSHA is issuing this final recordkeeping rule as a regulation pursuant to the authority expressly granted by sections 8 and 24 of the Occupational Safety and Health Act, 29 U.S.C. 657, 673. Section 8 authorizes the Secretary to issue regulations she determines to be necessary to carry out her statutory functions, including regulations requiring employers to record and report work-related deaths and non-minor injuries and illnesses.[1] Section 8(c)(1) of the Act requires each

[1] This rule excludes minor or insignificant injuries and illnesses from reporting requirements. The exclusion of minor illnesses represents a change from the former rule, and is discussed *infra*.

employer to ''make, keep and preserve, and make available to the Secretary [of Labor] or the Secretary of Health [and Human Services], such records regarding his activities relating to this Act as the Secretary, in cooperation with the Secretary of Health and Human Services, may prescribe by regulation as necessary or appropriate for the enforcement of this Act or for developing information regarding the causes and prevention of occupational accidents and illnesses.'' Section 8(c)(2) further provides that the ''Secretary, in cooperation with the Secretary of Health and Human Services, shall prescribe regulations requiring employers to maintain accurate records of, and to make periodic reports on, work-related deaths, injuries and illnesses other than minor injuries requiring only first aid treatment and which do not involve medical treatment, loss of consciousness, restriction of work or motion, or transfer to another job.'' Section 8(c)(3) empowers the Secretary to require employers to ''maintain accurate records of employee exposures to potentially toxic materials or harmful physical agents which are required to be monitored or measured under Section 6.''

Section 8(g)(1) authorizes the Secretary ''to compile, analyze, and publish, whether in summary or detailed form, all reports or information obtained under this section.'' Section 8(g)(2) of the Act empowers the Secretary ''to prescribe such rules and regulations as he may deem necessary to carry out his responsibilities under the Act.''

Section 24 contains a similar grant of regulatory authority. It requires the Secretary to ''develop and maintain an effective program of collection, compilation, and analysis of occupational safety and health statistics * * * The Secretary shall compile accurate statistics on work injuries and illnesses which shall include all disabling, serious, or significant injuries and illnesses, whether or not involving loss of time from work, other than minor injuries requiring only first aid treatment and which do not involve medical treatment, loss of consciousness, restriction of work or motion, or transfer to another job.'' Section 24 also empowers the Secretary to ''promote, encourage, or directly engage in programs of studies, information and communication concerning occupational safety and health statistics.'' Finally, Section 24 requires employers to ''file such reports with the Secretary as he shall prescribe by regulation, as necessary to carry out his functions under this chapter.''

Section 20 of the Act, 29 U.S.C. 669, contains additional implicit authority for collecting and disseminating data on occupational injuries and illnesses. Section 20(a) empowers the Secretaries of Labor and Health and Human Services to consult on research concerning occupational safety and health problems, and provides for the use of such research, ''and other information available,'' in developing criteria on toxic materials and harmful physical agents. Section 20(d) states that ''[i]nformation obtained by the Secretary and the Secretary of [HHS] under this section shall be disseminated by the Secretary to employers and employees and organizations thereof.''

Two federal circuit Courts of Appeals have held that rules imposing recordkeeping requirements are regulations and not standards, and are thus reviewable initially in the district courts, rather than the Courts of Appeals. *Louisiana Chemical Assn.* v. *Bingham,* 657 F.2d 777, 782–785 (5th Cir. 1981) (OSHA rule on Access to Employee Exposure and Medical Records); *Workplace Health & Safety Council* v. *Reich,* 56 F.3d 1465, 1467–1469 (D.C. Cir. 1995) (OSHA rule on Reporting of Fatality or Multiple Hospitalization Incidents). These courts applied a functional test to differentiate between standards and regulations: standards aim toward correction of identified hazards, while regulations serve general enforcement and detection purposes, including those outlined in section 8. E.g., *Workplace Health & Safety Council,* 56 F.3d at 1468. See also *United Steelworkers of America* v. *Reich,* 763 F.2d 728, 735 (3d Cir. 1985) (Hazard Communication rule is a standard because it aims to ameliorate the significant risk of inadequate communication about hazardous chemicals). Clearly, the recordkeeping requirements in this final rule serve general administrative functions: They are intended to ''aid OSHA's effort to identify the scope of occupational safety and health problems,'' to ''serve as the foundation for national statistics on the number and rate of workplace injuries and illnesses'' and ''to raise employers'' awareness of the kinds of injuries and illnesses occurring in their workplaces.'' See *Functions of the Recordkeeping System, supra.* Therefore, the final rule falls squarely within the mandate of sections 8 and 24 of the Act and is properly characterized as a regulation.

B. The Legal Standard: The Regulation Must Be Reasonably Related to the Purposes of the Enabling Legislation

Under section 8, the Secretary is empowered to issue ''such * * * regulations as [s]he may deem necessary to carry out [her] responsibilities under this Act[,]'' including regulations requiring employers to record and to make reports on ''work-related deaths, injuries and illnesses other than minor injuries requiring only first aid treatment and which do not involve medical treatment, loss of consciousness, restriction of work or motion or transfer to another job.'' 29 U.S.C. 657(g)(2), (c)(2). Similarly, section 24 directs the Secretary to compile accurate statistics on ''all disabling serious, or significant injuries and illnesses, whether or not involving loss of time from work, other than minor injuries. * * *'' 29 U.S.C. 673(a). Where an agency is authorized to prescribe regulations ''necessary'' to implement a statutory provision or purpose, a regulation promulgated under such authority is valid ''so long as it is reasonably related to the enabling legislation.'' *Mourning* v. *Family Publications Service, Inc.,* 411 U.S. 356, 369 (1973).

Section 8(g)(2) is functionally equivalent to the enabling legislation at issue in *Mourning*; therefore a reviewing court must examine the final recordkeeping rule's relationship to the purposes of section 8. Cf. *Louisiana Chemical Assn.* v. *Bingham,* 550 F. Supp. 1136, 1138–1140 (W.D. La. 1982), *aff'd*, 731 F.2d 280 (5th Cir. 1984) (records access rule is directly related to the goals stated in the Act and supported by the language of section 8).

C. The Final Recordkeeping Rule's Key Provisions Are Reasonably Related to the Purposes of the OSH Act

The goal of this final rule, as stated in the Summary, is to improve the quality and consistency of injury and illness data while simplifying the recordkeeping system to the extent consistent with the statutory mandate. To achieve this purpose, the final rule carries forward the key elements of the existing recordkeeping scheme, with changes designed to improve efficiency, equity, and flexibility while reducing, to the extent practicable, the economic burden on individual establishments. The central requirements in the final rule may be summarized as follows: All non-exempt employers must record all work-related, significant injuries and illnesses. As discussed below, OSHA's approach to each of these elements—the scope of the exemptions from recording requirements, the meaning of ''work-relationship,'' and the criteria for determining whether an injury or illness is ''significant''—is reasonable and directly related to the statutory language and purpose.

1. Exemptions From Recordkeeping Requirements

The final rule contains two categories of exemptions that, together, relieve most employers of the obligation routinely to record injuries and illnesses sustained by their employees. Section 1904.1 contains a ''very small-employer'' exemption: Employers need not record injuries or illnesses in the current year if they had 10 or fewer employees at all times during the previous year, unless required to do so pursuant to Sections 1904.41 or 1904.42. Section 1904.2 contains a ''low-hazard industry'' exemption: Individual business establishments are not required to keep records if they are classified in specific low-hazard retail, service, finance, insurance, or real estate industries.

a. The size-based exemption. Section 8(d) of the Act expresses Congress' intent to minimize, where feasible, the burden of recordkeeping requirements on employers, particularly small businesses: ''Any information obtained by the Secretary, the Secretary of [HHS], or a State agency under this Act shall be obtained with a minimum burden upon employers, especially those operating small businesses. Unnecessary duplication of efforts in obtaining information shall be reduced to the maximum extent feasible.'' 29 U.S.C. 657(d).

Since 1972, the Secretary has exempted very small businesses from most recordkeeping requirements. On October 4, 1972, OSHA issued a provision, codified at 29 CFR 1904.15(a), exempting employers from routine injury and illness reporting requirements for the current year if they had no more than seven employees during the previous year. The exemption did not relieve these businesses from the obligation to report fatality and multiple hospitalization incidents to OSHA and to participate in the BLS annual survey when selected to do so. 37 FR 20823 (October 4, 1972). In 1977, the Secretary amended section 1904.15 to make it applicable to businesses having ten or fewer employees during the year preceding the current reporting year. 42 FR 38568 (July 29, 1977). As support, the amendment cited the Department of Labor appropriations acts for fiscal years 1975 and 1976, which exempted employers having ten or fewer employees from most routine recordkeeping requirements, and Section 8(d) of the Act. *Id.* The Secretary determined that the amendment appropriately balanced the interest of very small businesses while preserving the essential purposes of the recordkeeping scheme:

> The [exemption] has been carefully designed to carry out the mandate of section 8(d) without impairing the Act's basic purpose. Thus, the [exemption] will not diminish the protections afforded employees under the Act because all employers * * * remain subject to the enforcement provisions of the Act. The [exemption] will continue to require * * * small employers * * * to report fatalities and multiple hospitalizations and to participate in the BLS annual survey when selected to do so.

42 FR 10016 (February 18, 1977).

In the present rulemaking, the Secretary proposed to enlarge the scope of the exemption to include employers, in industries other than construction, having 19 or fewer employees during the entire previous calendar year. 61 FR 4057 (February 2, 1996). At the same time, the proposal asked for public comment on whether ''the small employer partial exemption [should] remain the same, be eliminated, or be expanded?'' 61 FR 4043. In reaching a final decision on this matter, the Secretary resolved two interrelated questions. First, she determined that there is no sound basis for departing from OSHA's prior interpretation that the Act permits a carefully crafted exemption for very small employers. Second, she determined that limiting the exemption to employers with ten or fewer employees effectuates Congress' intent with the minimum degree of impairment to the overall recordkeeping scheme. The first question is essentially one of statutory construction, and is therefore considered below. The second question calls for an analysis of the record and is addressed in the preamble explanation for section 1904.1 of the final rule.

It is a fundamental principle of administrative law that an agency which chooses to reverse a previously held position must supply a ''reasoned analysis'' of its decision. *Motor Vehicle Mfgrs Assn.* v. *State Farm Mutual Automobile Insurance Co.,* 463 U.S. 27, 42 (1983). After careful consideration, the Secretary finds no persuasive basis for eliminating the small-employer exemption in this rule. As a threshold matter, nothing has changed the agency's long-held view that section 8(d) permits a carefully tailored exemption from recordkeeping requirements for very small businesses. 42 FR 10016 (February 18, 1977). This interpretation is consistent with the literal wording of the statute and is further confirmed by the provisions in the Department's appropriations acts for FY 1975 and 1976, exempting employers with ten or fewer employees from routine recordkeeping and reporting requirements. See 42 FR 5356 (January 28, 1977) (noting restriction in FY 1975 and 1976 appropriations acts and stating OSHA would continue to treat firms of up to 10 employees as exempt pending permanent change in the regulations to expand the small-employer exemption).

OSHA also concludes that a very small business exemption limited to the routine recording and reporting of non-fatal injuries and illnesses will not seriously undermine the recordkeeping system. OSHA explained in Section I. of the preamble that there are three primary purposes for recordkeeping and reporting requirements. First, the records are the foundation for national statistics published by the BLS on the number and rate of workplace injuries and illnesses, as well as their source, nature and type. Second, the records provide information useful to employers and employees in their efforts voluntarily to locate and eliminate workplace safety and health hazards. Finally, the records are useful to OSHA in targeting its enforcement efforts and in efficiently conducting its safety and health inspections.

Exempting very small businesses from routine recordkeeping will not significantly compromise these goals. The exemption has no effect upon the obligation of these businesses to participate in the national statistical survey administered by the BLS. See the discussion of § 1904.42 in Section V. Summary and Explanation. If a small business is selected for participation in the survey, it must keep a log of injuries and illnesses and make reports as required by the BLS. *Id.* Thus, even the smallest firms continue to be represented in the national injury and illness statistics.

The second purpose is not seriously compromised by the exemption because injury and illness records are less necessary as an aid to voluntary compliance efforts by very small employers and their employees than they are for larger employers. OSHA's experience is that, in establishments with only a few employees, management and production personnel typically work in close concert. Because of their size, such establishments also tend to record fewer occupational injuries and illnesses. Accordingly, in very small firms, managers are likely to have first-hand knowledge of those occupational injuries and illnesses that occur in their workplaces. By the same token, it is reasonable to believe that employees in very small firms are generally aware of the injuries that occur in their workplaces and do not

rely heavily upon access to employer records to inform themselves about occupational hazards. In short, review and analysis of injury and illness records by very small business employers, or by their employees, may not be required for awareness of workplace conditions.

Finally, routine injury and illness records are of limited usefulness to OSHA in targeting and conducting inspections. Many OSHA inspections are conducted in response to a specific complaint or referral alleging unsafe conditions, or in response to a workplace catastrophe or fatality. A large number of inspections are also conducted under special emphasis programs at the national and local level. The remaining inspections are conducted at specific worksites in the construction industry and in other non-construction industries selected under a planned schedule. Construction inspections are selected using an econometric model that predicts the best time to conduct an inspection at a specific construction project. The general industry scheduled inspections are targeted primarily toward employers with extremely high rates of occupational injury and illness, using data supplied by employers to the OSHA Data Initiative (ODI) under the requirements of former section 1904.17, *Annual OSHA Injury and Illness Survey of Ten or More Employers (now section 1904.41)*. Due to budget, paperwork burden and logistical constraints, OSHA collects data only from employers in high hazard industries, and has generally not collected data from employers with fewer than 40 workers.

OSHA is also prohibited from conducting scheduled inspections of employers with 10 or fewer employees in low hazard industries by an annual rider on OSHA's appropriations bills which has been renewed annually for many years. Thus, OSHA does not collect data from very small employers, and they are excluded from the general industry scheduled inspection program. Because very small firms have been wholly excluded from the general schedule inspection program, the routine injury and illness records of very small businesses have been of little use to OSHA in targeting inspections. Should OSHA wish to include very smaller employers in a special emphasis inspection program or other initiative, the agency may require any business, regardless of its size, to keep records and make reports as necessary. See 29 CFR 1904.41.

OSHA also finds that access to the Log and Incident Report would be of little value to compliance officers in conducting inspections of very small businesses initiated by a complaint or report of a fatality or an accident resulting in multiple hospitalizations. OSHA has long acknowledged that while injury and illness records are frequently useful in identifying hazardous areas or operations within larger establishments subject to programmed inspections, they are significantly less important in the conduct of inspections in the smallest businesses. As OSHA has stated, ''experience has shown that when dealing with small employers, the injury and illness records * * * are normally not needed by the CSHO to locate hazards during an inspection. In those cases where log information may be needed, the CSHO can easily obtain the information by interviewing the employees.'' 42 FR 10016 (February 18, 1977). See also 47 FR 57699, 5700 (December 28, 1982) (in conducting complaint or fatality inspections, the hazard information is usually provided by the complaint itself, or through prompt investigation.) For these reasons, the Secretary believes that an exemption for very small employers, reasonably tailored to the purposes served by recordkeeping requirements, is appropriate.

b. The hazard-based exemption. Since 1982, OSHA has exempted from routine recordkeeping requirements certain industries classified in OMB's Standard Industrial Classification (SIC) Manual. The 1982 exemption was limited to establishments in SIC Industry Groups that (1) were not subject to general schedule inspections, and (2) had average lost workday case injury rates, as published by the BLS, at or below 75% of the national average. In 1982, the industry groups that met these criteria were those classified as retail trade, finance, insurance, real estate, and services—SIC codes 52–89, excluding 52–54, 70, 75, 76, 79, and 80. 47 FR 57699–57,700 (December 28, 1982).

The purpose of the exemption ''was to further OSHA's continuing effort under section 8(d) of the Act to reduce the paperwork burden on employers without compromising worker safety and health.'' 47 FR 57700. Exempting low-hazard industries from routine record-keeping was justified, OSHA explained, for the same reasons that warranted exempting very small businesses. Injury and illness records from establishments in the affected SIC codes were not of significant benefit to OSHA because these industry groups were not then targeted for general schedule inspections. *Id.* The records were not a significant source of information for employers and employees because BLS data showed that approximately 94% of all establishments in the affected industry groups could be expected to have fewer than two injuries per establishment on an annual basis. *Id.* Finally, the exemption would not affect the reliability of safety and health statistics because the affected establishments would continue to participate in the BLS annual survey of occupational injuries and illnesses. *Id.*

OSHA continues to believe that a properly tailored exemption for low-hazard industries is appropriate. Congress intended in section 8(d) to minimize the recordkeeping burden on all employers, not only small businesses. Exempting from routine injury and illness reporting requirements those employers whose records are unlikely to be of significant benefit to OSHA, or to the employers and their employees, serves this important interest. However, OSHA recognizes that the balance between the interest of minimizing recordkeeping burdens and that of ensuring accurate, reliable and useful information is a delicate one. In the final rule, OSHA has substantially revised the list of exempt low-hazard industries based upon more reliable three-digit industry classification data. See the discussion of § 1904.1, in the following Summary and Explanation. With these changes, OSHA believes that the rule strikes the appropriate balance.

2. The Meaning of ''Work-Relationship''

Section 8 of the Act directs the Secretary to prescribe regulations requiring employers to ''maintain accurate records of * * * work-related deaths injuries and illnesses [of a non-minor nature]. 29 U.S.C. 657(c)(2). The definition of work-relationship in section 1904.5 of the final rule is consistent, in all but one respect, with the definition in the *Guidelines* to the former rule. The final rule states that an injury or illness is work-related ''if an event or exposure in the work environment either *caused or contributed to* [it] or significantly aggravated a pre-existing injury or illness. Work-relatedness is presumed for injuries and illnesses resulting from events or exposures occurring in the work environment, unless an exception listed in section 1904.5(b)(2) specifically applies'' (emphasis added).

The *Guidelines* state that, ''[i]f an event * * * occurred in the work environment *that caused or contributed to the* injury'', the case would be recordable, assuming it meets the other requirements for recordability. Ex. 2 at

p. 32 (original emphasis). Further instructions in the *Guidelines* provided that:

> The general rule is that all injuries and illnesses which result from events or exposures occurring to employees on the employer's premises are *presumed* to be work related. This presumption is rebuttable. * * * However, the nature of the activity which the employee is engaged in at the time of the event or exposure, the degree of employer control over the employee's activity, the preventability of the incident, or the concept of fault do not affect the determination.

Ex. 2 at p. 34 (original emphasis). The only significant difference between the final rule and the former rule is that the final rule requires that work ''significantly'' aggravate a pre-existing injury or illness before the case is recordable.

OSHA's approach to work-relationship in both the former and the final recordkeeping rules reflects two important principles. The first is that work need only be a causal factor for an injury or illness to be work-related. The rule requires neither precise quantification of the occupational cause, nor an assessment of the relative weight of occupational and non-occupational causal factors. If work is a tangible, discernible causal factor, the injury or illness is work-related. The second principle is that a ''geographic presumption'' applies for injuries and illnesses caused by events or exposures that occur in the work environment. These injuries and illnesses must be considered work-related unless an exception to the presumption specifically applies.

The final rule's geographic presumption reflects a theory of causation similar to that applied by courts in some workers' compensation cases. Under the ''positional-risk'' test, an injury may be found to ''arise out of'' employment for compensation purposes if it would not have occurred but for the fact that the conditions and obligations of employment placed the claimant in the position where he or she was injured. See 1 Larson's Workers' Compensation Law section 6.50 (1977). *Accord, Odyssey/Americare of Oklahoma* v. *Worden,* 948 P.2d 309, 311 (Okla. 1997). Under this ''but for'' approach to work-relationship, it is not necessary that the injury or illness result from conditions, activities or hazards that are uniquely occupational in nature. Accordingly, the presumption encompasses cases in which an injury or illness results from an event at work that is outside the employer's control, such as a lightning strike, or involves activities that occur at work but that are not directly productive, such as horseplay.

The proposed rule asked for comment on whether OSHA should abandon its historic approach and adopt a new test for determining work-relationship. 61 FR 4044, 4045. The proposal outlined three alternative tests in which the determination of work-relationship turned on the degree to which the injury or illness was linked to occupational causes, as compared with personal factors such as off-the job activities, aging, or pre-existing medical conditions. Two of these alternative tests required evidence of a high degree of work causation to establish work-relationship. Alternative 1 required that occupational factors be the ''sole cause'' of the injury or illness; any evidence of non-work related causal factors was sufficient to exclude the case. Alternative 2 required that occupational factors be the ''predominant cause'' before the case could be considered work-related. See 61 FR 4044. Some commenters suggested a modification to Alternative 2 that would have involved substitution of the word ''substantial'' or ''significant'' for ''predominant.''

The third alternative test was significantly more expansive than that adopted in the final rule. Under Alternative 3, an injury or illness would be considered work-related if the work environment had any possibility of playing a causal role. 61 FR 4044.

Some commenters favored a somewhat different test for work-relationship that focused on the nature of the injury-causing event in the workplace. This test would include in the OSHA records only those cases resulting from uniquely occupational or job-related activities or processes. Supporters of this approach argued that it would exclude injuries and illnesses caused by factors at work that are unrelated to production tasks, or that are unpreventable by the employer's safety and health program.

After careful consideration of the record, OSHA believes that the final rule's test for work-relationship is both more consistent with the Act's purpose and more practical than the ''quantified occupational cause'' tests or the ''unique occupational conditions'' test. The language of the statute itself indicates that Congress did not intend to give ''work-related'' a narrow or technical meaning, but rather sought to cover a variety of causal relationships that might exist in workplaces. Section 2 of the Act addresses injuries and illnesses arising out of ''work situations.'' Sections 2(b)(1), 2(b)(2), and 2(b)(4) refer to ''places of employment,'' and to the achievement of safe and healthful ''working conditions.'' Section 2(b)(7) seeks to assure that no employee will suffer diminished health or life expectancy as a result of his ''work experience.'' Section 2(b)(12) states that one of the Act's purposes is to provide for reporting procedures which ''accurately describe the nature of the occupational safety and health problem.'' Section 2(b)(13) encourages joint labor-management efforts to reduce injuries and disease ''arising out of employment.''

This conclusion is further supported by the Act's stated purpose to promote research into the causes and prevention of occupational injuries and illnesses. Section 2 of the Act establishes Congress' intent to improve occupational safety and health, *inter alia,* by:

> Providing for research in the field of occupational safety and health, including the psychological factors involved, and by developing innovative methods, techniques and approaches for dealing with occupational safety and health problems. 29 U.S.C. § 651(b)(5)
>
> [E]xploring ways to discover latent diseases, establishing causal connections between diseases and work in environmental conditions, and conducting other research relating to health problems. * * * 29 U.S.C. § 651(b)(6).
>
> Providing for appropriate reporting procedures with respect to occupational safety and health which will help achieve the objectives of this Act and accurately describe the nature of the occupational safety and health problems. 29 U.S.C. § 651(b)(12).

The legislative history of the Act demonstrates Congress' awareness of the importance of developing information for future scientific use. The Committee Report accompanying the Senate bill reported to the floor noted that,

> [i]n the field of occupational health, the view is particularly bleak, and due to the lack of information and records, may well be considerably worse than we currently know. * * * Recent scientific knowledge points to hitherto unsuspected cause-and-effect relationships between occupational exposures and many of the so-called chronic diseases—cancer, respiratory ailments, allergies, heart disease, and others. In some instances, the relationship appears to be direct: asbestos, ionizing radiation, chromates, and certain dye intermediaries, among others, are directly involved in the genesis of cancer. In other cases, occupational exposures are implicated as contributory factors. The distinction between occupational and non-occupational illnesses is growing increasingly difficult to define.

S. Rep. No. 1282, 91st Cong., 2d Sess. 2 (1970), *reprinted in* Subcommittee on Labor of the Senate Committee on Labor and Public Welfare, *Legislative History of the Occupational Safety and Health Act of 1970* (Committee Print 1971) at

142 (Leg. Hist.). With this background in mind, the committee stated that it ''expects the Secretary of Labor and the Secretary of [HHS] will make every effort through the authority to issue regulations and other means, to obtain complete data regarding the occurrence of illnesses, including those resulting from occupational exposure which may not be manifested until after the termination of such exposure.'' Leg. Hist. at 157.

Both the Senate and the House Committees expressed concern that the statute not be interpreted in a way that would result in under-reporting of injuries and illnesses. The Senate report states:

> The committee recognizes that some work-related injuries or ailments may involve only a minimal loss of work time or perhaps none at all, and may not be of sufficient significance to the Government to require their being recorded or reported. However, the committee was also unwilling to adopt statutory language which, in practice might result in under-reporting. The committee believes that records and reports prescribed by the Secretary should include such occurrences as work-related injuries and illnesses requiring medical treatment or restriction or reassignment of work activity, as well as work-related loss of consciousness.

Leg. Hist. at 157. The House Report similarly noted that while some injuries and illnesses might not be of enough value to require recordation, ''the greater peril'' lay in allowing under reporting. Leg. Hist. at 860. Therefore, the report added, ''[the] language 'all work-related injuries, [and illnesses]' should be treated as a minimum floor. * * *''

In light of these purposes, it is apparent that Congress did not, in Section 8, mean to limit recordable ''work-related'' injuries and illnesses only to those caused primarily or substantially by work. It is evident from the statute that Congress wanted employers to keep accurate records of non-minor injuries and illnesses, in part, to serve as a basis for research on the causes and prevention of industrial accidents and diseases. This research is needed, among other reasons, to further examine and understand those occupational factors implicated as contributory causes in injuries and diseases. To serve this purpose, the records should include cases in which there is a tangible connection between work and an injury or illness, even if the causal effect cannot be precisely quantified, or weighed against non-occupational factors.

The first two alternative quantification theories outlined in the preamble would exclude important information from the records. These theories would eliminate cases in which the work environment is believed to have played a definite role in the accident or the onset of disease, but not enough is known to quantify the effect of work factors or to assess the relative contribution of work and non-work factors. However, the information provided by cases having a tangible, yet unquantifiable, connection with the work environment is useful to employers, employees and researchers and thus serves the recordkeeping purposes envisioned by Congress.

On the other hand, the third alternative theory in the proposal would sweep too broadly. A work-relationship test that is met if work has ''any possibility of playing a role in the case'' would include virtually every injury or illness occurring in the work environment. 61 Fed. Reg. 4044. Recording cases in which the causal connection to work is so vague and indefinite as to exist only in theory would not meaningfully advance research, or serve the other purposes for requiring recordkeeping. For these reasons, OSHA has rejected the three alternative theories outlined in the proposal.

The ''unique occupational activity'' test, which some commenters favored instead of the geographic presumption, would limit recorded injuries and illnesses to those caused by an activity or process peculiarly occupational in nature. Supporters of this approach identified several types of cases that would be work-related under the geographic presumption, but not recordable under an activities-based approach. These include cases in which the injury or illness was not caused by the physical forces or hazards unique to industrial processes, cases in which the employee was not injured while performing an activity or task directly related to production, and cases in which the injury or illness was not preventable by the employer.

The ''unique occupational activity'' test is unsuitable for essentially the same reasons that militate against the first two alternatives described in the proposal. The statutory language and purpose do not reflect a Congressional intent to limit recording only to those cases resulting from uniquely occupational hazards or activities. Rather, the statute shows that Congress knew that employees were being injured and made ill in a variety of ways and under a variety of circumstances, and wanted employers to record all cases causally related to the work environment. The ''but-for'' theory underlying the geographic presumption is a widely accepted legal test for causation and is consistent with the statutory language and purpose.

The ''unique occupational activities'' test, like the ''quantification'' tests, would likely result in exclusion of important information from the records. An activity-based test for work-relationship could obscure the role of factors in the work environment not directly linked to production, such as violence perpetrated by employees and others or tuberculosis outbreaks. In addition, the precise causal mechanism by which an employee has been injured or made ill at work may not be known at the time of the accident, or may be misunderstood. To serve the statute's research purposes, the records must reflect not only those injuries and illnesses for which the precise causal mechanism is apparent at the time of recordation, but also those for which the mechanism is imperfectly understood. The alternative approaches to work-relationship would severely limit the usefulness of injury and illness data for research purposes, particularly research to uncover latent patterns of health impairment and disease and to establish causal connections between diseases and exposure to particular hazards.

The Occupational Safety and Health Review Commission has affirmed the approach to work-relationship taken in the former rule. *General Motors Corp., Inland Div.,* 8 O.S.H. Cas. (BNA) 2036, 2039–2040 (August 29, 1980). The issue in *General Motors* was whether the employer was required to record respiratory ailments of three employees, based on notations from the employees' treating physicians that their ailments were probably related to exposure to a chemical substance at work. The Commission rejected the employer's argument that the recordkeeping rule required recording only of illnesses directly caused by work activities, stating:

> To accept Respondent's interpretation would impose a static view of scientific knowledge. Only illnesses in which the known cause was the occupational environment would be recorded. Unknown medical correlations between disease and the workplace would be obscured by this inadequate recording obligation. Under this interpretation of the statute and regulations, OSHA and NIOSH would be significantly restrained from fulfilling their statutory obligation of making the workplace healthier. * * * [T]he primary purpose of the recording obligation is to develop information for future scientific use.

8 O.S.H. Cas. at 2040. Accordingly, OSHA believes that there is a sound legal basis for the definition of work-relationship in the final rule.

There are also sound policy justifications. The approach to ''work-relationship'' adopted in the final rule is more cost-effective than the alternative approaches and will result in more accurate injury and illness data. OSHA expects that for each reported injury or illness, employers generally will be able to apply the geographic presumption more easily and quickly than a test requiring an assessment of the relative contribution of employment and personal causes. The incremental reduction in the time necessary to complete each entry, when multiplied by the total number of entries per year, will result in a substantial cumulative saving in paperwork burden in comparison to the burden that would be imposed by the alternatives.

The geographic presumption will also produce more consistent and accurate reporting. OSHA believes that it would be difficult to measure the precise degree to which personal and occupational factors cause accidents or illnesses. Accordingly, any test requiring that job duties or tasks be ''significant'' or ''predominant'' causative factors would necessarily involve a high degree of subjective judgment. There is likely to be substantial inconsistency, both in the treatment of successive, similar cases by the same employer, and in the treatment of such cases among different employers. Moreover, such a test would fail to capture cases in which the workplace contribution to an injury or illness was imperfectly known or misunderstood at the time the case was reported. Recording all cases caused by events or exposures at work, with only limited exceptions, produces data that enables OSHA, employers and others to better understand the causal relationships present in the work environment. Although OSHA has not adopted a test for determining significant contribution by work, the final rule does include provisions to make sure that workplace aggravation of a pre-existing injury must be significant before work relationship is established (see discussion of 1904.5(b)(4)).

A number of commenters argued that because OSHA's mission is to eliminate preventable occupational injuries and illnesses, the determination of work-relatedness must turn upon whether the case could have been prevented by the employer's safety and health program. Dow expressed this view as follows:

> [T]he goal of this recordkeeping system should be to accurately measure the effectiveness of safety and health programs in the workplace. Activities where safety and health programs could have no impact on preventing or mitigating the condition should not be logged and included in the Log and Summary nor used by OSHA to determine its inspection schedule. If the event was caused by something beyond the employer's control, it should not be considered a recordable event that calls into question a facility's safety and health program. * * * Credibility in this regulation rests on whether the recorded data accurately reflects the safety and health of the workplace. Including events where the workplace had virtually no involvement undermines the credibility of the system and results in continued resistance to this regulation.

Ex. 15–335B. The law firm of Constangy, Brooks and Smith, LLC, urged OSHA to adopt the second alternative definition in the proposal because cases that are ''predominantly caused by workplace conditions'' are the ones most likely to be preventable by workplace controls. They stated, ''[s]ince OSHA's ultimate mission is the prevention of workplace injuries and illnesses, it is reasonably necessary to require recording only when the injury or illness can be prevented by the employer.'' Ex. 15–345.

OSHA believes that these comments reflect too narrow a reading of the purposes served by injury and illness records. Certainly one important purpose for recordkeeping requirements is to enable employers, employees and OSHA to identify hazards that can be prevented by compliance with existing standards or recognized safety practices. However, the records serve other purposes as well, including facilitating the research necessary to support new occupational safety and health standards and to better understand causal connections between the work environment and the injuries and illnesses sustained by employees. As discussed above, these purposes militate in favor of a general presumption of work-relationship for injuries and illnesses that result from events or exposures at the worksite, with exceptions for specific types of cases that can be safely excluded without significantly impairing the usefulness of the database.

3. The Criteria for Determining the Significance of an Injury or Illness

Section 1904.7 of the final rule sets forth the criteria to be used by employers in determining whether work-related occupational injuries and illnesses are significant, and therefore recordable. Under § 1904.7, a work-related injury or illness is significant for recordkeeping purposes if it results in any of the following: death, days away from work, restricted work or transfer to another job, medical treatment beyond first aid, or loss of consciousness. Employers must also record any significant injury or illness diagnosed by a physician or other licensed health care professional even if it does not does not result in the one of the listed outcomes. OSHA's definition of a ''significant'' injury or illness in this context is based on two key principles discussed below. The first is that the requirement for recording only significant cases applies equally to ''injuries'' and ''illnesses'' for recordkeeping purposes. The second principle is that the criteria expressly mentioned in the Act, such as death, loss of consciousness or restriction of work, are mandatory but not exclusive indicia of significance; any significant injury or illness diagnosed by a physician or other licensed health care professional must also be recorded. These two principles are addressed below, while the definitions applicable to the specific criteria themselves, and related evidentiary issues, are discussed in the preamble explanation for section 1904.7.

a. The significant case requirement applies equally to injuries and illnesses; employers are no longer to report insignificant illnesses. OSHA distinguishes between injuries and illnesses based on the nature of the precipitating event or exposure. Cases which result from instantaneous events are generally considered injuries, while cases which result from non-instantaneous events, such as a latent disease or cumulative trauma disorder, are considered illnesses. *Id.*

Under the former recordkeeping regulations, occupational injuries had to be recorded if they were non-minor in nature; that is, if they resulted in loss of consciousness, or required medical treatment, time off work, restriction of work, lost time, or transfer to another job. 61 FR 4036. However, all occupational illnesses had to be reported, regardless of severity. *Id.* This difference in the severity threshold for recording injuries and illnesses had, in the past, been based upon the particular phrasing of section 8(c)(2) of the Act:

> The Secretary * * * shall prescribe regulations requiring employers to maintain accurate records of, and to make periodic reports on, work-related deaths, injuries and illnesses, other than minor injuries requiring only first aid treatment and which do not involve medical treatment, loss of consciousness, restriction of work or motion, or transfer to another job.''

29 U.S.C. 657(c)(2). Because the severity criteria appear in the clause defining ''minor injuries,'' OSHA had construed the section to require recordation of all work-related illnesses, even those that do not meet the severity

characteristics expressly applicable to ''injuries.''

OSHA has reconsidered its position in this rulemaking, and has concluded that the former rule was inappropriate in several respects. First, although the severity characteristics listed in section 8(c)(2) of the Act apply expressly to ''injuries,'' the Act contains persuasive indications that Congress also meant to require recordation only of ''significant'' illnesses, as determined by reasonable criteria. Section 24(a) states that ''[t]he Secretary shall compile accurate statistics on work injuries and illnesses which shall include all disabling, serious, or significant injuries and illnesses * * * other than minor injuries requiring only first aid treatment and which do not involve medical treatment * * * .'' 29 U.S.C. 673 (a). The legislative history also supports this view. The statement of the House managers on the resolution of conflicting House and Senate bills states that:

> A Senate bill provision without a counterpart in the House amendment permitted the Secretary to require an employer to keep records and make reports on ''all work-related deaths, injuries and illnesses.'' The House receded with an amendment limiting the reporting requirement to injuries and illnesses other than of a minor nature, with a specific definition of what is not of a minor nature.

Leg. Hist. at 1190 (emphasis supplied). The former rule did not appropriately implement this intent. In the first place, OSHA's prior interpretation that section 8(c)(2) limits the applicability of the listed severity criteria only to injuries does not necessarily mean that illnesses must be recorded without regard to their significance. As a textual matter, such a reading simply leaves open the question of what, if any, severity criteria apply to illnesses.

OSHA believes that the Act does not support a different severity threshold for injuries than for illnesses. OSHA is now persuaded that its prior reading of section 8(c)(2) placed too much emphasis on the fact that the severity criteria modify the word ''injuries'' in the clause, ''other than minor injuries requiring only first aid treatment and which do not involve medical treatment, loss of consciousness, restriction of work or motion or transfer to another job.'' 29 U.S.C. 657(c)(2). Congress' failure to list specific severity criteria for illnesses, as it did for injuries, does not, in itself, compel the inference that two different sets of criteria must apply. Congress meant to limit recordation to significant injuries and illnesses alike, and absent strong indications to the contrary, it is reasonable to presume that Congress meant the same severity threshold to apply to both conditions.

In addition, there are strong policy reasons for avoiding a distinction between injuries and illnesses based on severity. OSHA explained in the proposal that the current distinction between injuries and illnesses based on the nature of the precipitating event has caused some degree of confusion and uncertainty. Using one set of criteria for severity means that employers will not have to decide whether a case is an injury or an illness in determining its recordability. This simplifies the recordkeeping system, resulting in more accurate injury and illness data while reducing the recordkeeping burden for employers who are required to maintain records (61 FR 4036). Employers will continue to classify each recordable case as either an injury or an illness on the OSHA 300 Log, but the decision no longer has any effect on whether or not the case must be recorded.

b. The criteria listed in the Act are mandatory but not exclusive indicia of significance. A final issue relating to significance is the effect to be given a finding that an injury or illness results in, or does not result in, one of the outcomes listed in the statute: death, days away from work, restricted work or transfer to another job, medical treatment beyond first aid, or loss of consciousness. The implication arising from the wording of section 8(c)(2) and section 24 is that if an injury or illness results in one of the listed outcomes, it must be deemed significant for recordkeeping purposes. This position, which reflects OSHA's longstanding, consistent interpretation of the statute, was not seriously questioned in the rulemaking. Accordingly, the final rule requires that a work-related injury or illness be recorded if it results in one of the outcomes mentioned in the statute.

The final rule also requires that a case be recorded, whether or not it results in one of the listed outcomes, if it involves a significant injury or illness diagnosed by a physician or other licensed health care professional. 29 CFR 1904.10(b). Nothing in the statute compels the conclusion that the criteria mentioned in sections 8 and 24 are the exclusive indicia of severity for recordkeeping purposes. Congress directed the Secretary to collect data on ''all disabling, serious, or significant injuries and illnesses, whether or not involving loss of time from work,'' other than minor injuries * * * which [do not result in one of the listed outcomes]. 29 U.S.C. 673(a). A reasonable reading of this language is that while an injury that meets one of the listed criteria is non-minor and must be recorded, the converse does not necessarily follow. An injury or illness may reasonably be viewed as significant, and therefore recordable, even if it is not immediately followed by death, loss of consciousness, or job-related disability. For example, an employee diagnosed with an unquestionably serious work-related disease, such as asbestosis or mesothelioma, may forego or postpone medical treatment and continue temporarily to perform his or her normal job duties. Focusing exclusively on the basic criteria listed in the statute in cases such as these could result in underrecording of serious cases. Accordingly, the final rule requires employers to record any significant injury or illness that is diagnosed. A thorough discussion of this requirement, including a definition of what constitutes a ''significant'' injury or illness for this purpose, is contained in the preamble discussion of section 1904.7.

Because the provisions of the final recordkeeping rule, as explained above and in the subsequent sections of this preamble, are reasonably related to the statutory purposes, the Secretary finds that the rule is necessary to carry out her responsibilities under the Act. The rule is therefore a valid exercise of the Secretary's general rulemaking authority under Section 8. Cf. *Mourning* v. *Family Publications Services*, 411 U.S. 356.

VII. Summary and Explanation

The following sections discuss the contents of the final 29 CFR Part 1904 and section 1952.4 regulations. OSHA has written these regulations using the plain language guidance set out in a Presidential Memo to the heads of executive departments and agencies on June 1, 1998. The Agency also used guidance from the Plain Language Action Network (PLAN), which is a government-wide group working to improve communications from the Federal government to the public, with the goals of increasing trust in government, reducing government costs, and reducing the burden on the public. For more information on PLAN, see their Internet site at http://www.plainlanguage.gov/.

The plain language concepts encourage government agencies to adopt a first person question and answer format, which OSHA used for the Part 1904 rule. The rule contains several types of provisions. Requirements are described using the ''you must * * *'' construction, prohibitions are described using ''you may not * * *'', and optional actions that are not

requirements or prohibitions are preceded by ''you may * * *.'' OSHA has also included provisions to provide information to the public in the rule.

Subpart A. Purpose

The Purpose section of the final rule explains why OSHA is promulgating this rule. The Purpose section contains no regulatory requirements and is intended merely to provide information. A Note to this section informs employers and employees that recording a case on the OSHA recordkeeping forms does not indicate either that the employer or the employee was at fault in the incident or that an OSHA rule has been violated. Recording an injury or illness on the Log also does not, in and of itself, indicate that the case qualifies for workers' compensation or other benefits. Although any specific work-related injury or illness may involve some or all of these factors, the record made of that injury or illness on the OSHA recordkeeping forms only shows three things: (1) that an injury or illness has occurred; (2) that the employer has determined that the case is work-related (using OSHA's definition of that term); and (3) that the case is non-minor, *i.e.,* that it meets one or more of the OSHA injury and illness recording criteria. OSHA has added the Note to this first subpart of the rule because employers and employees have frequently requested clarification on these points.

The following paragraphs describe the changes OSHA has made to the Purpose provisions in Subpart A of the final rule, and discusses the Agency's reasons for these changes. Proposed section 1904.1 of Subpart A contained three separate paragraphs. Proposed paragraph (a) stated that the purpose of the recordkeeping rule (Part 1904) was ''to require employers to record and report work-related injuries, illness and fatalities.'' It also described several ways in which such records were useful to employers, employees, OSHA officials, and researchers evaluating and identifying occupational safety and health issues.

Proposed paragraph (b) noted that the recording of a job-related injury, illness or fatality did not necessarily impute fault to the employer or the employee, did not necessarily mean that an OSHA rule had been violated when the incident occurred, and did not mean that the case was one for which workers' compensation or any other insurance-related benefit was appropriate. The third paragraph in proposed section 1904.1, proposed paragraph (c), stated that the regulations in Part 1904 had been developed ''in consultation with the Secretary of Health and Human Services'' (HHS), as required by Section 24(a) of the Act.

In the final rule, OSHA has moved much of this material, which was explanatory in nature, from the regulatory text to the preamble. This move has simplified and clarified the regulatory text. The final rule's Purpose paragraph simply states that: ''The purpose of this rule (Part 1904) is to require employers to record and report work-related fatalities, injuries and illnesses.'' This final rule statement is essentially identical to the first sentence of the proposed Purpose section. It clearly and succinctly states OSHA's reasons for issuing the final rule.

A number of commenters (see, *e.g.*, Exs. 25; 15: 199, 305, 313, 346, 348, 352, 353, 375, 418, 420) specifically addressed proposed section 1904.1. The principal points raised by these commenters concerned: (1) Statements in proposed paragraph (a) about the quality of the data captured by the records; (2) proposed paragraph (b)'s discussion of the relationship between OSHA recordkeeping and employer/employee fault, violations of OSHA rules, and the workers' compensation system, and (3) the statement in proposed paragraph (c) that discussed OSHA's consultation with the Secretary of Health and Human Services in developing this rule. Each of these issues is discussed in detail below.

Most comments on proposed paragraph (a) took issue with the language that OSHA used to describe the statistical use of the records (see, *e.g.*, Exs. 25, 15: 305, 346, 348, 375, 420). Typical of these comments is one from the National Association of Manufacturers: ''We urge OSHA to remove the following unverified and conclusory statement from § 1904.1(a): ''The records: * * * accurately describe the nature of occupational safety and health problems for the Nation, State or establishment'' (Exs. 25, 15: 305). OSHA did not intend this statement to attest with certainty to the validity of national occupational statistics. Proposed section 1904.1(a) merely paraphrased section 2(b) of the Act, which states that such records ''will help achieve the objectives of this Act and accurately describe the nature of the occupational safety and health problem.'' In response to commenters, OSHA has simplified the final rule by deleting the proposed listing of the functions of the records required by this rule.

As discussed earlier, proposed paragraph (b) stated that the recording of a case did not ''necessarily mean that the employer or employee was at fault, that an OSHA standard was violated, or that the employee is eligible for workers' compensation or other insurance benefits.'' The last sentence of proposed paragraph (b) described the various types of workplace events or exposures that may lead to a recordable injury or illness.

A number of commenters agreed with the proposed statements on fault, compliance, and the relationship between the recording of a case and workers' compensation or other insurance (see, *e.g.*, Exs. 25, 15: 305, 346, 420). Employers have frequently asked OSHA to explain the relationship between workers' compensation reporting systems and the OSHA injury and illness recording and reporting requirements. As NYNEX (Ex. 15: 199) noted,

> [t]he issue of confusion between OSHA recordkeeping and workers' compensation/insurance requirements cannot be totally eliminated as the workers' compensation criteria vary somewhat from state to state. There will always be some differences between OSHA recordability and compensable injuries and illnesses. The potential consequences of these differences can be minimized, however, if all stakeholders in the recordkeeping process (i.e., employers, employees, labor unions, OSHA compliance officials) are well informed that OSHA recordability does not equate to compensation eligibility. This can be facilitated by printed reminders on all of the OSHA recordkeeping documents (*e.g.*, forms, instructions, pamphlets, compliance directives, etc.).

As NYNEX observed, employers must document work-related injuries and illnesses for both OSHA recordkeeping and workers' compensation purposes. Many cases that are recorded in the OSHA system are also compensable under the State workers' compensation system, but many others are not. However, the two systems have different purposes and scopes. The OSHA recordkeeping system is intended to collect, compile and analyze uniform and consistent nationwide data on occupational injuries and illnesses. The workers' compensation system, in contrast, is not designed primarily to generate and collect data but is intended primarily to provide medical coverage and compensation for workers who are killed, injured or made ill at work, and varies in coverage from one State to another.

Although the cases captured by the OSHA system and workers' compensation sometimes overlap, they often do not. For example, many injuries and illnesses covered by workers' compensation are not required to be recorded in the OSHA records. Such a situation would arise, for example, if an employee were injured on the job, sent to a hospital emergency

room, and was examined and x-rayed by a physician, but was then told that the injury was minor and required no treatment. In this case, the employee's medical bills would be covered by workers' compensation insurance, but the case would not be recordable under Part 1904.

Conversely, an injury may be recordable for OSHA's purposes but not be covered by workers' compensation. For example, in some states, workers' compensation does not cover certain types of injuries (*e.g.*, certain musculoskeletal disorders) and certain classes of workers (*e.g.*, farm workers, contingent workers). However, if the injury meets OSHA recordability criteria it must be recorded even if the particular injury would not be compensable or the worker not be covered. Similarly, some injuries, although technically compensable under the state compensation system, do not result in the payment of workers' compensation benefits. For example, a worker who is injured on the job, receives treatment from the company physician, and returns to work without loss of wages would generally not receive workers' compensation because the company would usually absorb the costs. However, if the case meets the OSHA recording criteria, the employer would nevertheless be required to record the injury on the OSHA forms.

As a result of these differences between the two systems, recording a case does not mean that the case is compensable, or vice versa. When an injury or illness occurs to an employee, the employer must independently analyze the case in light of both the OSHA recording criteria and the requirements of the State workers' compensation system to determine whether the case is recordable or compensable, or both.

The American Federation of Labor and Congress of Industrial Organizations (AFL–CIO) urged OSHA to emphasize the no-fault philosophy of the Agency's recordkeeping system, stating:

> The AFL–CIO is encouraged by some provisions currently in the proposed rulemaking which indirectly address underreporting. But, we believe the Agency must take it one step further. To adequately address this problem, the Agency must encourage employers to adopt a ''no fault system'' philosophy in the workplace and remove barriers which discourage the reporting of injuries and illnesses by employees. This philosophy will not only encourage workers to report injuries and illnesses, but also encourage those individuals (*e.g.*, supervisors, safety personnel) responsible for recording this data to report all recordable incidents (Ex. 15: 418).

OSHA believes that the note to the Purpose paragraph of the final rule will allay any fears employers and employees may have about recording injuries and illnesses, and thus will encourage more accurate reporting. Both the Note to Subpart A of the final rule and the new OSHA Form 300 expressly state that recording a case does not indicate fault, negligence, or compensability.

The Workplace Health and Safety Council, the American Coke and Coal Chemicals Institute, and the National Oilseed Processors Association (Exs. 15: 313, 352, 353) all urged OSHA to improve on this paragraph of the proposed rule in two ways. First, these commenters asked OSHA to remove the word ''necessarily'' from the language of proposed paragraph (b), which stated that recording did not ''necessarily mean'' that anyone was at fault, that a standard had been violated, or that the case was compensable:

> The qualification ''necessarily'' robs the [proposed] sentences of their meaning and makes them inaccurate. Using the word erroneously implies that merely listing an injury sometimes does mean that the employer or employee was at fault, that an OSHA standard was violated, or that the employee is eligible for workers' compensation. Clearly, this is not what OSHA intended to convey. Indeed, the word ''necessarily'' may actually worsen the problem OSHA seeks to solve, for attorneys and consultants reading the proposed provision might well advise employers that the provision actually endorses some uses of a listing against an employer.
>
> OSHA should, therefore, delete the word ''necessarily. * * *'' Alternatively, the sentence in the regulation should read: ''That an injury or illness is recordable has no bearing on whether the employer or employee was at fault, an OSHA standard violated, or the employee is eligible for workers' compensation. * * *'' The legend in the form would be similarly changed (Exs. 15: 313, 352, 353).

These three commenters (Exs. 15: 313, 352, 353) also suggested the following:

> (a) much preferred additional solution, would be for OSHA to promulgate in the final version a provision that makes inadmissible in all proceedings, both those under the OSH Act and those under any state or federal law, the entries in Form OSHA 300 and 301 as evidence of fault or culpability. Such a regulation would give employers the necessary assurance that their recordkeeping forms would not be used against them. Injured employees would lose nothing by this, for they could still be permitted to prove the fact of injury, its work-relatedness, and its consequence, with normal proof. They would simply not be permitted to introduce the forms as evidence of culpability. Such a rule would implement, be consistent with, and be authorized by Section 4(b)(4) of the Act, which prohibits the Act from affecting workers' compensation and tort schemes.

OSHA agrees with the point made by these commenters about the proposed rule's use of the word ''necessarily.'' Accordingly, the word necessarily has been deleted from the Note to the Purpose paragraph of the final rule. However, OSHA has rejected the suggestion made by these commenters to limit the admissibility of the forms as evidence in a court proceeding. Such action is beyond the statutory authority of the agency, because OSHA has no authority over the courts, either Federal or State.

In the proposal, the no-fault statement was followed by a listing of the various causes of recordable injuries and illnesses: ''Recordable workplace injuries and illnesses result from a variety of workplace events or exposures, including but not limited to: accidents, exposure to toxic materials or harmful physical agents, intentional acts of violence, or naturally occurring events such as a tornado or earthquake.'' The American Petroleum Institute (API) (Ex. 15: 375) objected to this proposed sentence describing the various examples of injury and illness causality, stating:

> To help the system have much-needed credibility, ''regardless of fault or preventability'' should not be applied beyond reasonable limits. Specifically, it shouldn't mean ''tornado or earthquake'' or other sudden, unforeseen catastrophic events over which the employer clearly could not have any control. Employers can, however, exercise control to prevent injury from some types of naturally occurring events. The terms ''tornado or earthquake'' should be replaced with more reasonable examples.

In the final rule, OSHA has decided to eliminate the sentence of examples to make the regulatory text clearer and more concise. However, OSHA notes that many circumstances that lead to a recordable work-related injury or illness are ''beyond the employer's control,'' at least as that phrase is commonly interpreted. Nevertheless, because such an injury or illness was caused, contributed to, or significantly aggravated by an event or exposure at work, it must be recorded on the OSHA form (assuming that it meets one or more of the recording criteria and does not qualify for an exemption to the geographic presumption). This approach is consistent with the no-fault recordkeeping system OSHA has adopted, which includes work-related injuries and illnesses, regardless of the level of employer control or non-control involved. The issue of whether different

types of cases are deemed work-related under the OSHA recordkeeping rule is discussed in the Legal Authority section, above, and in the work-relationship section (section 1904.5) of this preamble.

In a comment on proposed paragraph (a), the National Association of Manufacturers (NAM) (Exs. 25, 15: 305) argued that the OSHA recordkeeping system should only collect information on

''the most significant hazards, those that lead to the most significant injuries and illnesses * * *'' and that the purpose paragraph of the final rule be revised to state ''The purpose of this Part is to require employers to record and report disabling, serious and significant work-related injuries and illnesses, and work-related fatalities.''

OSHA does not agree with this interpretation of the OSH Act. As discussed in the Legal Authority section, above, Congress stated clearly that the OSHA recordkeeping system was intended to capture ''work-related deaths, injuries and illnesses, *other than minor injuries* requiring only first aid treatment and which do not involve medical treatment, loss of consciousness, restriction of work or motion, or transfer to another job'' (Sec. 8(c)(2)) (emphasis added). The words ''disabling, serious, and significant,'' suggested by NAM, are at variance with Congress' clear intent. OSHA concludes that the guidance given by Congress—that employers should record and report on work-related deaths, and on injuries and illnesses other than minor injuries, establishes the appropriate recording threshold for cases entered into the OSHA recordkeeping system.

A few commenters recommended that OSHA delete paragraph (c) of the proposed Purpose section (see, *e.g.*, Exs. 25, 15: 305, 346, 348, 420), and in the final rule, OSHA has done so because the paragraph merely attested to OSHA's cooperation with other agencies on this rule. Although the rule has, in fact, been developed in cooperation with the Department of Health and Human Services, and specifically with the National Institute for Occupational Safety and Health (NIOSH), there is no need to include this information in the regulatory text itself.

Subpart B. Scope

The coverage and partial exemption provisions in Subpart B of the final rule establish which employers must keep OSHA injury and illness records at all times, and which employers are generally exempt but must keep records under specific circumstances. This subpart contains sections 1904.1 through 1904.3 of the final rule.

OSHA's recordkeeping rule covers many employers in OSHA's jurisdiction but continues to exempt many employers from the need to keep occupational injury and illness records routinely. This approach to the scope of the rule is consistent with that taken in the former recordkeeping rule. Whether a particular employer must keep these records routinely depends on the number of employees in the firm and on the Standard Industrial Classification, or SIC code, of each of the employer's establishments. Employers with 10 or fewer employees are not required to keep OSHA records routinely. In addition, employers whose establishments are classified in certain industries are not required to keep OSHA records under most circumstances. OSHA refers to establishments exempted by reason of size or industry classification as ''partially exempt,'' for reasons explained below.

The final rule's size exemption and the industry exemptions listed in non-mandatory Appendix A to Subpart B of the final rule do not relieve employers with 10 or fewer employees or employers in these industries from *all* of their recordkeeping obligations under 29 CFR Part 1904. Employers qualifying for either the industry exemption or the employment size exemption are not routinely required to record work-related injuries and illnesses occurring to their employees, that is, they are not normally required to keep the OSHA Log or OSHA Form 301. However, as sections 1904.1(a)(1) and 1904.2 of this final recordkeeping rule make clear, these employers must still comply with three discrete provisions of Part 1904. First, all employers covered by the Act must report work-related fatalities or multiple hospitalizations to OSHA under § 1904.39. Second, under § 1904.41, any employer may be required to provide occupational injury and illness reports to OSHA or OSHA's designee upon written request. Finally, under § 1904.42, any employer may be required to respond to the Survey of Occupational Injuries and Illnesses conducted by the Bureau of Labor Statistics (BLS) if asked to do so. Each of these requirements is discussed in greater detail in the relevant portion of this summary and explanation.

Section 1904.1 Partial Exemption for Employers With 10 or Fewer Employees

In § 1904.1 of the final rule, OSHA has retained the former rule's size-based exemption, which exempts employers with 10 or fewer employees in all industries covered by OSHA from most recordkeeping requirements. Section 1904.1, ''Partial exemption for employers with 10 or fewer employees,'' states that:

(a) Basic requirement.

(1) If your company had ten (10) or fewer employees at all times during the last calendar year, you do not need to keep OSHA injury and illness records unless OSHA or the BLS informs you in writing that you must keep records under § 1904.41 or § 1904.42. However, as required by § 1904.39, all employers covered by the OSH Act must report to OSHA any workplace incident that results in a fatality or the hospitalization of three or more employees.

(2) If your company had more than ten (10) employees at any time during the last calendar year, you must keep OSHA injury and illness records unless your establishment is classified as a partially exempt industry under § 1904.2.

(b) Implementation.

(1) Is the partial exemption for size based on the size of my entire company or on the size of an individual business establishment?

The partial exemption for size is based on the number of employees in the entire company.

(2) How do I determine the size of my company to find out if I qualify for the partial exemption for size?

To determine if you are exempt because of size, you need to determine your company's peak employment during the last calendar year. If you had no more than 10 employees at any time in the last calendar year, your company qualifies for the partial exemption for size.

The Size-Based Exemption in the Former Rule

The original OSHA injury and illness recording and reporting rule issued in July 1971 required all employers covered by the OSH Act to maintain injury and illness records. In October 1972, an exemption from most of the recordkeeping requirements was put in place for employers with seven or fewer employees. In 1977, OSHA amended the rule to exempt employers with 10 or fewer employees, and that exemption has continued in effect to this day. All employers, however, have always been required to report fatalities and catastrophes to OSHA and to participate in the BLS survey, if requested to do so.

As discussed in the Legal Authority section of this preamble, the 10 or fewer employee threshold is consistent with Congressional intent: the 1977 **Federal Register** notice announcing the new exemption cited the Department of Labor appropriations acts for fiscal years 1975 and 1976, which exempted employers having 10 or fewer employees from most routine recordkeeping requirements, and Section 8(d) of the Act, as the major reasons for raising the exemption size threshold from seven to 10 employees. The 1977 Notice stated that the new size

threshold appropriately balanced the interest of small businesses while preserving the essential purposes of the recordkeeping scheme:

> The [exemption] has been carefully designed to carry out the mandate of section 8(d) without impairing the Act's basic purpose. Thus, the [exemption] will not diminish the protections afforded employees under the Act because all employers * * * remain subject to the enforcement provisions of the Act. The [exemption] will continue to require * * * small employers * * * to report fatalities and multiple hospitalizations and to participate in the BLS annual survey when selected to do so (42 FR 38568 (July 29, 1977)).

The Size-Based Exemption in the Final Rule

The final rule published today maintains the former rule's partial exemption for employers in all covered industries who have 10 or fewer employees. Under the final rule (and the former rule), an employer in any industry who employed no more than 10 employees at any time during the preceding calendar year is not required to maintain OSHA records of occupational illnesses and injuries during the current year unless requested to do so in writing by OSHA (under § 1904.41) or the BLS (under § 1904.42). If an employer employed 11 or more people at a given time during the year, however, that employer is not eligible for the size-based partial exemption.

The Size-Based Exemption in the Proposed Rule

In the 1996 proposal, OSHA contemplated raising the threshold for the size-based exemption to 19 employees for all employers except those in the construction industry. In proposing this more extensive exemption, OSHA stated that BLS Annual Survey data appeared to indicate that small businesses in this size category had proportionately fewer injuries and illnesses and were thus safer places to work. However, since the proposal, OSHA has analyzed the record evidence on this point and now believes that small businesses are not generally likely to be less hazardous than larger businesses and, in fact, are likely, as a general matter, to be more hazardous than large businesses. OSHA's reasoning is described below.

Comments to the record make clear that the recording of fewer injuries and illnesses by very small firms could have many causes other than a lower level of hazards. For example, the National Institute for Occupational Safety and Health (NIOSH) submitted a comment to the record that described numerous studies based on fatality and workers' compensation data that suggest that smaller businesses are at least as hazardous as larger businesses (Ex. 15: 407). NIOSH also argued that the BLS estimated injury and illness incidence rates for small employers may be erroneously low, i.e., may be the result of underreporting rather than a lower injury rate. The following comment from NIOSH explains these concerns:

> From a public standpoint, NIOSH does not support a partial exemption from recordkeeping requirements for employers in the construction industry with 10 or fewer employees, and non-construction employers with 19 or fewer employees. Research indicates significant safety and health problems in ''small'' establishments which employ a substantial proportion of the workforce. One-quarter of the civilian, full-time workforce is employed in establishments with fewer than 25 employees (Oleinick et al. 1995).
>
> The Occupational Safety and Health Administration (OSHA) notes [in the proposal to the recordkeeping rule] that ''the Annual Survey data show that small employers generally experience much lower patterns of injuries and illnesses than medium size firms.'' However, recent literature comparing Annual Survey data and workers compensation data questions the validity of the estimated rates for small employers obtained through the Bureau of Labor Statistics (BLS) Annual Survey. Moreover, fatal and nonfatal work injuries are a significant risk among small businesses in hazardous industries and many industries with high fatal and nonfatal injury rates are comprised primarily of small companies. In addition, NIOSH research indicates that small companies have less access to safety and health programs that might reduce injuries and illnesses than larger companies [NIOSH 1988a].
>
> Though the Annual Survey of Occupational Injuries and Illnesses has consistently reported that employers with fewer than 20 employees have significantly lower rates of injuries and illnesses, there is concern that these low incidence rates are an artifact of the reporting system. Analysis of compensable injuries with >7 missed workdays in Michigan indicates that the pattern of lower injury rates among small employers is not consistent across industry divisions. Though the services and trade industry divisions show a marked decline in compensable injury rate for small size firms, the higher risk industries of construction and transportation/utilities show relatively little decline in the compensable injury rate for employers with fewer than 25 employees. Comparison of the demographic characteristics of the Michigan work force with the demographic characteristics of injured workers suggest that high risk groups (*e.g.*, males, younger workers [<35 years of age], construction, manufacturing, transportation, and blue collar workers) are over-represented among workers injured in small size firms (<25 workers). Using cumulative lost work time as a surrogate for severity of injury, the Michigan study also found that with one exception (construction), compensable injuries to workers in small firms were at least as serious as compensable injuries in larger firms [Oleinick et al. 1995] (Ex. 15: 407).

Since publication of the recordkeeping proposal, OSHA has done considerable research into the issue of fatality, injury, and illness rates in small companies. The results of this research also point to underreporting, rather than safer workplaces, as a likely reason for the lower-than-average injury and illness numbers reported by small employers. The most telling evidence that injury and illness underreporting is prevalent among small firms is the substantial discrepancy between the fatality rates in these firms and their injury and illness rates.

Most professionals agree that occupational fatality data are more reliable than occupational injury and illness data, primarily because fatalities are more likely to be reported than injuries. The work-related BLS fatality data appear to confirm this belief, showing that although businesses with fewer than 10 employees account for only 4% of the total workforce, they account for 28% of occupational fatalities. Furthermore, although businesses with fewer than 20 employees comprise only 26% of the total workforce, they account for 36% of all occupational fatalities (see Mendeloff, ''Using OSHA Accident Investigations to Study Patterns in Work Fatalities,'' *J. Occup. Med* 32: 1117, 1119 (1990) (Ex. 15: 407 F)). These data strongly suggest that very small businesses are disproportionately hazardous places to work.

Many safety and health professionals also believe that injuries and illnesses are substantially underreported by small employers (see, *e.g.*, Exs. 4, 5, 15: 407). However, the occupational injury and illness data reported by employers to the BLS in connection with its Annual Survey of Occupational Injuries and Illnesses show lower rates of injuries and illnesses for firms in the smallest size classes than for those in larger classes. In an effort to understand why smaller firms might have lower injury and illness incidence rates, the authors of one study found that: (1) occupational fatality rates were highest in businesses with fewer than 50 employees; (2) businesses with fewer than 50 employees were least likely to have occupational health services available; and (3) lost workday injury rates in several major industry categories are highest (i.e., the injuries are most severe) in these facilities. From these findings, the authors concluded:

It is difficult to imagine a set of workplace conditions in small establishments that would lead simultaneously to lower injury rates, higher fatality rates, and equal, or greater, injury severity measured by missed work time, especially since these establishments were less likely to provide injury prevention and safety services (Oleinick *et al.,* ''Establishment Size and Risk of Occupational Injury,'' *Am. J. Med.* 28(1): 2–3 (1995) (Ex. 15: 407 N)).

After considering a number of explanations that might explain this apparent incongruity, these authors rejected all explanations except one—underreporting by small firms:

With the rejection of alternative explanations, there is a strong likelihood of underreporting as the explanation, and we estimate that the annual [BLS] survey substantially undercounts injuries in small establishments (Oleinick et al., 1995 (Ex. 15: 407 N)).

NIOSH agrees, noting that ''recent literature comparing Annual Survey data and workers compensation data questions the validity of the estimated rates for small employers obtained through the BLS Annual Survey'' (Ex.15: 407). Thus, the apparent discrepancy between the high fatality rate in the smallest firms (i.e., those with fewer than 20 employees) and the low rates of injuries and illnesses reported by those same firms is likely to be the result of underreporting rather than lower relative hazards.

A *Wall Street Journal* (Feb. 3, 1994) computer analysis of more than 500,000 Federal and State safety-inspection records came to the same conclusions, i.e., that employees of small businesses are at greater risk of exposure to workplace hazards than employees of larger businesses, and that BLS data for small firms seriously understate injuries and illnesses in such firms. From 1988 through 1992, the analysis found an incidence of 1.97 deaths per 1,000 workers at workplaces with fewer than 20 employees, compared with an incidence of just 0.004 deaths per 1,000 workers at workplaces with more than 2,500 workers. Thus, an employee's risk of death was approximately 500 times higher at the smallest businesses compared with the risk at the largest businesses. Similarly, while one in six employees at small businesses worked in an area cited for a serious safety violation, only one in 600 did so at the largest businesses. This means that employees in small businesses are 100 times more likely to be exposed to a serious hazard at work than those in the largest businesses, a finding that is consistent with the higher fatality rates in very small workplaces (*Wall Street Journal,* February 3, 1994).

In the final rule, OSHA has decided to continue the Agency's longstanding practice of partially exempting employers with 10 or fewer employees from most recordkeeping requirements, but not to extend the exemption to non-construction businesses with 19 or fewer employees, as was proposed. OSHA has determined that increasing the number of employers partially exempted is not in the best interests of the safety and health of their employees. First, as NIOSH's comments (Ex. 15: 407), the Oleinick et al. study (1995), the Mendeloff article (1990), and the *Wall Street Journal* study (1994) all indicate, businesses with 20 or fewer employees tend to be relatively hazardous places to work, and their employees have a disproportionately high risk of work-related death. Second, as NIOSH and others point out, there is reason to believe that these very small workplaces also experience disproportionately high numbers of injuries and illnesses, and that the BLS statistics for these workplaces substantially underreport the extent of job-related incidents at these establishments (Ex. 15: 407, Oleinick et al. 1995, *Wall Street Journal* 1994 (Ex. 15: 407 N). Finally, under the 10 or fewer employee partial exemption threshold, more than 80% of employers in OSHA's jurisdiction are exempted from routinely keeping records. Increasing the threshold for the size exemption would deprive even more employers and employees of the benefits of the information provided by these injury and illness records and reduce the number of establishments where the records can be of use to the government during an on-site visit. OSHA also believes that keeping the OSHA Log and Incident Report is important for national statistical purposes.

Size Exemption Threshold for Construction Companies

The final rule also retains the former rule's size exemption threshold (10 or fewer employees) for construction employers. OSHA proposed separate size thresholds for construction and nonconstruction firms, i.e., the Agency proposed to exempt firms in construction with 10 or fewer employees and non-construction firms with 19 or fewer employees from routine recordkeeping requirements. Comments on this aspect of the proposal were mixed. Some commenters agreed that OSHA should continue the exemption for construction employers with ten or fewer employees (see, *e.g.*, Exs. 15: 145, 170, 197, 288). Other commenters urged that employers in the construction industry not be exempted from recordkeeping at all (see, *e.g.*, Exs. 15: 62, 74, 414). For example, Robert L. Rowan, Jr. stated that:

[s]mall contractors often lack adequate safety knowledge, programs and safeguards to prevent injuries and illnesses. I believe that data obtained from these small contractors will point to a trend that these employees have a relatively high frequency of injuries that are related to tasks involving construction work such as excavations and fall hazards. I suggest that there be no exemptions for recordkeeping for any construction employer (Ex. 15: 62).

Other commenters asked OSHA to use a single size threshold for employees in all industries and to raise the size exemption threshold to more than 19 employees across the board (see, *e.g.*, Exs. 15: 67, 304, 312, 344, 437). For example, the Sheet Metal and Air Conditioning Contractors' National Association (SMACNA) remarked:

The recordkeeping standard is considered to be a horizontal standard, which by definition, means that it covers all industries. SMACNA members own and operate sheet metal fabrication shops where they design and create the products which are then installed in the construction process, including duct work and all types of specialty and architectural sheet metal. Sheet metal fabrication shops fall under the manufacturing classification and are therefore subject to general industry standards. SMACNA contractors also construct with the components that they fabricate. Therefore, as contractors they must also comply with the OSHA standards for construction.

OSHA's arbitrary two tier record keeping requirement will cause confusion among SMACNA contractors as to which classification they are under and when they have to maintain records. With the volumes of regulations that contractors already must comply with, it is only logical that if OSHA truly wishes to simplify its recordkeeping requirements it would create a uniform standard for all industries. * * *

SMACNA urges OSHA to create a uniform horizontal standard and increase the exemption for the construction industry to cover employers with 19 or fewer employees (Ex. 15: 116).

After a review of the record and reconsideration of this issue, OSHA agrees that there should be only one size exemption threshold across all industries and finds that the threshold should be 10 or fewer employees. This threshold comports both with longstanding Agency practice and Congressional intent. Further, as discussed above, OSHA finds that extending this threshold to include firms with 11 to 19 employees is not warranted by the evidence. Firms in this size range have a disproportionately large number of fatalities, and their

lower reported injury and illness rates are likely to be the result of underreporting rather than fewer hazards. Thus, companies in this size class need the information their OSHA records provide to improve conditions in their workplaces and to protect their employees from job-related injuries, illnesses, and deaths. Likewise, OSHA does not believe that it would be appropriate to remove the partial exemption for construction employers with 10 or fewer employees, as some commenters suggested (see, *e.g.*, Exs. 15: 67, 304, 312, 344, 437). Using the same size threshold for all OSHA-covered industries also makes the rule simpler and is more equitable from industry to industry.

Comments on Raising the Size-Based Exemption

Many commenters supported raising the size-based exemption threshold (see, *e.g.*, Exs. 27, 15: 26, 27, 67, 102, 123, 145, 170, 173, 182, 198, 247, 288, 304, 359, 375, 378, 392, 401, 437). For example, the American Society of Safety Engineers (ASSE) remarked:

> ASSE supports exempting businesses under twenty (20) employees from the standard with some specific industry exemptions. Enforcing this regulation for businesses of less than twenty (20) employees would be detrimental to small business from the recordkeeping/bureaucracy perspective, and may not generate any significant data. ASSE wishes to clarify, however, that this position should not be interpreted to mean that small businesses should be exempted from safety and health laws. We believe that all employees are entitled to an equal level of safety and health regardless of the size of their place of employment. Exempting a paperwork requirement does not change this level of commitment (Ex. 15: 182).

Two commenters suggested that OSHA use an even higher threshold for determining the size-based exemption (Exs. 15: 357, 408). The Synthetic Organic Chemical Manufacturers Association (SOCMA) stated ''* * * SOCMA believes that OSHA should modify the small employer exemption by increasing it to 40 employees. This alternative approach would reduce the employer paperwork burden while improving the accuracy of injury and illness information'' (Ex. 15:357). Similarly, the American Dental Association (ADA) commented ''The ADA suggests that OSHA expand the proposed exemption from 'fewer than 20 employees' to 'fewer than 25 employees.' This would bring the small-employer exception into conformity with many federal and state employment laws. It would also serve as a more reasonable dividing line between small employers and others'' (Ex. 15:408).

Some commenters, however, objected to OSHA's proposed exemption of employers in the 11 to 20 employee size range (see, *e.g.*, Exs. 15:62, 369, 379, 407, 415, 418). Among these was the International Brotherhood of Teamsters (IBT), which stated:

> IBT maintains the importance of recording of all occupational injuries and illnesses. For that same reason, International Brotherhood of Teamsters does not support increasing the trigger for non-construction employers from ten to nineteen employees. Although injuries due to preventable causes occur in all types and sizes [of businesses], a disproportionately high number of fatalities occur in the smallest businesses. According to an analysis of BLS and OSHA data, then assistant secretary of labor, Joe Dear, told the House of Representative's Small Business Committee, ''Businesses with fewer than eleven workers account for 33 percent of all fatalities even though they account for less than 20 percent of employees.'' According to a study by the National Federation of Independent Businesses, ''generally businesses with fewer employees do less to improve safety than those with more.'' Large corporations can afford the full-time services of a safety engineer and industrial hygienist, whereas often small firms cannot. IBT contends that it is up to OSHA to protect the workers and institute prevention measures. The use of required recordkeeping of data helps to reach that aim by providing hard data. If the data is going to be used as a prevention tool, it must be collected from the entire workforce not just a subgroup (Ex. 15:369).

Reliance on a single size exemption threshold also addresses the point made by SMACNA: that many small employers perform construction work and also manufacture products and would therefore be uncertain, if the rule contained two size exemption thresholds, as to whether they are required to keep records or not.

OSHA's proposed rule stated that the size exemption would apply to employers based on the number of employees employed by the employer ''for the entire previous calendar year.'' The Office of Advocacy of the Small Business Administration (SBA) observed (Ex. 15:67, p. 4) that this statement could be interpreted in various ways, and expressed concern that it could be taken to refer to the total number of employees who had been employed at one time or another during the year rather than the total employed at any one time of the year. The SBA office recommended that OSHA provide clearer guidance. OSHA agrees with the SBA that the proposed regulatory language was ambiguous. Accordingly, the final rule clarifies that the 10 or fewer size exemption is applicable only if the employer had fewer than 11 employees at all times during the previous calendar year. Thus, if an employer employs 11 or more people at any given time during that year, the employer is not eligible for the small employer exemption in the following year. This total includes all workers employed by the business. All individuals who are ''employees'' under the OSH Act are counted in the total; the count includes all full time, part time, temporary, and seasonal employees. For businesses that are sole proprietorships or partnerships, the owners and partners would not be considered employees and would not be counted. Similarly, for family farms, family members are not counted as employees. However, in a corporation, corporate officers who receive payment for their services are considered employees.

Consistent with the former rule, the final rule applies the size exemption based on the total number of employees in the firm, rather than the number of employees at any particular location or establishment. Some commenters suggested that the size exemption should be based on the number of employees in each separate establishment rather than the entire firm (see, *e.g.*, Exs. 15: 67, 201, 437). For example, Caterpillar Inc. (Ex. 15: 201) noted:

> We do object to the note to [proposed] paragraph 1904.2(b)(2) which bases size exemptions on the total number of employees in a firm rather than the establishment size. Size exemptions must be based upon individual establishment size. The factors that make recordkeeping difficult and unproductive for small facilities are not eliminated by adding small facilities together. Small facilities are usually unique and adding together the injury and illness experience of different small facilities will not produce a valid database for accident analysis or accident prevention planning. Injury and illness data collection is difficult because of small facility size and lack of recordkeeping expertise and resources. The benefits of collecting information in small facilities does not justify the costs. It is illogical to base the size exemption on anything other than the size of each separate establishment.

OSHA does not agree with this comment because the resources available in a given business depend on the size of the firm as a whole, not on the size of individual establishments owned by the firm. In addition, the analysis of injury records should be of value to the firm as a whole, regardless of the size of individual establishments. Further, an exemption based on individual establishments would be difficult to administer, especially in

cases where an individual employee, such as a maintenance worker, regularly reports to work at several establishments.

Section 1904.2 Partial Exemption for Establishments in Certain Industries

Section 1904.2 of the final rule partially exempts employers with establishments classified in certain lower-hazard industries. The final rule updates the former rule's listing of partially exempted lower-hazard industries. Lower-hazard industries are those Standard Industrial Classification (SIC) code industries within SICs 52–89 that have an average Days Away, Restricted, or Transferred (DART) rate at or below 75% of the national average DART rate. The former rule also contained such a list based on data from 1978–1980. The final rule's list differs from that of the former rule in two respects: (1) the hazard information supporting the final rule's lower-hazard industry exemptions is based on the most recent three years of BLS statistics (1996, 1997, 1998), and (2) the exception is calculated at the 3-digit rather than 2-digit level.

The changes in the final rule's industry exemptions are designed to require more employers in higher-hazard industries to keep records all of the time and to exempt employers in certain lower-hazard industries from keeping OSHA injury and illness records routinely. For example, compared with the former rule, the final rule requires many employers in the 3-digit industries within retail and service sector industries that have higher rates of occupational injuries and illnesses to keep these records but exempts employers in 3-digit industries within those industries that report a lower rate of occupational injury and illness. Section 1904.2 of the final rule, ''Partial exemption for establishments in certain industries,'' states:

(a) Basic requirement.

(1) If your business establishment is classified in a specific low hazard retail, service, finance, insurance or real estate industry listed in Appendix A to this Subpart B, you do not need to keep OSHA injury and illness records unless the government asks you to keep the records under § 1904.41 or § 1904.42. However, all employers must report to OSHA any workplace incident that results in a fatality or the hospitalization of three or more employees (see § 1904.39).

(2) If one or more of your company's establishments are classified in a non-exempt industry, you must keep OSHA injury and illness records for all of such establishments unless your company is partially exempted because of size under § 1904.1.

(b) Implementation.

(1) Does the partial industry classification exemption apply only to business establishments in the retail, services, finance, insurance or real estate industries (SICs 52–89)?

Yes. Business establishments classified in agriculture; mining; construction; manufacturing; transportation; communication, electric, gas and sanitary services; or wholesale trade are not eligible for the partial industry classification exemption.

(2) Is the partial industry classification exemption based on the industry classification of my entire company or on the classification of individual business establishments operated by my company?

The partial industry classification exemption applies to individual business establishments. If a company has several business establishments engaged in different classes of business activities, some of the company's establishments may be required to keep records, while others may be exempt.

(3) How do I determine the Standard Industrial Classification code for my company or for individual establishments?

You determine your Standard Industrial Classification (SIC) code by using the Standard Industrial Classification Manual, Executive Office of the President, Office of Management and Budget. You may contact your nearest OSHA office or State agency for help in determining your SIC.

Employers with establishments in those industry sectors shown in Appendix A are not required routinely to keep OSHA records for their establishments. They must, however, keep records if requested to do so by the Bureau of Labor Statistics in connection with its Annual Survey (section 1904.42) or by OSHA in connection with its Data Initiative (section 1904.41). In addition, all employers covered by the OSH Act must report a work-related fatality, or an accident that results in the hospitalization of three or more employees, to OSHA within 8 hours (section 1904.39).

In 1982, OSHA exempted establishments in a number of service, finance and retail industries from the duty to regularly maintain the OSHA Log and Incident Report (47 FR 57699 (Dec. 28, 1982)). This industry exemption to the Part 1904 rule was intended to ''reduce paperwork burden on employers without compromising worker safety and health.''

The 1982 list of partially exempt industries was established by identifying lower hazard major industry groups in the SIC Divisions encompassing retail trade, finance, insurance and real estate, and the service industries (SICs 52–89). Major industry groups were defined as the 2-digit level industries from the SIC manual published by the U.S. Office of Management and Budget (OMB). Industries in these major industry groups were partially exempted from coverage by Part 1904 if their average lost workday injury rate (LWDI) for 1978–80 was at or below 75% of the overall private sector LWDI average rate for that year. Industries traditionally targeted for OSHA enforcement (those in SICs 01 through 51, comprising the industry divisions of agriculture, construction, manufacturing, transportation and public utilities, mining, and wholesale trade) remained subject to the full recordkeeping requirements. Although the 1982 **Federal Register** notice discussed the possibility of revising the exempt industry list on a routine basis, the list of partially exempt industries compiled in 1982 has remained unchanged until this revision of the Part 1904 rule.

The proposed rule would have updated the industry exemption based on more current data, and would have relied on 3-digit SIC code data to do so. The only change from the former rule taken in the proposal would have been reliance on LWDI rates for industries at the 3-digit, rather than 2-digit, level.

Evaluating industries at the 3-digit level allows OSHA to identify 3-digit industries with high LWDI rates (DART rates in the terminology of the final rule) that are located within 2-digit industries with relatively low rates. Conversely, use of this approach allows OSHA to identify lower-hazard 3-digit industries within a 2-digit industry that have relatively high LWDI (DART) rates. Use of LWDI (DART) rates at the more detailed level of SIC coding increases the specificity of the targeting of the exemptions and makes the rule more equitable by exempting workplaces in lower-hazard industries and requiring employers in more hazardous industries to keep records.

Under the proposal, based on their LWDI (DART) rates, the following industries would have been required to keep records for the first time since 1982:

SIC 553 Auto and Home Supply Stores
SIC 555 Boat Dealers
SIC 571 Home Furniture and Furnishings Stores
SIC 581 Eating Places
SIC 582 Drinking Places
SIC 596 Nonstore Retailers
SIC 598 Fuel Dealers
SIC 651 Real Estate Operators and Lessors
SIC 655 Land Subdividers and Developers
SIC 721 Laundry, Cleaning, and Garment Services
SIC 734 Services to Dwellings and Other Buildings
SIC 735 Miscellaneous Equipment Rental and Leasing
SIC 736 Personnel Supply Services
SIC 833 Job Training and Vocational Rehabilitation Services
SIC 836 Residential Care

SIC 842 Arboreta and Botanical or Zoological Gardens, and
SIC 869 Membership Organizations Not Elsewhere Classified

The following industries would have been newly exempted by the proposal:

SIC 525 Hardware Stores
SIC 752 Automobile Parking
SIC 764 Reupholstery and Furniture Repair
SIC 793 Bowling Centers
SIC 801 Offices and Clinics of Doctors of Medicine
SIC 807 Medical and Dental Laboratories, and
SIC 809 Miscellaneous Health and Allied Services, Not Elsewhere Classified

In the Issues section of the preamble to the proposed rule, OSHA asked the public to comment on the appropriateness of the proposed exemption procedure, and on whether or not OSHA should expand this approach to industries in SICs 01 through 51. The Agency also asked for alternative approaches that would reduce employer paperwork burden while retaining needed injury and illness information, and for estimates of the costs and benefits associated with these alternatives. OSHA notes that the final rule is based on the most recent data available (1996–1998). Although it has relied on the methodologies proposed (3-digit SIC codes, industries below 75% of the national average LWDI rate), there have been a few shifts in the industries proposed to be covered and those actually covered by the final rule. Thus this final rule will continue to exempt eating and drinking places (SICs 581 and 582) but will not exempt automobile parking (SIC 752).

Comments on the Proposed Industry Exemptions

A number of commenters supported OSHA's proposal to apply the 1982 exemption criteria to the service and retail industries at the three-digit SIC level (see, *e.g.*, Exs. 27; 15: 26, 199, 229, 247, 272, 299, 359, 375, 378, 392). However, a number of commenters opposed any exemptions from the Part 1904 requirements on the basis of industry classification (see, *e.g.*, Exs. 15: 9, 13, 31, 62, 78, 83, 129, 153, 154, 163, 186, 197, 204, 234, 350, 379, 399, 414). The International Paper Company explained its reasons for opposing industry exemptions as follows:

> Exempting employers with low incidence rates is inconsistent with a major objective of the recordkeeping rules; specifically, measuring the magnitude of work-related injuries and illnesses. Exemption of specific industrial classifications or small employers may bias statistics which are used by OSHA for identifying industries for inspections. These exemptions may also impact statistics related to less traditional, but increasingly more frequent exposures such as bloodborne pathogens, tuberculosis, motor vehicle incidents or workplace violence.
>
> Exempting employers with low incidence rates does not provide any measurable relief from paperwork requirements. Time spent on recordkeeping is primarily dedicated to decision making regarding work relationship and recordability, not actual Log entries or completing supplemental reports. Simplifying the decision making process is the best way to reduce the burden of recordkeeping, not exempting employers (Ex. 15:399).

The Service Employees International Union (SEIU) agreed:

> Injury and illness recordkeeping is the most basic step an employer must take in order to begin to address workplace hazards. Responsible employers recognize that injury and illness records are a useful tool for development of sound company safety and health programs. This information is also critical to the workers themselves, by raising awareness about how and where people are getting hurt, they in turn use this information to work to eliminate the causes of such injuries and illnesses. Therefore it is disturbing that in the proposed revised standard, there still exist industry exemptions for recordkeeping and reporting. Prior to 1983, all employers covered by OSHA with more than ten employees were required to maintain injury and illness records.
>
> * * * SEIU believes that such exemptions are unwarranted and violate the specific language of the Occupational Safety and Health Act. * * * The Act does not provide for excluding entire classes of occupationally injured and sick workers. Furthermore, little recordkeeping will be required for industries that are safe and experience low rates of injuries and illnesses. It is critical that OSHA require recordkeeping for all industries, especially since many previously exempt sectors now experience increasing rates of injury and illness. Many of these industry sectors are also dramatically expanding—therefore, continued recordkeeping is even more critical (Ex. 15:379).

The National Safety Council (Ex. 15:359) cautioned:

> From the point of view of injury and illness prevention. * * * an establishment that does not track its injury and illness experience cannot effectively administer a prevention program. * * *

Although OSHA encourages employers to track the occupational injuries and illnesses occurring among their employees and agrees that doing so is important for safety and health prevention efforts, OSHA has decided in the final rule to continue the long-established practice of exempting employers in industries with lower average lost workday incidence rates from most OSHA recordkeeping requirements but to tie the exemption as closely as possible to specific 3-digit SIC code data.

Accordingly, non-mandatory Appendix A of the final rule identifies industries for exemption at the 3-digit SIC code level. Although this approach does make the list of exempt industries longer and more detailed, it also targets the exemption more effectively than did the former rule's list. For example, the final rule does not exempt firms in many of the more hazardous 3-digit SIC industries that are embedded within lower rate 2-digit SIC industries. It does, however, exempt firms in relatively low-hazard 3-digit SIC industries, even though they are classified in higher hazard 2-digit SIC industries. Where Days Away, Restricted, or Transferred (DART, formerly LWDI) rate calculations exempt all of the 3-digit SIC industries within a given 2-digit industry, the exempt industry list in Appendix A displays only the 2-digit SIC classification. This approach merely provides a shorter, simpler list.

For multi-establishment firms, the industry exemption is based on the SIC code of each establishment, rather than the industrial classification of a firm as a whole. For example, some larger corporations have establishments that engage in different business activities. Where this is the case, each establishment could fall into a different SIC code, based on its business activity. The Standard Industrial Classification manual states that the establishment, rather than the firm, is the appropriate unit for determining the SIC code. Thus, depending on the SIC code of the establishment, one establishment of a firm may be exempt from routine recordkeeping under Part 1904, while another establishment in the same company may not be exempt.

Several commenters suggested that OSHA use an alternate method for determining exemptions (see, *e.g.*, Exs. 15: 97, 201, 359). The National Safety Council (Ex. 15: 359), for example, urged OSHA to ''evaluate other exemption procedures before incorporating one into proposed section 1904.2.''

OSHA has evaluated other approaches but has decided that the 3-digit DART rate method is both simpler and more equitable than the former 2-digit method. By exempting lower-hazard industry sectors within SICs 52–89, OSHA hopes both to concentrate its recordkeeping requirements in sectors that will provide the most useful data and to minimize paperwork burden. No exemption method is perfect: any method that exempts broad classes of employers from recordkeeping obligations will exempt some more hazardous workplaces and cover some less hazardous workplaces. OSHA has

attempted to minimize both of these problems by using the most current injury and illness statistics available, and by applying them to a more detailed industry level within the retail, financial and service sectors than was formerly the case. OSHA has also limited the scope of the exemptions by using an exemption threshold that is well below the national average, including only those industries that have average DART rates that are at or below 75% of the national average DART rate. The rule also limits the exempt industries to the retail, financial and service sectors, which are generally less hazardous than the manufacturing industry sector.

The Orlando Occupational Safety and Health Customer Council asked: ''What is the criteria for exemptions? For example, large auto dealers who also perform auto repair work are exempt, while smaller auto repair shops are not exempt. Why not classify the organization by the most hazardous occupation [within that organization]?'' (Ex. 15: 97).

In response to this query, OSHA notes that the exemption procedure is reasonably straightforward, as the following example illustrates: the automobile dealer industry is exempt because its DART rate, as indicated by its average over three years of BLS data, is below 75% of the national average rate. Automobile repair shops are not exempted, however, because their rate is higher than the 75% cutoff. If OSHA were to base its recordkeeping requirements on the most hazardous occupation within a given industry, assuming that occupation-specific within-industry injury and illness data were available, as this commenter suggests, the number of establishments in individual industries that would have to keep records would greatly increase. This is because even relatively safe industries have some number of employees who engage in relatively hazardous occupations. For example, workers who transport currency, coins, and documents for banks and other financial institutions are engaged in a fairly hazardous occupation. They may be injured in many different ways, ranging from highway accidents, to lifting of heavy parcels, to robberies. However, the experience of these few employees within the industry does not accurately reflect the relative degree of hazard confronting the vast majority of employees in the financial industries. Although it is certainly not perfect, OSHA believes that the BLS lost workday injury rate (DART rate) is a better comparative statistic than the injury rate for a particular occupation because it reflects the risk to the average worker within the particular industry. Moreover, while it is relatively easy to classify employees according to occupation, it is unclear how to classify individual employers with regard to detailed occupation, and OSHA is also not aware of data that would permit such classification.

The Caterpillar Corporation (Ex. 15: 201) suggested that OSHA adjust the formula used to determine which industries are exempted:

> You propose to base your exemption on achieving less than 75% of the average private sector lost workday injury rate; however, we would recommend expanding the size of the exemption to include all industries below the private sector average. We have no objection to your proposal to eliminate the ''nesting'' problem within 2-digit SIC code groups, as long as the exemption size is maximized. The recordkeeping paperwork burden for small and relatively safe industries is significant and not justified based upon the benefits received.

OSHA has decided in the final rule to continue to use a formula that will exempt retail, finance and services industries from most recordkeeping requirements if they have a Days Away, Restricted, or Transferred (DART) rate that is at or below 75% of the national average rate. OSHA believes that the 75% threshold will ensure that only industries with relatively low injury and illness rates are exempted from these requirements. Using the national average DART rate, rather than 75% of the national DART rate, as the threshold for exemption purposes would exempt employers whose industries were merely average in terms of their DART rate.

OSHA received many comments from firms in industries that have been exempt from most OSHA recordkeeping requirements since 1982 but that would have been required by the proposed rule to keep records. Most of these commenters opposed their industry's inclusion within the scope of the proposed rule. For example, several commenters from the restaurant industry objected to the fact that SICs 581 and 582, eating and drinking places, would have been covered (see, *e.g.*, Exs. 15: 3, 4, 5, 6, 7, 8, 12, 20, 22, 55, 96, 125, 202, 311). The National Restaurant Association remarked:

> The Association opposes elimination of this exemption on the bases that:
>
> —the proposal, if promulgated, will cost eating and drinking establishments an estimated $17 million in the first year alone;
>
> —the additional recordkeeping obligations under the proposed rule duplicate data already available to OSHA from other sources; and
>
> —the current data does not justify removal of the partial recordkeeping exemption for eating and drinking establishments (Ex. 15: 96).

In the final rule, the exemption for eating and drinking places is retained, because the recent data indicate that these industries have DART rates that are below 75% of the national rate.

Two commenters addressed the proposed removal of the exemption for SIC 553, auto and home supply stores (Ex. 15: 367, 402). For example, the Automotive Parts and Accessories Association (APAA) stated:

> The vast majority of auto parts stores are similar to other retailers which would still be exempt under this proposal. * * * [m]ore than three quarters of the automotive parts retailers which are proposed to be saddled with the full Log requirements would have little or no potential injury or illness experience to justify the added mandate (Ex. 15: 367).

Several commenters discussed the proposed removal of the exemption for SIC 721, laundry, dry cleaning and textile rental services (see, *e.g.*, Exs. 15: 183, 244, 326). Typical of the views expressed by these commenters was the comment of the Textile Rental Services Association of America (TRSA):

> TRSA is strongly opposed to OSHA's proposal to eliminate the partial exemption from recordkeeping and reporting requirements for laundry, cleaning, and garments services for Standard Industrial Classification (SIC) 721. TRSA believes that the proposed inclusion of the textile rental industry is unjustified. Because the textile rental industry has historically been proactive when it comes to workplace safety and has been 75% below the industry average for lost work days, we contend that OSHA's plan to eliminate the partial exemption from injury/illness recordkeeping requirements is unwarranted (Ex. 15: 183).

The National Association of Home Builders (NAHB) commented on the proposed inclusion in the recordkeeping system of a variety of industries closely associated with the home building industry:

> As a result of using a 3 digit Standard Industrial Classification (SIC), ''Real Estate Offices'' (SIC 651) will now be required to report and record injury and illness data if they have more than 19 workers during the year. A cursory analysis of the hazards associated with real estate offices seems to indicate limited exposure to high hazards (Ex. 15: 323).

The primary arguments put forth by these commenters are as follows: (1) The occupational injury and illness data collected under Part 1904 are available to OSHA from other sources; (2) OSHA's data requirements are burdensome; (3) the use of even more current data would change the list of exempted industries;

and (4) some of the individual industries that would be covered are relatively safe.

In response, OSHA notes that, although statistical information on average work-related injury and illness rates in industries is available from the BLS and other sources, information about the hazards present at specific workplaces is not available to OSHA from those same sources. OSHA recognizes that the maintenance of these records imposes some burden on businesses in the form of paperwork. However, the benefits of keeping records are also clearly substantial: informed employers can use the data to provide greater protection for their employees and to receive the benefits that accrue from prevention efforts in the form of fewer injuries and illnesses. In addition, the records are useful to OSHA in the inspection process. OSHA also believes that the process for selecting exempt industries must be as objective as possible, and that exemptions must rely upon timely and objective information about the safety and health experience of a given industry. The lost workday injury rates published by the Bureau of Labor Statistics provide the most consistent and reliable nationwide statistics available for this purpose, and OSHA is therefore relying on these data. The 75% of the national rate cutoff strikes a reasonable balance between collecting data likely to be useful and avoiding unnecessary burden. OSHA has used the most recent data available at this time in establishing the final list of partially exempt industries. OSHA also has used data from a three-year period (1996–1998) rather than a one-year period to reduce year-to-year variation in the data.

Other commenters argued that their industry should not be exempt because their workplaces continue to pose risk to the workers in them. For example, the American Nurses Association (ANA) opposed the partial exemption of doctor's offices and health services:

> ANA urges OSHA to remember the purpose of the Act, to protect the health and safety of ALL workers, when deliberating on exempting employers from this standard. As stated before, health care workers risk of exposure to injury and illness is not limited to one setting. Therefore, the Standard Industrial Classifications (SICs) 801 Offices and Clinics of Doctors of Medicine and SIC 809 Miscellaneous Health and Allied Services should not be exempt from this standard (Ex. 15: 376).

The International Brotherhood of Teamsters (IBT) also argued against excluding certain health care service industries:

> IBT has concerns when the use of this analysis will grant partial exemptions to SIC codes 801 (offices and clinics of doctors), 807 (medical and dental offices), and 809 (miscellaneous health and allied services). All three of these SIC codes are covered under other OSHA rules (such as the bloodborne pathogen standard and ethylene oxide standard) and have medical surveillance requirements to detect adverse health effects. OSHA should require that these workplaces keep records of work related illnesses or injuries that occur. Especially, since OSHA has already determined that there is a significant risk of harm from exposures in these workplaces (Ex. 15: 369).

OSHA recognizes that workers in establishments that are exempt under the 75% DART rate criterion will continue to be exposed to job-related hazards and to experience workplace injuries and illnesses. However, because these industries' overall injury rate is below the 75% cutoff, they qualify for exemption, along with other financial, service and retail industries that fall below that injury rate threshold. Exemption of an industry on the basis of its lower-than-average DART rate does not mean that all establishments within that industry have such rates or that workers in that industry will not experience injuries and illnesses. The 1904 partial exemption does not exempt employers from any other OSHA regulation or standard, so employees in these industries will continue to benefit from the protection offered by the OSHA standards. For example, while doctors' and dentists' offices are partially exempt under the 1904 regulation, they are still required to comply with the OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030). Use of the 75% criterion merely provides a cutoff point, based on BLS injury and illness rates, for different industry sectors. OSHA believes that it is appropriate to use the 75% cutoff point because, in general, it is an appropriate overall indicator of the relative hazard rank of an industry. OSHA recognizes that no average across-establishment statistic can capture the injury and illness experience of all occupations or establishments within that industry.

For some SIC codes, the BLS Annual Survey does not publish data at the three-digit level. The survey is designed to provide data at the four-digit level in the manufacturing industries and at the three-digit level in all other industries, primarily because of budget constraints that limit the amount of data the BLS can collect and process. However, the survey has other publication criteria that make some of the data at this detailed level unpublishable. Under the proposal, coverage would have been based on the industry's LWDI rate. If a 3-digit sector did not have published data, OSHA proposed to use the data for the two-digit industry group for that sector.

One 3-digit sector affected by this approach was dental offices (SIC 802), which the proposal would have covered because the entire 2-digit health care sector has a relatively high injury and illness rate. The American Dental Association (ADA) suggested that OSHA use an alternative approach to exempt dentists from coverage rather than rely on a strict data protocol for making the decision:

> [d]ental offices are very much like physicians' offices in terms of size, scope of activity, and degree of occupational health risk. For purposes of this rulemaking, however, physicians' offices have been granted a categorical exemption while dentists' offices (SIC Code 802) have not. Even dental laboratories (SIC Code 807) have been granted a categorical exemption from this rule, although it is unlikely that anyone would assert that dental laboratories are safer and more healthful places to work than dental offices. The ADA is unaware of any data suggesting that dental offices should be treated differently than either physicians' offices or dental laboratories (Ex. 15: 408).

The more recent data published by the BLS for the years 1996, 1997, and 1998 include specific estimates of the injury and illness experience for SIC 802 (dental offices) in that period. The dental office industry experienced a 3-year average rate of days away, restricted, or transferred injuries of 0.2 per 100 workers in those years, a rate well below 75% of the national average. Therefore, the final rule exempts employers classified in SIC 802 from routine recordkeeping requirements.

The proposed rule would have removed SIC 736 (personnel supply services) from the list of exempted industry sectors; however, because this industry's more recent average DART (formerly LWDI) rate (for the years 1996, 1997, and 1998, the base years OSHA is using to determine lower-hazard industry exemptions) is above 75% of the national average cutoff, SIC 736 is not exempted under the final rule. The final rule (see section 1904.31(b)(2)) requires the ''using firm'' to record the injuries and illnesses of temporary workers that are ''leased'' from a personnel supply service, providing that the using firm supervises these workers on a day-to-day basis.

The National Association of Temporary and Staffing Services commented on the proposed removal of the exemption for SIC 736:

The proposed rules also would lift the partial exemption for employers classified under SIC Code 7363 (help supply services). Those employers, among others, were exempted from injury and illness record keeping requirements in 1982 because they had low work place injury rates. The proposal to lift the exemption is based on reported increased injury rates for these employers. However, since records for the vast majority of staffing firm employees are maintained by the worksite employer as explained above, the practical effect of lifting the exemption for staffing firms would be to require them to maintain records for their home office clerical and administrative workers—for whom there is no evidence of increased work place illnesses or injuries. Hence, we urge OSHA to retain the partial exemption for SIC 7363.

If the exemption is not retained in the case of SIC 7363 employers, it would be especially important for the final rules to expressly provide, as set forth above, that there is no intent to impose a dual reporting requirement. At least one state OSH office already has construed the proposed lifting of the partial exemption as creating an obligation on the part of staffing firms to maintain records for all of its employees, including temporary employees supervised by the worksite employer. This is clearly inconsistent with the intent of the proposed rule and should be clarified (Ex. 15: 333).

The final rule makes clear that, when a ''leased'' or ''temporary'' employee is supervised on a day-to-day basis by the using firm, the using firm must enter that employee's injuries and illnesses on the using firm's establishment Log and other records. Injuries and illnesses occurring to a given employee should only be recorded once, either by the temporary staffing firm or the using firm, depending on which firm actually supervises the temporary employees on a day-to-day basis. (see the discussion for § 1904.31, Covered employees, for an in-depth explanation of these requirements.)

Some commenters suggested that OSHA should grant partial exemptions to specific industries within SICs 01 through 51 (agriculture, forestry and fishing; mining; construction; manufacturing; transportation, communications, electric, gas and sanitary services; and wholesale trade) that had lost workday incidence rates that were below 75% of the average rate for all industries instead of limiting such exemptions to industries in SICs 52–89 (see, *e.g.*, Exs. 15: 77, 95, 184, 201, 357, 359, 374, 375). Typical of these comments was one from the Synthetic Organic Chemical Manufacturers Association (SOCMA):

SOCMA believes that the partial exemption from recordkeeping requirements should be consistent for all standard industrial classifications. SOCMA supports the use of injury rates, rather than SIC Codes, as a criterion for partial exemption from recordkeeping requirements, provided the same criterion is applied to all work sites. For example, if the performance measure was 75 percent of the private sector average, then all industries with injury rates below this average should be exempt.

There is sound basis for this shift in OSHA's approach. It has been found in the past that some industries in partially exempt SIC Codes 52—89 have had high injury rates while some in the ''manufacturing'' SIC Codes 01–51 have had low injury rates. This has resulted in insufficient or unavailable injury and illness information for some facilities in SIC Codes 52–89 with high injury rates. Inspection resources are wasted if injury and illness information is not available during the inspection of high injury rate facilities. Conversely, requiring full recordkeeping for facilities with low injury rates results in a facility wasting resources on unnecessary recordkeeping. All businesses, regardless of SIC Code, should be treated equally and should have the opportunity to be exempt based on injury rates (Ex. 15: 357).

The National Automobile Dealers Association (NADA) urged OSHA to exempt truck dealerships [classified in SIC 50], even though they are considered wholesale rather than retail establishments, because of their similarity to automobile dealerships [SIC 551], which are exempted:

NADA strongly urges OSHA to exempt truck dealerships (SIC 5012), the overwhelming majority of whom are small businesses as recognized by the Small Business Administration (SBA).* * * A limited exemption for truck dealerships is justified under the same criteria used for automobile dealerships (Ex. 15: 280).

On the other hand, some commenters agreed with OSHA's proposal to require all businesses in SICs 01–51 to keep injury and illness records (see, *e.g.*, Exs. 15: 170, 199, 369). The International Brotherhood of Teamsters (IBT) remarked: ''IBT does not support using the same analysis of data at the three digit level of those industries in SIC 01 through 51 (industries historically not exempted from recordkeeping requirements). IBT maintains the importance of recording of all occupational injuries and illnesses'' (Ex. 15: 369). A major utility, New England Power, agreed: ''We believe that the existing exemption criteria for SICs 52–89 should remain the same. Although many industries would fall within the exemption criteria in SICs 01–51, they are still higher hazard industries producing valuable data on injury/illness experience'' (Ex. 15: 170). The NYNEX Corporation also agreed with OSHA's proposed approach:

We are not in favor of extending the concept of industry-wide recordkeeping exemptions to the list of three digit codes in the group 01–51 that were identified in the proposal. Even though these groups have average injury and illness case rates that are less than 75% of the private sector average, the nature of the work operations performed within these industries suggests that the variation above and below average for individual establishments could be much greater than with SIC Codes 52–89. An exemption for this group of establishments could mask the existence of some very high case rates within this group (Ex. 15: 199).

After a review of the recent BLS data, OSHA's own experience, and the record of this rulemaking, OSHA has decided that it is appropriate to require firms in industries within the SIC 01 through 51 codes to comply with OSHA's requirements to keep records. Thus, the final rule, like the proposed rule and the rule published in 1982, does not exempt firms with more than 10 employees in the industry divisions of agriculture, mining, construction, manufacturing, wholesale trade, transportation and public utilities (SICs 01—52) from routine recordkeeping.

Although OSHA no longer restricts its inspection targeting schemes to employers in these SICs, these industries have traditionally been, and continue to be, the focus of many of the Agency's enforcement programs. OSHA believes that it is important for larger employers (i.e., those with more than 10 employees) in these industries to continue to collect and maintain injury and illness records for use by the employer, employees and the government. As noted in the comments there is a wide variation in injury/illness rates among establishments classified in these industries. Further, as a whole, these industries continue to have injury and illness rates that are generally higher than the private sector average and will thus benefit from the information that OSHA-mandated records can provide about safety and health conditions in the workplace. In 1998, the lost workday injury and illness rate for the entire private sector was 3.1. As can be seen in the following table of lost workday injury and illness rates by industry division, all of the covered divisions exceeded 75% of the national average LWDI rate (2.325) for the private sector as a whole, while the exempted industry divisions had substantially lower rates.

Industry sector	1998 lost workday injury and illness rate
Agriculture, forestry and fishing (SIC 01–09)	3.9
Mining (SIC 10–14)	2.9
Construction (SIC 15–17)	4.0
Manufacturing (SIC 20–39)	4.7

Industry sector	1998 lost workday injury and illness rate
Transportation, communications, electric, gas and sanitary services (SIC 40–49)	4.3
Wholesale trade (SIC 50 & 51)	3.3
Retail trade (SIC 52–59)	2.7
Finance, Insurance & Real Estate (SIC 60–67)	0.7
Services (SIC 70–87)	2.4

(U.S. Department of Labor Press Release USDL 98–494, December 16, 1999)

The problems that may be encountered by exempting additional industries are exemplified by an analysis of the petrochemical industry and the manufacturers of chemicals and petroleum products, classified in SICs 28 and 29. If the industry exemption were applied to these industries, injury and illness records would not be required for highly specialized plants that make industrial inorganic chemicals, plastics materials and synthetic resins, pharmaceuticals, industrial organic chemicals, and petroleum refineries. These industries have relatively low occupational injury and illness rates, but they are not truly low-hazard industries. All of these facilities make, use and handle highly toxic chemicals and consequently have the potential for both acute overexposure and chronic exposures of their employees to these substances. These industries, for example, are the industries to which OSHA health standards, such as the benzene, ethylene oxide, and methylene chloride standards, apply. Because occupational illnesses, particularly chronic illnesses, are notoriously underreported (see, *e.g.*, Exs. 15: 407, 4, 5), the LWDI rates for these industries do not accurately reflect the level of hazard present in these facilities. In addition, these types of facilities are prone to major safety and health problems, including explosions, toxic releases and other events that often lead to fatalities and serious injuries. The safety and health problems of these facilities are not limited to workers, but extend to hazards posed to the general public. In addition, OSHA frequently inspects these facilities because of their potential for catastrophic releases, fires, and explosions, and the Part 1904 injury and illness records have been extremely useful for this purpose.

The Agency finds that continuing, and improving on, the Agency's longstanding approach of partially exempting those industries in SIC codes 52–89 that have DART rates, based on 3 years of BLS data, below 75% of the private-sector average strikes the appropriate balance between the need for injury and illness information on the one hand, and the paperwork burdens created by recording obligations, on the other. The BLS Annual Survey will, of course, continue to provide national job-related statistics for all industries and all sizes of businesses. As it has done in the past, the BLS will sample employers in the partially exempt industries and ask each sampled employer to keep OSHA records for one year. In the following year, BLS will collect the records to generate estimates of occupational injury and illness for firms in the partially exempt industries and size classes, and combine those data with data for other industries to generate estimates for the entire U.S. private sector. These procedures ensure the integrity of the national statistics on occupational safety and health.

The list of partially exempted industry sectors in this rule is based on the current (1987) revision of the SIC manual. The Office of Management and Budget (OMB) is charged with maintaining and revising the system of industrial classification that will replace the SIC. The new system is used by U.S. statistical agencies (including the BLS). Under the direction of OMB, the U.S. government has adopted a new, comprehensive system of industrial classification that will replace the SIC. The new system is called the North American Industrial Classification System (NAICS). NAICS will harmonize the U.S. classification system with those of Canada and Mexico and make it easier to compare various economic and labor statistics among the three countries. Several commenters expressed concern about this change in industrial classification systems (see, *e.g.*, Exs. 15: 70, 182, 183, 379). For example, the American Society of Safety Engineers (ASSE) stated:

> The Society is concerned with the recent Office of Management Budget (OMB), proposal to change the Economic Classification Policy from the Standard Industrial Classification System to the North American Industry Classification System. We recommend that OSHA study what the effect would be of promulgating a new regulation partially based on SIC codes when these codes could be potentially replaced/revised with a new classification system (Ex. 15: 182).

Although the NAIC industry classification system has been formally adopted by the United States, the individual U.S. statistical agencies (including the BLS) are still converting their statistical systems to reflect the new codes and have not begun to publish statistics using the new industry classifications. The new system will be phased into the nation's various statistical systems over the next several years. The BLS does not expect to publish the first occupational injury and illness rates under the new system until the reference year 2003. Given the lag time between the end of the year and the publication of the statistics, data for a full three-year period will not be available before December of 2006.

Because data to revise the Part 1904 industry exemption based on the NAIC system will not be available for another five years, OSHA has decided to update the industry exemption list now based on the most recent SIC-based information available from BLS for the years 1996, 1997 and 1998. OSHA will conduct a future rulemaking to update the industry classifications to the NAIC system when BLS publishes injury and illness data that can be used to make appropriate industry-by-industry decisions.

The proposal inquired whether OSHA should adopt a procedure for adjusting the industry exemption lists as the injury and illness rates of various industries change over time. A number of commenters urged OSHA to update the exemption list periodically (see, *e.g.*, Exs. 15: 27, 87, 170, 181, 199, 272, 280, 359, 374, 375, 392, 407). Some commenters suggested various time periods, such as annually (Ex. 15: 374), every 3 years (see, *e.g.*, Exs. 15: 87, 181, 199, 407), every 5 years (see, *e.g.*, Exs. 15: 170, 181, 262, 272, 359, 375), or every 5 to 10 years (Ex. 15: 392). Southwestern Bell Telephone suggested that the list should be modified whenever changes in the injury and illness rates warrant a change (Ex. 15: 27). In the opinion of the National Safety Council, ''How often the SIC exemption should be updated depends on how well and how quickly OSHA can communicate changes in the exempt industry list to those affected. The Council recommends updating the list every 3 to 5 years'' (Ex. 15: 280).

Several commenters, however, opposed frequent updating of the SIC exemption list. For example, the Orlando Safety and Health Customer Council stated: ''Changes to SIC exemptions should be limited to a minimum of every 5 years. This would reduce confusion'' (Ex. 15: 97). The National Institute for Occupational Safety and Health (NIOSH) generally opposed industry exemptions but recommended that, if they were continued, they be updated as follows:

If OSHA continues to provide this exemption for low injury rate SICs, NIOSH

recommends that the list of partially exempt SICs be placed in an Appendix. Because the injury and illness experience of an industry can change over time (*e.g.*, SIC 58 and SIC 84 had injury rates at or below 75% of the private sector average in 1983, but above 75% of the private sector average in 1990 and 1992), OSHA should periodically review and modify the list of partially exempt industries. NIOSH recommends that the criteria for partial exemptions be placed in the regulatory text, while placing the list of partially exempt industries in an Appendix as noted so that the list could be updated periodically by administrative means rather than by changing the regulation. In addition to the partial exemption criteria, the regulatory text should specify the interval (in years) for reviewing and revising the list of those industries that qualify. NIOSH recommends an interval of 3 years for the review and revision process (Ex. 15: 407).

OSHA agrees with those commenters who favored regular updating of the SIC code exemption list. For the list to focus Agency resources most effectively on the most hazardous industries, it must be up-to-date. Industries that are successful in lowering their rates to levels below the exemption threshold should be exempted, while those whose rates rise sufficiently to exceed the criterion should receive additional attention. Unfortunately, the change in industry coding systems from the Standard Industrial Classification (SIC) system to the North American Industry Classification (NAIC) system will require a future rulemaking to shift to that system. Therefore, there is no value in adding an updating mechanism at this time. The automatic updating issue will be addressed in the same future rulemaking that addresses the NAIC system conversion.

Partial Exemptions for Employers Under the Jurisdiction of OSHA-Approved State Occupational Safety and Health Plans

Robert L. Rowan, Jr. expressed a concern that the OSHA State-Plan States could have differing industry exemptions from those applying to federal OSHA states, commenting:

In regard to the note in OSHA's Coverage and Exemption Table that ''some states with their own occupational safety and health programs do not recognize the federal record keeping exemptions''. I am deeply concerned. I would prefer that all jurisdictions enforce the same requirements. This will be confusing and create needless problems for businesses with sites in numerous states if requirements are not enforced equally (Ex. 15: 62).

For those States with OSHA-approved State plans, the state is generally required to adopt Federal OSHA rules, or a State rule that is at least as effective as the Federal OSHA rule. States with approved plans do not need to exempt employers from recordkeeping, either by employer size or by industry classification, as the final Federal OSHA rule does, although they may choose to do so. For example, States with approved plans may require records from a wider universe of employers than Federal OSHA does. These States cannot exempt *more* industries or employers than Federal OSHA does, however, because doing so would result in a State rule that is not as effective as the Federal rule. A larger discussion of the effect on the State plans can be found in Section VIII of this preamble, State Plans.

Recordkeeping Under the Requirements of Other Federal Agencies

Section 1904.3 of the final rule provides guidance for employers who are subject to the occupational injury and illness recording and reporting requirements of other Federal agencies. Several other Federal agencies have similar requirements, such as the Mine Safety and Health Administration (MSHA), the Department of Energy (DOE), and the Federal Railroad Administration (FRA). The final rule at section 1904.3 tells the employer that OSHA will accept these records in place of the employer's Part 1904 records under two circumstances: (1) if OSHA has entered into a memorandum of understanding (MOU) with that agency that specifically accepts the other agency's records, the employer may use them in place of the OSHA records, or (2) if the other agency's records include the same information required by Part 1904, OSHA would consider them an acceptable substitute.

OSHA received very few comments on the issue of duplicate recordkeeping under different agency rules. The Fertilizer Institute (TFI) recommended that OSHA make the data mandated by OSHA and MSHA more consistent (Ex. 15:154). However, MSHA and OSHA have different recordkeeping requirements because the agencies' mandate and uses of the data differ. The approach OSHA takes in the final rule, which is to continue to accept data kept by employers under other Federal requirements if the two federal agencies have made an agreement to do so, or if the data are equivalent to the data required to be kept by Part 1904, appears to be the best way to handle the problem raised by the TFI.

Subpart C. Recordkeeping Forms and Recording Criteria

Subpart C of the final rule sets out the requirements of the rule for recording cases in the recordkeeping system. It contains provisions directing employers to keep records of the recordable occupational injuries and illnesses experienced by their employees, describes the forms the employer must use, and establishes the criteria that employers must follow to determine which work-related injury and illness cases must be entered onto the forms. Subpart C contains sections 1904.4 through 1904.29.

Section 1904.4 provides an overview of the requirements in Subpart C and contains a flowchart describing the recording process. How employers are to determine whether a given injury or illness is work-related is set out in section 1904.5. Section 1904.6 provides the requirements employers must follow to determine whether or not a work-related injury or illness is a new case or the continuation of a previously recorded injury or illness. Sections 1904.7 through 1904.12 contain the recording criteria for determining which new work-related injuries and illnesses must be recorded on the OSHA forms. Section 1904.29 explains which forms must be used and indicates the circumstances under which the employer may use substitute forms.

Section 1904.4 Recording Criteria

Section 1904.4 of the final rule contains provisions mandating the recording of work-related injuries and illnesses that must be entered on the OSHA 300 (Log) and 301 (Incident Report) forms. It sets out the recording requirements that employers are required to follow in recording cases.

Paragraph 1904.4(a) of the final rule mandates that each employer who is required by OSHA to keep records must record each fatality, injury or illness that is work-related, is a new case and not a continuation of an old case, and meets one or more of the general recording criteria in section 1904.7 or the additional criteria for specific cases found in sections 1904.8 through 1904.12. Paragraph (b) contains provisions implementing this basic requirement.

Paragraph 1904.4(b)(1) contains a table that points employers and their recordkeepers to the various sections of the rule that determine which work-related injuries and illnesses are to be recorded. These sections lay out the requirements for determining whether an injury or illness is work-related, if it is a new case, and if it meets one or more of the general recording criteria. In addition, the table contains a row addressing the application of these and additional criteria to specific kinds of cases (needlestick and sharps injury cases, tuberculosis cases, hearing loss

cases, medical removal cases, and musculoskeletal disorder cases). The table in paragraph 1904.4(b)(1) is intended to guide employers through the recording process and to act as a table of contents to the sections of Subpart C.

Paragraph (b)(2) is a decision tree, or flowchart, that shows the steps involved in determining whether or not a particular injury or illness case must be recorded on the OSHA forms. It essentially reflects the same information as is in the table in paragraph 1904.4(b)(1), except that it presents this information graphically.

The former rule had no tables or flowcharts that served this purpose. However, the former *Recordkeeping Guidelines* (Ex. 2) contained several flowcharts to help employers make decisions and understand the overall recording process. The proposed rule included a flowchart as Appendix C to Part 1904—Decision Tree for Recording Occupational Injuries and Illnesses. OSHA received very few comments in response to proposed Appendix C, and no commenters objected to the decision tree concept. The commenters who discussed the decision tree supported it, and many suggested that it should be incorporated into the computer software OSHA develops to assist employers with keeping the records (see, *e.g.*, Exs. 51, 15: 38, 67, 335, 407, 438).

In the final rule, OSHA has decided to include the flowchart because of its usefulness in depicting the overall recording process. OSHA has not labeled the flowchart non-mandatory, as some commenters (see, *e.g.*, Ex. 15: 335) suggested, because the recording of injuries and illnesses is a mandatory requirement and labeling the flowchart as non-mandatory could be confusing.

Section 1904.5 Determination of Work-Relatedness

This section of the final rule sets out the requirements employers must follow in determining whether a given injury or illness is work-related. Paragraph 1904.5(a) states that an injury or illness must be considered work-related if an event or exposure in the work environment caused or contributed to the injury or illness or significantly aggravated a pre-existing injury or illness. It stipulates that, for OSHA recordkeeping purposes, work relationship is presumed for such injuries and illnesses unless an exception listed in paragraph 1904.5(b)(2) specifically applies.

Implementation requirements are set forth in paragraph (b) of the final rule. Paragraph (b)(1) defines ''work environment'' for recordkeeping purposes and makes clear that the work environment includes the physical locations where employees are working as well as the equipment and materials used by the employee to perform work.

Paragraph (b)(2) lists the exceptions to the presumption of work-relatedness permitted by the final rule; cases meeting the conditions of any of the listed exceptions are not considered work-related and are therefore not recordable in the OSHA recordkeeping system.

This section of the preamble first explains OSHA's reasoning on the issue of work relationship, then discusses the exceptions to the general presumption and the comments received on the exceptions proposed, and then presents OSHA's rationale for including paragraphs (b)(3) through (b)(7) of the final rule, and the record evidence pertaining to each.

Section 8(c)(2) of the OSH Act directs the Secretary to issue regulations requiring employers to record ''work-related'' injuries and illnesses. It is implicit in this wording that there must be a causal connection between the employment and the injury or illness before the case is recordable. For most types of industrial accidents involving traumatic injuries, such as amputations, fractures, burns and electrocutions, a causal connection is easily determined because the injury arises from forces, equipment, activities, or conditions inherent in the employment environment. Thus, there is general agreement that when an employee is struck by or caught in moving machinery, or is crushed in a construction cave-in, the case is work-related. It is also accepted that a variety of illnesses are associated with exposure to toxic substances, such as lead and cadmium, used in industrial processes. Accordingly, there is little question that cases of lead or cadmium poisoning are work-related if the employee is exposed to these substances at work.

On the other hand, a number of injuries and illnesses that occur, or manifest themselves, at work are caused by a combination of occupational factors, such as performing job-related bending and lifting motions, and factors personal to the employee, such as the effects of a pre-existing medical condition. In many such cases, it is likely that occupational factors have played a tangible role in causing the injury or illness, but one that cannot be readily quantified as ''significant'' or ''predominant'' in comparison with the personal factors involved.

Injuries and illnesses also occur at work that do not have a clear connection to a specific work activity, condition, or substance that is peculiar to the employment environment. For example, an employee may trip for no apparent reason while walking across a level factory floor; be sexually assaulted by a co-worker; or be injured accidentally as a result of an act of violence perpetrated by one co-worker against a third party. In these and similar cases, the employee's job-related tasks or exposures did not create or contribute to the risk that such an injury would occur. Instead, a causal connection is established by the fact that the injury would not have occurred but for the conditions and obligations of employment that placed the employee in the position in which he or she was injured or made ill.

The theory of causation OSHA should require employers to use in determining the work-relationship of injuries and illnesses was perhaps the most important issue raised in this rulemaking. Put simply, the issue is essentially whether OSHA should view cases as being work-related under a ''geographic'' or ''positional'' theory of causation, or should adopt a more restrictive test requiring that the occupational cause be quantified as ''predominant,'' or ''significant,'' or that the injury or illness result from activities uniquely occupational in nature. This issue generated substantial comment during this rulemaking, and the Agency's evaluation of the various alternative tests, and its decision to continue its historic test, are discussed below.

The final rule's test for work-relationship and its similarity to the former and proposed rules.—The final rule requires that employers consider an injury or illness to be ''work-related'' if an event or exposure in the work environment either caused or contributed to the resulting condition or significantly aggravated a pre-existing injury or illness. Work relatedness is presumed for injuries and illnesses resulting from events or exposures occurring in the work environment, unless an exception in § 1904.5(b)(2) specifically applies.

Under paragraph 1904.5(b)(1), the ''work environment'' means ''the establishment and other locations where one or more employees are working or are present as a condition of their employment. The work environment includes not only physical locations, but also equipment or materials used by the employee during the course of his or her work.''

The final rule's definition of work-relationship is essentially the same as that in both the former and proposed rules except for the final rule's requirement that the work event or exposure ''significantly'' aggravate a

pre-existing injury or illness. The *Guidelines* interpreting the former rule stated that

> Work-relationship is established under the OSHA recordkeeping system when the injury or illness results from an event or exposure in the work environment. The work environment is primarily composed of: (1) The employer's premises, and (2) other locations where employees are engaged in work-related activities or are present as a condition of their employment. (Ex. 2 at p. 32).

The proposed rule also contained a similar definition of ''work-related'' and ''work environment.'' The only significant difference between the proposed and the final rule definitions is that the proposed rule also would not have required a ''significant'' aggravation of a pre-existing condition before it became recordable; under the proposal, any aggravation would have been sufficient (see 61 FR 4059).

The Alternative Tests for Work-Relationship

Although OSHA proposed to continue its existing definition of work-relationship, it sought comment on the following three alternative tests:

1. Exclude cases with any evidence of non-work etiology. Only cases where the work event or exposure was the *sole* causative factor would be recorded;
2. Record only cases where work was the *predominant* causative factor;
3. Record all cases where the work event or exposure had *any possibility* of contributing to the case (emphasis added). (61 FR 4045)

Comments on the ''Quantified Occupational Cause'' Test

The first two alternative tests described in the proposal would have required the employer to quantify the contribution of occupational factors as compared to that of personal factors. These tests are referred to in the Legal Authority section, and in this preamble, as the ''quantified occupational cause'' tests. Of these tests, Alternative 2—record only injuries and illnesses predominantly caused by occupational factors—received the most comment. Typical of these comments were those of the Dow Chemical Company, which expressed the view of many in industry that ''[a] system that labels an injury or illness attributable to the workplace even though the workplace contribution may be insignificant does not lead to an effective, credible or accurate program'' (Ex. 15: 335). Other commenters stated that recording only those cases where work was the predominant cause would improve the system by focusing attention on cases that are amenable to employer abatement (see, *e.g.*, Exs. 22, 15: 13, 27, 34, 38, 52, 60, 69, 71, 72, 82, 97, 102, 108, 109, 122, 136, 137, 141, 146, 147, 149, 152, 154, 159, 163, 169, 171, 174, 176, 181, 197, 198, 199, 200, 201, 214, 218, 224, 230, 231, 238, 239, 260, 262, 265, 266, 272, 273, 277, 278, 287, 288, 290, 297, 301, 302, 303, 307, 313, 317, 318, 330, 335, 346, 352, 353, 370, 375, 382, 378, 383, 384, 386, 388, 396, 401, 402, 404, 405, 425, 426, 430).

Some commenters (see, *e.g.*, Exs. 15: 185, 199, 205, 332, 338, 349, 354, 358, 375, 421, 440) offered a slight modification on Alternative 2. They suggested that using a term other than predominant, such as ''substantial'' or ''significant,'' would avoid the need to define ''predominant'' as a percentage. For example, United Technologies (Ex. 15: 440) opposed ''placing a percentage on the degree of contribution'' because doing so would not be practical. Further, according to this commenter, ''work relationship should be established in cases where the workplace contributed substantially to the injury or illness, as determined by an occupational physician.'' Arguing along the same lines, the American Petroleum Institute (API) (Ex. 15: 375) stated that it supported ''in principle the work-relatedness concept presented by OSHA as Alternative 2, but feels ''predominant'' might be too difficult to administer as a fundamental criterion. API proposes that work-relatedness should exist when an event or exposure in the workplace is a significant factor resulting in an injury or illness. * * *'' Organization Resource Counselors, Inc. (Ex. 15: 358) added: ''[T]he Congressional intent in drafting these sections was to require the collection of work-related information about significant work-related injuries and illnesses.'' The General Electric Company (Ex. 15: 349) said that ''OSHA needs to allow the facility the flexibility to record only those cases that are ''more likely than not'' related to workplace exposure or tasks. This determination can be made during the incident investigation. A good test of work-relatedness is whether the injury would have been prevented by full compliance with the applicable OSHA standard.''

Proposed Alternative 1, which would have required the recording only of cases where work was the sole cause, was also supported by a large number of commenters (see, *e.g.*, Exs. 15: 9, 39, 87, 95, 119, 123, 145, 151, 152, 179, 180, 183, 185, 204, 205, 225, 229, 234, 242, 259, 263, 269, 270, 304, 341, 363, 377, 389, 393, 414, 433, 443). Typical of this view was the comment of the American Health Care Association (Ex. 15: 341):

> If OSHA's primary concern is to address those workplace hazards or risks that cause or may cause employee injury/illness then the agency should confine recordability to those injuries and illnesses that are directly caused by a workplace event or exposure. This approach, in turn, will focus the employer's attention on those unsafe workplace conditions that need to be corrected to protect all workers exposed to or at risk from the unsafe conditions.

The National Federation of Independent Business (Ex. 15: 304) supported Alternative 1 ''because under such a system evidence of non-work-related factors is excluded thus the decision-making process is dramatically simplified and the tally is very credible.'' The Painting and Decorator Contractors of America (Ex. 15: 433) added: ''[T]his approach is also consistent with OSHA's intent (and the Congressional mandate in the Paperwork Reduction Act of 1995) to reduce compliance burdens as this would be the simplest method for employers to apply.''

Comments on the ''Unique Occupational Activities'' Test

Some commenters favored a closely related test for work relationship that would place primary emphasis on the nature of the activity that the employee was engaged in when injured or made ill. This test is referred to the Legal Authority section and in this preamble section as the ''unique occupational activities'' test. Its supporters argued that whether an injury or illness occurs or manifests itself at work is less important than whether or not the harm has been caused by activities or processes peculiar to the workplace. The AISI argued that:

> [I]t is clear that Congress intended OSHA's authority to regulate to be limited to ''occupational hazards'' and conceived of such hazards as ''processes and materials'' peculiar to the workplace. * * * Congress did not give OSHA the authority to regulate hazards if they ''grow out of economic and social factors which operate primarily outside the workplace. The employer neither controls nor creates these factors as he controls or creates work processes and materials.'' Congress was concerned with dangerous conditions peculiar to the workplace; it did not have in mind the recording of illnesses simply because they appear at work (internal citations omitted) (Ex. 15: 395).

Dow Chemical made a similar point in arguing that the criteria for determining work-relationship should include whether the activity the employee was engaged in at the time of the injury or onset of illness was for the direct benefit of the employer or was a required part of the job (Ex. 15: 335B).

According to Dow, the activity-based test would be more accurate than the geographic presumption (OSHA's historic test) because it would omit injuries due to hazards beyond the employer's control:

> Examples to illustrate this point include the employee who during his break attempts to remove a plastic insert in a condiment container with a knife and ends up cutting himself which requires three stitches. This activity, while it happened on company grounds, was not for the direct benefit of the company nor a requirement of his job, and there was no way for the employer to prevent it (Ex. 15: 335B).

Comments on OSHA's Historical Test

A significant number of commenters supported OSHA's long-standing test in which work factors must be a cause, but not necessarily a ''significant'' or ''predominant'' cause, and a geographic presumption applies if ''events or exposures'' in the work environment either caused or contributed to the resulting condition, or aggravated a pre-existing condition (see, *e.g.*, Exs. 15: 74, 153, 362, 369, 394, 407, 418, 429). For example, NIOSH (Ex. 15: 407) favored this approach because ''[o]verreported cases can be identified and accounted for in data analysis, in contrast to the other alternatives which stress specificity at the expense of sensitivity and would result in unreported cases.'' The AFL–CIO argued that:

> * * * [c]apturing all workplace illnesses and injuries, even those for which the predominant cause cannot be proven to be work-related, can lead to early recognition of problems and abatement of hazardous conditions. Our experience has shown us that when comprehensive records of all possible cases are kept, patterns of injury and illness emerge, enabling us to target problem areas/factors that previously may not have been associated with that specific work environment. The inclusion of all cases will lead to prevention strategies that can reduce the risk of serious illness and injury to workers. Inclusion of all cases that have a workplace link will also assist in the recognition of diseases that are caused by synergistic effects. (Ex. 15: 418)

The American Industrial Hygiene Association (AIHA) argued that continuing OSHA's historic approach to work-relationship is particularly important in the case of occupational illnesses because:

> Occupational illnesses differ from injuries in that minor or early symptoms of illness are often an important indicator of a more serious disease state, while a minor injury usually goes away without further developments. By the time serious disabling symptoms have surfaced. a disease may be very far progressed and irreversible. Training courses such as Hazard Communication are geared toward educating the workforce to recognize and report symptoms of overexposure, presumably for disease prevention. AIHA does not want this information to be de-emphasized or lost (Ex. 15: 153).

Comments on the ''Mere Possibility'' Test

Alternative 3 described in the proposal would have required that an injury or illness be considered work related ''if the worker ever experienced a workplace event or exposure that had any possibility of playing a role in the case.'' This ''mere possibility'' test is substantially different than OSHA's historical definition of work-relationship, which required that the injury or illness have a tangible connection with the work environment. Although some commenters supported Alternative 3, apparently on the assumption that it was in fact OSHA's proposed definition, analysis of these comments suggests that the parties involved recognized that an injury must have a real, not merely theoretical, link to work to be work-related. No commenter suggested a rationale for recording cases having only a theoretical or speculative link to work.

OSHA's Reasons for Rejecting the Alternative Tests for Work-Relationship

OSHA has given careful consideration to all of the comments and testimony received in this rulemaking and has decided to continue to rely in the final rule on the Agency's longstanding definition of work-relationship, with one modification. That modification is the addition of the word ''significantly'' before ''aggravation'' in the definition of work-relatedness set forth in final rule section 1904.5. The relevant portion of the section now states ''an injury or illness is to be considered work-related if an event or exposure in the work environment either caused or contributed to the injury or illness or *significantly* aggravated a pre-existing injury or illness'' (emphasis added).

In the final rule, OSHA has restated the presumption of work-relationship to clarify that it includes any non-minor injury or illness occurring as a result of an event or exposure in the work environment, unless an exception in paragraph 1904.5(b)(2) specifically applies. OSHA believes that the final rule's approach of relying on the geographic presumption, with a limited number of exceptions, is more appropriate than the alternative approaches, for the following reasons.

The Geographic Presumption Is Supported by the Statute

One important distinction between the geographic test for causation and the alternative causation tests is that the geographic test treats a case as work-related if it results in whole or in part from an event or exposure occurring in the work environment, while the alternative tests would only cover cases in which the employer can determine the degree to which work factors played a causal role. Reliance on the geographic presumption thus covers cases in which an event in the work environment is believed likely to be a causal factor in an injury or illness but the effect of work cannot be quantified. It also covers cases in which the injury or illness is not caused by uniquely occupational activities or processes. These cases may arise, for example, when: (a) an accident at work results in an injury, but the cause of the accident cannot be determined; (b) an injury or illness results from an event that occurs at work but is not caused by an activity peculiar to work, such as a random assault or an instance of horseplay; (c) an injury or illness results from a number of factors, including both occupational and personal causes, and the relative contribution of the occupational factor cannot be readily measured; or (d) a pre-existing injury or illness is significantly aggravated by an event or exposure at work.

As discussed in the Legal Authority section, the statute's language and the Legislative History support a definition of work-relationship that encompasses all injuries and illnesses resulting from harmful events and exposures in the work environment, not only those caused by uniquely occupational activities or processes. A number of commenters acknowledged the broad purposes served by OSHA's recordkeeping requirements and urged continued reliance on the former rule's definition of ''work-related'' (see, *e.g.*, Exs. 15: 65, 198, 350, 369, 418). For example, the AFL–CIO noted, ''[o]ur experience has shown us that when comprehensive records of all possible cases are kept, patterns of injury and illness emerge, enabling us to target problem areas/factors that previously may not have been associated with that specific work environment'' (Ex. 15: 418) (emphasis added).

On the other hand, those commenters favoring the ''quantified occupational cause'' test or the ''unique occupational activity'' test maintained that injury and illness records have more limited functions. Some commenters argued that because OSHA's mission is to

eliminate preventable occupational injuries and illnesses, the determination of work-relationship must turn on whether the case could have been prevented by the employer's safety and health program. The Dow Chemical Company expressed this view as follows:

> [T]he goal of this recordkeeping system should be to accurately measure the effectiveness of safety and health programs in the workplace. Activities where safety and health programs could have no impact on preventing or mitigating the condition should not be logged and included in the Log and Summary nor used by OSHA to determine its inspection schedule. If the event was caused by something beyond the employer's control it should not be considered a recordable event that calls into question a facility's safety and health program.
>
> . . . Credibility in this regulation rests on whether the recorded data accurately reflects the safety and health of the workplace. Including events where the workplace had virtually no involvement undermines the credibility of the system and results in continued resistance to this regulation (Ex. 15: 335B).

The law firm of Constangy, Brooks and Smith, LLC, urged OSHA to adopt the proposal's second alternative (''predominant cause'') because cases that are ''predominantly caused by workplace conditions'' are the ones most likely to be preventable by workplace controls. Their comment stated, ''[s]ince OSHA's ultimate mission is the prevention of workplace injuries and illnesses, it is reasonably necessary to require recording only when the injury or illness can be prevented by the employer'' (Ex. 15–345). Other commenters opposed the recording of cases in which the injury or illness arises while the employee is on break, in the rest room, or in storage areas located on the employer's premises. These commenters claimed that use of the geographic presumption results in recording many injuries and illnesses that have little or no relationship to the work environment (see, *e.g.*, Exs. 15: 231, 423, 424G).

OSHA believes that the views of Dow Chemical and others in support of the proposal's alternative tests for work-relationship reflect too narrow a reading of the purposes served by the OSHA injury and illness records. Certainly, one important purpose for recordkeeping requirements is to enable employers, employees, and OSHA to identify hazards that can be prevented by compliance with existing standards or recognized safety practices. However, the records serve other purposes as well, including providing information for future scientific research on the nature of causal connections between the work environment and the injuries and illnesses sustained by employees. For example, the records kept by employers under Part 1904 produced useful data on workplace assaults and murders, which has permitted OSHA, employers, and others to focus on the issue of violence in the workplace. This has led, in turn, to efforts to reduce the number of such cases by implementing preventive measures. Although this issue was not anticipated by the 1904 system, the broad collection of injury, illness and fatality data allowed useful information to be extracted from the 1904 data. As discussed in the Legal Authority section, these purposes militate in favor of a general presumption of work-relationship for injuries and illnesses that result from events or exposures occurring in the work environment, with exceptions for specific types of cases that may safely be excluded without significantly impairing the usefulness of the national job-related injury and illness database.

At the same time, OSHA is sensitive to the concerns of some commenters that the injury and illness records are perceived as a measure of the effectiveness of the employer's compliance with the Act and OSHA standards. OSHA emphasizes that the recording of an injury or illness on the Log does not mean that a violation has occurred. The explanatory materials accompanying the revised OSHA Forms 300 and 301 contain the following statement emphasizing this point: ''Cases listed on the Log of Work-Related Injuries and Illnesses are not necessarily eligible for Workers Compensation or other insurance benefits. Listing a case on the Log does not mean that the employer or worker was at fault or that an OSHA standard was violated.''

The Alternative Tests for Work-Relationship Will Likely Lead Both to Inconsistent Determinations and to Underreporting of Cases

Under the first two alternative tests for work-relationship described in the proposal, the decision on work-relationship would depend upon the degree to which the injury or illness resulted from distinctly occupational causes. Whether labeled ''sole cause,'' ''predominant cause,'' or ''significant cause,'' these alternative tests would require the employer, in each case, to distinguish between the occupational and non-occupational causal factors involved, and to weigh the contribution of the occupational factor or factors. Requiring the occupational cause to be quantified in this way creates practical problems militating against the use of these alternative tests in the final recordkeeping rule.

The most serious problem is that there is no reliable, objective method of measuring the degree of contribution of occupational factors. The absence of a uniform methodology for assessing the extent of work contribution caused several industry commenters to endorse the former rule's position on work-relationship. For example, the American Automobile Manufacturers Association (AAMA) noted that an ideal system would focus on cases in which the work environment was a major contributor to the injury or illness. Nevertheless, the AAMA argued against adopting the predominant cause test, stating: ''until a system is developed in which employers can measure objectively and consistently whether or not the work environment is a major contributor to a workplace injury or illness, we favor continuing the definition of work-relationship as it currently exists'' (Ex. 15: 409). The Ford Motor Co. also argued in favor of continuing the existing definition:

> Ford feels that the work environment should be a major contributor to an injury or illness for the case to be considered work-related. However, we are unsure how employers can measure objectively, consistently and equally whether the work environment is a major contributor. The use of a checklist by a health care provider to determine whether the work environment was a major contributor for a case to be considered work-related would be overly burdensome and subjective. Until a system is developed by which employers can measure objectively, consistently and equally whether or not the work environment is a major contributor to a workplace injury or illness, we favor continuing the definition of work relationship as it currently exists (Ex. 15: 347).

Based on a review of the record, OSHA agrees with those commenters who supported a continuation of the Agency's prior practice with regard to reliance on the geographic presumption for determinations of work-relatedness. OSHA finds that this approach, which includes all cases with a tangible connection with work, better serves the purposes of recordkeeping. Accordingly, the final rule relies on the geographic presumption, with a few limited exceptions, as the recordkeeping system's test for work-relationship.

Who Makes the Determination?

In addition to the definition of work-relatedness, commenters addressed the issue of who should make the determination of work-relatedness in a given case (see, *e.g.*, Exs. 15: 27, 35, 102, 105, 127, 193, 221, 281, 305, 308, 324, 325, 341, 345, 347, 385, 387, 390, 392,

397, 420). Some commenters believed that a trained medical professional should make this determination, while others argued that the employer should make the ultimate decision about the work-relatedness of occupational injuries and illnesses. Some supported the use of the work-relatedness checklist for specific disorders included by OSHA in the proposal. For example, the American Public Health Association (Ex. 15: 341) commented:

> We also believe that work-relatedness should only be established by the documented determination of a qualified health care provider with specific training related to the type of case reported. OSHA's checklist for determining work-relatedness. . . .should be used and expanded to include potentially recordable cases, i.e., excluding first aid treatment.

The Dow Corning Corporation (Ex. 15: 374) argued that the employer should make the determination, albeit with the assistance of a health care professional:

> This assessment process should include interviews with knowledgeable people regarding the duties and hazards of the employee's job tasks in addition to the employee interview. If inaccurate or misleading information is given to the health care provider improper or inaccurate conclusions may be reached with regard to the incident cause. A health care provider's assessment of work-relationship is typically viewed as difficult to overcome, even if it is made with incomplete information. We recommend that the health care provider's checklist be used as only one input in the work-relationship decision and that the final decision should still rest with the employer.

Deere and Company (Ex. 15: 253) opposed leaving the determination of work-relatedness to a health care professional:

> We strongly disagree with any provision that would allow a physician to make a final determination of work-relatedness. The only time a physician should have any input into the actual determination of work-relatedness is if they are knowledgeable of the employer's workplace environment and the specific job tasks performed by employees. Frequently, physicians will state that a condition was caused by an employee's job without having any knowledge of the specific tasks being performed by the employee. This is an unacceptable usurpation of employers' rights and we oppose any attempt to codify it in a federal regulation.

However, several participants opposed making any work-relatedness checklist mandatory (such as the one OSHA proposed) (see, *e.g.*, Exs. 15: 68, 170, 201, 283, 434). The American Trucking Association's comment (Ex. 15: 397) was typical of this view:

> We do not, however, support a requirement that employers must use a mandatory checklist to determine work-relatedness. . . . Because the checklist asks for medical information, the employer would find itself in conflict with the confidentiality requirements imposed under the Americans With Disabilities Act. 29 C.F.R. § 1630.14. Moreover, a mandatory checklist would be unnecessarily time-consuming and subjective. Finally, we note that inclusion of item 5(b), ''possible work contribution,'' biases the checklist in favor of work-relatedness. In the absence of a clear indication of whether or not the workplace caused or substantially caused the condition, asking a provider or employee if it were ''possible'' that the workplace contributed to or aggravated the injury/illness invites an affirmative response.

OSHA has concluded that requiring employers to rely on a health care professional for the determination of the work-relatedness of occupational injuries and illnesses would be burdensome, impractical, and unnecessary. Small employers, in particular, would be burdened by such a provision. Further, if the professional is not familiar with the injured worker's job duties and work environment, he or she will not have sufficient information to make a decision about the work-relatedness of the case. OSHA also does not agree that health care professional involvement is necessary in the overwhelming majority of cases. Employers have been making work-relatedness determinations for more than 20 years and have performed this responsibility well in that time. This does not mean that employers may not, if they choose, seek the advice of a physician or other licensed health care professional to help them understand the link between workplace factors and injuries and illnesses in particular cases; it simply means that OSHA does not believe that most employers will need to avail themselves of the services of such a professional in most cases.

Accordingly, OSHA has concluded that the determination of work-relatedness is best made by the employer, as it has been in the past. Employers are in the best position to obtain the information, both from the employee and the workplace, that is necessary to make this determination. Although expert advice may occasionally be sought by employers in particularly complex cases, the final rule provides that the determination of work-relatedness ultimately rests with the employer.

The Final Rule's Exceptions to the Geographic Presumption

Paragraph 1904.5(b)(2) of the final rule contains eight exceptions to the work environment presumption that are intended to exclude from the recordkeeping system those injuries and illnesses that occur or manifest in the work environment, but have been identified by OSHA, based on its years of experience with recordkeeping, as cases that do not provide information useful to the identification of occupational injuries and illnesses and would thus tend to skew national injury and illness statistics. These eight exceptions are the only exceptions to the presumption permitted by the final rule.

(i) *Injuries or illnesses will not be considered work-related if, at the time of the injury or illness, the employee was present in the work environment as a member of the general public rather than as an employee.* This exception, which is codified at paragraph 1904.5(b)(2)(i), is based on the fact that no employment relationship is in place at the time an injury or illness of this type occurs. A case exemplifying this exception would occur if an employee of a retail store patronized that store as a customer on a non-work day and was injured in a fall. This exception allows the employer not to record cases that occur outside of the employment relationship when his or her establishment is also a public place and a worker happens to be using the facility as a member of the general public. In these situations, the injury or illness has nothing to do with the employee's work or the employee's status as an employee, and it would therefore be inappropriate for the recordkeeping system to capture the case. This exception was included in the proposal, and OSHA received no comments opposing its adoption.

(ii) *Injuries or illnesses will not be considered work-related if they involve symptoms that surface at work but result solely from a non-work-related event or exposure that occurs outside the work environment.* OSHA's recordkeeping system is intended only to capture cases that are caused by conditions or exposures arising in the work environment. It is not designed to capture cases that have no relationship with the work environment. For this exception to apply, the work environment cannot have caused, contributed to, or significantly aggravated the injury or illness. This exception is consistent with the position followed by OSHA for many years and reiterated in the final rule: that any job-related contribution to the injury or illness makes the incident work-related, and its corollary—that any injury or illness to which work makes no actual contribution is not work-related. An example of this type of injury would be a diabetic incident that occurs while an employee is working. Because no event or exposure at work contributed in any

way to the diabetic incident, the case is not recordable. This exception allows the employer to exclude cases where an employee's non-work activities are the sole cause of the injury or illness. The exception was included in the proposal, and OSHA received no comments opposing its adoption.

(iii) *Injuries and illnesses will not be considered work-related if they result solely from voluntary participation in a wellness program or in a medical, fitness, or recreational activity such as blood donation, physical, flu shot, exercise classes, racquetball, or baseball.* This exception allows the employer to exclude certain injury or illness cases that are related to personal medical care, physical fitness activities and voluntary blood donations. The key words here are ''solely'' and ''voluntary.'' The work environment cannot have contributed to the injury or illness in any way for this exception to apply, and participation in the wellness, fitness or recreational activities must be voluntary and not a condition of employment.

This exception allows the employer to exclude cases that are related to personal matters of exercise, recreation, medical examinations or participation in blood donation programs when they are voluntary and are not being undertaken as a condition of work. For example, if a clerical worker was injured while performing aerobics in the company gymnasium during his or her lunch hour, the case would not be work-related. On the other hand, if an employee who was assigned to manage the gymnasium was injured while teaching an aerobics class, the injury would be work-related because the employee was working at the time of the injury and the activity was not voluntary. Similarly, if an employee suffered a severe reaction to a flu shot that was administered as part of a voluntary inoculation program, the case would not be considered work-related; however, if an employee suffered a reaction to medications administered to enable the employee to travel overseas on business, or the employee had an illness reaction to a medication administered to treat a work-related injury, the case would be considered work-related.

This exception was included in the proposal, and received support from a number of commenters (see, *e.g.*, Exs. 15: 147, 181, 188, 226, 281, 304, 341, 345, 363, 348, 373). Other commenters supported this proposal but suggested consolidating it with the proposed exception for voluntary activities away from the employer's establishment (see, *e.g.*, Exs. 15–176, 231, 248, 249, 250, 273, 301). OSHA has decided not to combine this exception with another exception because questions are often asked about injuries and illnesses that arise at the employer's establishment and the Agency believes that a separate exception addressing voluntary wellness programs and other activities will provide clearer direction to employers.

(iv) *Injuries and illnesses will not be considered work-related if they are solely the result of an employee eating, drinking, or preparing food or drink for personal consumption (whether bought on the premises or brought in).* This exception responds to a situation that has given rise to many letters of interpretation and caused employer concern over the years. An example of the application of this exception would be a case where the employee injured himself or herself by choking on a sandwich brought from home but eaten in the employer's establishment; such a case would not be considered work-related under this exception. On the other hand, if the employee was injured by a trip or fall hazard present in the employer's lunchroom, the case would be considered work-related. In addition, a note to the exception makes clear that if an employee becomes ill as a result of ingesting food contaminated by workplace contaminants such as lead, or contracts food poisoning from food items provided by the employer, the case would be considered work-related. As a result, if an employee contracts food poisoning from a sandwich brought from home or purchased in the company cafeteria and must take time off to recover, the case is not considered work related. On the other hand, if an employee contracts food poisoning from a meal provided by the employer at a business meeting or company function and takes time off to recover, the case would be considered work related. Food provided or supplied by the employer does not include food purchased by the employee from the company cafeteria, but does include food purchased by the employer from the company cafeteria for business meetings or other company functions. OSHA believes that the number of cases to which this exception applies will be few. This exception was included in the proposal and received generally favorable comments (see, *e.g.*, Exs. 15: 31, 78, 105, 159, 176, 181, 184, 188, 345, 359, 428).

(v) *Injuries and illnesses will not be considered work-related if they are solely the result of employees doing personal tasks (unrelated to their employment) at the establishment outside of their assigned working hours.* This exception, which responds to inquiries received over the years, allows employers limited flexibility to exclude from the recordkeeping system situations where the employee is using the employer's establishment for purely personal reasons during his or her off-shift time. For example, if an employee were using a meeting room at the employer's establishment outside of his or her assigned working hours to hold a meeting for a civic group to which he or she belonged, and slipped and fell in the hallway, the injury would not be considered work-related. On the other hand, if the employee were at the employer's establishment outside his or her assigned working hours to attend a company business meeting or a company training session, such a slip or fall would be work-related. OSHA also expects the number of cases affected by this exception to be small. The comments on this exception are discussed in more detail in the section concerning proposed Exception B–5, Personal Tasks Unrelated To Employment Outside of Normal Working Hours, found later in this document.

(vi) *Injuries and illnesses will not be considered work-related if they are solely the result of personal grooming, self-medication for a non-work-related condition, or are intentionally self-inflicted.* This exception allows the employer to exclude from the Log cases related to personal hygiene, self-administered medications and intentional self-inflicted injuries, such as attempted suicide. For example, a burn injury from a hair dryer used at work to dry the employee's hair would not be work-related. Similarly, a negative reaction to a medication brought from home to treat a non-work condition would not be considered a work-related illness, even though it first manifested at work. OSHA also expects that few cases will be affected by this exception.

(vii) *Injuries will not be considered work-related if they are caused by motor vehicle accidents occurring in company parking lots or on company access roads while employees are commuting to or from work.* This exception allows the employer to exclude cases where an employee is injured in a motor vehicle accident while commuting from work to home or from home to work or while on a personal errand. For example, if an employee was injured in a car accident while arriving at work or while leaving the company's property at the end of the day, or while driving on his or her lunch hour to run an errand, the case would not be considered work-related. On the other hand, if an employee was injured in a car accident while leaving

the property to purchase supplies for the employer, the case would be work-related. This exception represents a change from the position taken under the former rule, which was that *no* injury or illness occurring in a company parking lot was considered work-related. As explained further below, OSHA has concluded, based on the evidence in the record, that some injuries and illnesses that occur in company parking lots are clearly caused by work conditions or activities—*e.g.*, being struck by a car while painting parking space indicators on the pavement of the lot, slipping on ice permitted to accumulate in the lot by the employer—and by their nature point to conditions that could be corrected to improve workplace safety and health.

(viii) *Common colds and flu will not be considered work-related.*

Paragraph 1904.5(b)(2)(viii) allows the employer to exclude cases of common cold or flu, even if contracted while the employee was at work. However, in the case of other infectious diseases such as tuberculosis, brucellosis, and hepatitis C, employers must evaluate reports of such illnesses for work relationship, just as they would any other type of injury or illness.

(ix) *Mental illness will not be considered work-related unless the employee voluntarily provides the employer with an opinion from a physician or other licensed health care professional with appropriate training and experience (psychiatrist, psychologist, psychiatric nurse practitioner, etc.) stating that the employee has a mental illness that is work-related.*

Exception (ix) is an outgrowth of proposed Exception B–11—Mental illness, unless associated with post-traumatic stress. There were more than 70 comments that addressed the issue of mental illness recordkeeping. Two commenters suggested that OSHA postpone any decision on the issue: the National Safety Council (Ex. 15: 359) recommended further study, and the AFL–CIO (Ex. 15: 418) stated that the problem of mental illness in the workplace was so prevalent and so important that it should be handled in a separate rulemaking devoted to this issue.

A few commenters, including NIOSH (Ex. 15: 407), the American Psychological Association (Ex. 15: 411), the AFL–CIO (Ex. 14: 418), the United Steelworkers of America (Ex. 15: 429), and the United Brotherhood of Carpenters Health and Safety Fund of North America (Ex. 15: 350) argued that recording should not be limited to post-traumatic stress as OSHA had proposed but should instead include a broader range of mental disorders. The primary arguments of this group of comments were:

- Workers are afflicted with a number of mental disorders caused or exacerbated by work, and the statistics should include those disorders just as they include physical disorders;
- If the records include only post-traumatic stress as a mental disorder, many work-related cases of mental illness will go unreported (6,000 mental illness cases are reported to the BLS and involve days away from work, but less than 10% of these are post-traumatic stress cases), and the statistics will be skewed and misinterpreted;
- Workers' compensation does not restrict compensable mental illnesses to post-traumatic stress cases;
- Employers are recording and reporting all mental disorders now and thus would not be burdened by continuing the practice.

Arguments in support of treating mental illnesses no differently from any other injury or illness were made by the American Psychological Association (Ex. 15: 411):

> The American Psychological Association strongly opposes OSHA's proposal to consider a mental illness to be work related only if it is ''associated with post-traumatic stress.'' We feel that this proposal disregards an accumulating body of research showing the relationship between mental health/illness and workplace stressors. Mental illness associated with post traumatic stress is only one form of mental illness and use of this singular definition would exclude much of the mental illness affecting our nation's workforce.
>
> Job stress is perhaps the most pervasive occupational health problem in the workplace today. There are a number of emotional and behavioral results and manifestations of job stress, including depression and anxiety. These mental disorders have usually been captured under the ''mental illness'' category but would no longer be recognized if the proposed reporting guidelines were enacted.
>
> The 1985 National Health Interview Survey (Shilling & Brackbill, 1987) indicated that approximately 11 million workers reported health-endangering levels of ''mental stress'' at work. A large and growing body of literature on occupational stress has identified certain job and organizational characteristics as having deleterious effects on the psychological and physical health of workers, including their mental health. These include high workload demands coupled with low job control, role ambiguity and conflict, lack of job security, poor relationships with coworkers and supervisors, and repetitive, narrow tasks (American Psychological Association, 1996). These include role stressors and demands in excess of control. More precise analyses reveal that specific occupations and job factors present particular risks. For example, machine-paced workers (involving limited worker control of job demands) have one of the highest levels of anxiety, depression, and irritation of 24 occupations studied (Caplan et al., 1975). Health professionals (*e.g.*, physicians, dentists, nurses, and health technologists) have higher than expected rates of suicide which is most often related to depression (Milham, 1983) and of alcohol and drug abuse (Hoiberg, 1982). Nurses and other health care workers have increased rates of hospitalizations for mental disorders (Gundersson & Colcord, 1982; Hoiberg, 1982). This information about specific risks within different occupations provides important information for possible intervention and training to improve conditions while at the same time, indicating the possibility of specific stressors that need to be addressed within the job. This type information would be lost with the proposed reporting guidelines.

Fourteen commenters opposed having to record mental illness cases of any kind (Exs. 15: 78, 133, 184, 248, 249, 250, 304, 348, 378, 395, 406, 409, 412, 424). Their primary arguments were:

- The diagnosis of mental illnesses is subjective and unreliable;
- It is often impossible, even for a health care professional, to determine objectively which mental disorders are work-related and which are not;
- Workers have a right to privacy about mental conditions that should not be violated; employers fear the risk of invasion of privacy lawsuits if they record these cases on ''public records''; because of confidentiality concerns, workers are unlikely to disclose mental illnesses, and employers will therefore be unable to obtain sufficient information to make recordability determinations;
- Mental illnesses are beyond the scope of the OSHA Act; Congress intended to include only ''recognized injuries or illnesses'';
- Recording mental disorders opens the door to abuse; workers may ''fake'' mental illnesses, and unions may encourage workers to report mental problems as a harassment tactic; and
- No useful statistics will be generated by such recording.

The American Iron and Steel Institute (AISI) (Ex.15: 395) expressed the concerns of the group of employers opposed to any recording of mental conditions:

> OSHA should eliminate its proposed recording requirements for mental illness. OSHA's proposed rule includes changes in an employee's psychological condition as an ''injury or illness,'' and [proposed] Appendix A presumes that mental illness ''associated with post-traumatic stress'' is work related. Employers, employees, and OSHA have been wrestling for 25 years with the proper recording of fairly simple injuries like back

injuries, sprains, and illnesses caused by chemical exposures. Requiring employers to record something as vague as psychological conditions will impose impossible burdens on employers (and compliance officers) and thus will create an unworkable recordkeeping scheme.

Moreover, too little is known about the etiology of most mental conditions to justify any presumption or conclusion that a condition that surfaces at work was ''caused'' by something in the work environment. It is hard to imagine a mental illness appearing at work that is not a manifestation of a preexisting condition or predisposition. Thus, the only sensible approach is to exclude all mental illnesses from recording requirements.

Many commenters from business and trade associations either agreed with OSHA's proposal or recommended an even stricter limitation on recordable mental disorders (see, *e.g.*, Exs. 33, 15: 27, 31, 38, 46, 79, 122, 127, 132, 153, 170, 176, 181, 199, 203, 226, 230, 231, 273, 277, 289, 301, 305, 307, 308, 313, 325, 332, 352, 353, 368, 384, 387, 389, 392, 410, 427, 430, 434). Points raised by these commenters included recommendations that OSHA should require:

- Recording only of those mental illnesses that arise from a single, work-related traumatic or catastrophic event, such as a workplace explosion or an armed robbery;
- Recording only of those mental illnesses that are directly and substantially caused by a workplace incident;
- Recording only of diagnosed mental illnesses resulting from a single workplace event that is recognized as having the potential to cause a significant and severe emotional response;
- Recognition only of post-traumatic stress cases or related disorders that include physical manifestations of illness and that are directly related to specific, objectively documented, catastrophic work-related events; and
- Recording only of diagnosed conditions directly attributable to a traumatic event in the workplace, involving either death or severe physical injury to the individual or a co-worker.

Several commenters suggested the use of a medical evaluation to determine diagnosis and/or work-relationship in cases of mental illness (see, *e.g.*, Exs. 15: 65, 78, 105, 127, 170, 181, 184, 226, 230). For example, the Aluminum Company of America (Ex. 15: 65) stated that:

OSHA should define mental health conditions for recordkeeping purposes as conditions diagnosed by a licensed physician or advanced health care practitioner with specialized psychiatric training (*i.e.*, psychiatric nurse practitioner). Work-relatedness of the mental health condition should be determined by a psychiatric independent medical evaluation.

A comment from the Department of Energy (Ex. 15: 163) stated that any diagnosis of mental illness should be made by at least two qualified physicians, and CONSOL Inc. (Ex. 15: 332) and Akzo Nobel (Ex. 15: 387) wanted the rule to require that any such diagnosis meet the criteria of the Diagnostic and Statistical Manual, Version IV (DSM–IV). Commenters had different opinions about the minimum qualifications necessary for a health care professional to make decisions about mental health conditions; specifically, some commenters urged OSHA to exclude ''counselors'' (Ex. 15: 226) or to include ''only psychiatrists and Ph.D. psychologists'' (Ex. 15: 184).

A number of commenters suggested excluding from the requirement to record any mental illness related to personnel actions such as termination, job transfer, demotions, or disciplinary actions (see, *e.g.*, Exs. 15: 68, 127, 136, 137, 141, 176, 184, 224, 231, 266, 273, 278, 301, 395, 424). The New York Compensation Board (Ex. 15: 68) noted that New York's workers' compensation law excludes such cases by specifying that mental injuries are compensable with the exception of injuries that are the ''direct consequence of a lawful personnel decision involving a disciplinary action, work evaluation, job transfer, demotion, or termination taken in good faith by the employer.''

Finally, several employers raised the issues of the privacy of an employee with a mental disorder, the need to protect doctor-patient confidentiality, and the potential legal repercussions of employers breaching confidentiality in an effort to obtain injury and illness information and in recording that information (see, *e.g.*, Exs. 15: 78, 153, 170, 195, 260, 262, 265, 277, 348, 392, 401, 406, 409). Some of these commenters suggested that an employer should only have the obligation to record after the employee has brought the condition to the attention of the employer, either directly or through medical or workers' compensation claims, and in no case should doctor-patient confidentiality be breached. (Issues related to confidentiality of the Log are discussed in detail in the summary and explanation of § 1904.35, *Employee Involvement*.)

After a review of the comments and the record on this issue, OSHA has decided that the proposed exception, which would have limited the work-relatedness (and thus recordability) of mental illness cases to those involving post-traumatic stress, is not consistent with the statute or the objectives of the recordkeeping system, and is not in the best interest of employee health. The OSH Act is concerned with both physical and mental injuries and illnesses, and in fact refers to ''psychological factors'' in the statement of Congressional purpose in section 2 of the Act (29 U.S.C. 651(b)(5)).

In addition, discontinuing the recording of mental illnesses would deprive OSHA, employers and employees, and safety and health professionals of valuable information with which to assess occupational hazards and would additionally skew the statistics that have been kept for many years. Therefore, the final rule does not limit recordable mental disorders to post traumatic stress syndrome or any other specific list of mental disorders. OSHA also does not agree that recording mental illnesses will lead to abuse by employees or others. OSHA has required the recording of these illnesses since the inception of the OSH Act, and there is no evidence that such abuse has occurred.

However, OSHA agrees that recording work-related mental illnesses involves several unique issues, including the difficulty of detecting, diagnosing and verifying mental illnesses; and the sensitivity and privacy concerns raised by mental illnesses. Therefore, the final rule requires employers to record only those mental illnesses verified by a health care professional with appropriate training and experience in the treatment of mental illness, such as a psychiatrist, psychologist, or psychiatric nurse practitioner. The employer is under no obligation to seek out information on mental illnesses from its employees, and employers are required to consider mental illness cases only when an employee voluntarily presents the employer with an opinion from the health care professional that the employee has a mental illness and that it is work related. In the event that the employer does not believe the reported mental illness is work-related, the employer may refer the case to a physician or other licensed health care professional for a second opinion.

OSHA also emphasizes that work-related mental illnesses, like other illnesses, must be recorded only when they meet the severity criteria outlined in § 1904.7. In addition, for mental illnesses, the employee's identity must be protected by omitting the employee's name from the OSHA 300 Log and instead entering ''privacy concern case'' as required by § 1904.29.

Exceptions Proposed but Not Adopted

The proposed rule contained eleven exceptions to the geographic presumption. Some of these exceptions are included in the final rule, and therefore are discussed above, while others were rejected for various reasons. The following discussion addresses those proposed exemptions not adopted in the final rule, or not adopted in their entirety.

Proposed Exception B–5. Personal Tasks Unrelated To Employment Outside of Normal Working Hours. The proposed rule included an exception for injuries and illnesses caused solely by employees performing personal tasks at the establishment outside of their normal working hours. Some aspects of this proposed exception have been adopted in the final, but others have not. Almost all the comments on this proposed exception supported it (see, *e.g.*, Exs. 15: 31, 78, 105, 121, 159, 281, 297, 336, 341, 350), and many suggested that the exception be expanded to include personal tasks conducted *during* work hours (see, *e.g.*, Exs. 15: 176, 184, 201, 231, 248, 249, 250, 273, 301, 335, 348, 374). Caterpillar, Inc. (Ex. 15: 201) offered an opinion representative of the views of these commenters: ''We agree with this exception but it should be expanded to include any personal tasks performed during work hours if the work environment did not cause the injury or illness. Expanding this exemption will be consistent with the exemptions for voluntary wellness program participation and eating, drinking, and preparing one's own food.''

One commenter disagreed with the proposed exception (the Laborers Safety and Health Fund of North America (Ex. 15: 310)) and cited as a reason the difficulty of determining the extent to which, for example, a case involving an employee misusing a hazardous chemical after hours because he or she did not receive the necessary Right-to-Know training from the employer would qualify for this exception.

Several commenters suggested that OSHA clarify what it meant by the terms ''personal tasks'' and ''normal working hours'' (see, *e.g.*, Exs. 15: 102, 304, 345). For example, a representative of Constangy, Brooks & Smith recommended that:

> More explanation be provided regarding the further limitation on this exclusion. For example, does this section of the proposal envision the exclusion of injuries and illnesses resulting from personal tasks performed during overtime (i.e., outside of normal working hours)? If I am injured while talking to my spouse on the phone during regular business hours, must the case be recorded, while if the same injury occurs during overtime, the case is non-recordable? Also, how are injuries to salaried employees (who are exempt from overtime) treated under this aspect of the proposal? I submit that if these issues are not fully ''fleshed out'' in the proposal or its preamble, this subparagraph will result in the creation of more questions than it resolves.

The National Federation of Independent Business (NFIB) (Ex. 15: 304) asked OSHA ''to specify that the 'normal working hours' refers to the work schedule of the employee not the employer. If this distinction is not made clear, this proposal arguably could deny this exemption to establishments which operate during non-standard operating hours (*e.g.*, 24 hours a day, weekends, after 5 PM, etc.)—and we assume this is not OSHA's intent.''

OSHA believes that injuries and illnesses sustained by employees engaged in purely personal tasks at the workplace, outside of their assigned working hours, are not relevant for statistical purposes and that information about such injuries and illnesses would not be useful for research or other purposes underlying the recordkeeping requirements. OSHA has therefore decided to include some parts of the proposed exception in the final rule. Additional language has been added to the exception since the proposal to clarify that the exception also applies when the employee is on the premises outside of his or her assigned working hours, as the NFIB pointed out.

OSHA does not agree, however, with those commenters who suggested that the exception be expanded to include personal tasks performed by employees during work hours. As discussed in preceding sections of this summary and explanation and in the Legal Authority discussion, there are strong legal and policy reasons for treating an injury or illness as work-related if an event or exposure in the work environment caused or contributed to the condition or significantly aggravated a pre-existing condition. Under this ''but-for'' approach, the nature of the activity the employee was engaged in at the time of the incident is not relevant, except in certain limited circumstances. Moreover, OSHA believes that it would be difficult in many cases for employers to distinguish between work activities and personal activities that occur while the employee is on-shift. Accordingly, the final rule codifies parts of this proposed exception in paragraph 1904.5(b)(v) in the following form: ''The injury or illness is solely the result of an employee doing personal tasks (unrelated to their employment) at the establishment outside of the employee's assigned working hours.''

Proposed Exception B–6. Cases Resulting From Acts of Violence by Family Members or Ex-spouses When Unrelated to Employment, Including Self-inflicted Injuries. The final rule does not exempt workplace violence cases from the Log, although it does allow employers to exclude cases that involve intentionally self-inflicted injuries. The final rule thus departs substantially from the proposal in this respect. The proposed exception, which would have exempted domestic violence and self-inflicted cases from the Log, drew many comments. The comments generally fell into four categories: (1) those urging OSHA to require the recording of all cases of violence occurring at the establishment; (2) those recommending that no violence cases at the establishment be recorded; (3) those recommending recordation only of violence cases perpetrated by certain classes of individuals; and (4) those urging OSHA to require the recording of cases involving violence related to employment without regard to the perpetrator. The comments on the proposed exception are discussed below.

No exemption/record all injuries and illnesses arising from violent acts. A number of commenters objected to OSHA's proposed exemption of domestic violence cases from the list of recordable injuries, arguing that all acts of violence occurring at the workplace should be recorded (see, *e.g.*, Exs. 15: 31, 54, 56, 88, 90, 91, 93, 94, 99, 101, 103, 104, 106, 111, 114, 115, 144, 186, 187, 238, 345, 362, 407, 418, 439). For example, the North Carolina Department of Labor stated that ''if an employer must log the injuries sustained as a result of workplace violence then the employer may also institute needed security measures to protect the employees at the establishment. An employer should be required to log any 'preventable' injury (above first aid) that an employee sustains at the establishment'' (Ex. 15: 186). The Miller Brewing Company also supported recording all acts of workplace violence, based on the following rationale: ''I envision a scenario involving an angry husband attempting to kill his wife but, because he is a ''bad shot,'' another employee is killed. Why should killing an innocent bystander be a reportable event, whereas a fatality involving a spouse is excluded?'' (Ex. 15: 442).

Exception for all violent acts. There were commenters who thought injuries and illnesses resulting from violence were outside of OSHA's purview and

should not be recorded at all (see, *e.g.*, Exs. 15: 28, 75, 96, 107, 203, 254, 289). For example, the Quaker Oats Company (Ex. 15: 289) stated that ''[w]orkplace violence in any form is a personal criminal act, and in no way, shape or form should violence be labeled under hazards in the workplace or even [be] monitored by OSHA. A person who may turn to violent behavior from family, personal, or job dispute is a matter of NLRB [National Labor Relations Board], law enforcement or state employment statutes, not industrial safety.'' The National Restaurant Association (Ex. 15: 96) agreed:

> Congress passed the Occupational Safety and Health Act to regulate workplace hazards dealing with the workplace environment or processes that employers could identify and possibly protect. The Congress did not contemplate that this statute would be used to redress incidents over which the employer has no ability to control, such as the unpredictability of workers or nonworkers committing violent, tortuous acts towards others. This issue was litigated unsuccessfully by OSHA in Secretary of Labor v. Megawest Financial, Inc., OSHRC Doc. No. 93–2879 (June 19, 1995). OSHA apparently is attempting in this NPR to obtain by regulatory fiat what was rejected by case law and to displace state tort law actions by using the OSH Act to police social behavior.

Recording work-related violence except acts of certain classes of individuals. There were many commenters who supported the proposed exception, which would only have excluded acts of violence on employees committed by family members and ex-spouses and self-inflicted injuries and illnesses. The proposed exception as drafted was supported by some commenters (see, *e.g.*, Exs. 15: 78, 198, 350, 359). Others thought the exception should be expanded to include not only family members and ex-spouses, but also live-in partners, friends, and other intimates (see, *e.g.*, Exs. 15: 80, 122, 153, 181, 213, 325, 363, 401), while others argued that the exemption should apply to the general public, i.e., to all people (see, *e.g.*, Exs. 15: 9, 111, 119, 151, 152, 179, 180, 239, 260, 262, 265, 272, 303, 304, 341, 356, 375, 401, 430).

Typical of comments in support of a broader exception were the remarks of the National Oilseed Processors Association (Ex. 15: 119):

> The only time violence in the work place should be considered work-related is when it is associated with a work issue and committed by an employee or other person linked to the business, *e.g.*, a customer. Any other act of violence is not under the control of the employer and should not be considered work-related.

Alabama Shipyard Inc. (Ex. 15: 152) added:

> Exempting acts of violence based strictly on acts committed by family members, a spouse, or when self-inflicted is too limited. Instead, the exemption should be based on the relationship of the perpetrator to the employer. The employer should be no more responsible for some random act of violence by a crazy individual walking in off the street who is in no way associated with the employer than it should be for an act of violence by a family member.

Southern California Edison (Ex. 15: 111) stated that ''violence is another example that should be excluded from being work-related if the employee personally knows the attacker. This would include family members or coworkers. Only those acts of violence that result from random criminal activity should be included (i.e., robbery, murder, etc.).'' TU Services (Ex. 15: 262) recommended ''that only cases that involve acts of violence that are the result of random criminal activity should be recorded. Cases that involve anyone with a personal relationship with the employee should be excluded.'' The American Feed Industry Association (Ex. 15: 204) and United Parcel Service (Ex. 15: 424), on the other hand, argued that cases involving workplace violence should only be recorded if the perpetrator was a fellow employee.

Record all violent acts directly related to employment regardless of who commits the act. Commenters favoring this approach suggested that violence by family members or others should be recorded if linked to work, but that all personal disputes should be exempt (see, *e.g.*, Exs. 15: 105, 146, 176, 184, 231, 273, 297, 301, 313, 336, 348, 352, 353, 374, 389, 392). The Workplace Health and Safety Council (Ex. 15: 313) proposed the following exception:

> Cases will not be considered work-related if they result solely from acts of violence committed by one's family, or ex-spouse, or other persons when unrelated to the worker's employment, including intentionally self-inflicted injuries. Violence by persons on the premises in connection with the employer's business (including thieves and former employees) is considered work related even if committed by one's family or ex-spouse.

The American Ambulance Association (Ex. 15: 226) stated simply: ''AAA believes that OSHA should define what is work-related violence and assume that all other acts are not work-related, and eliminate the family and non-family distinction.'' The United Auto Workers (Ex. 15: 438) agreed:

> Incidents of intentional violence should be recorded only if they arise from employment activities. Incidents between employees, or between employees and non-employees which rise from personal disputes should not be recorded. Existing data show that the number of incidents of interpersonal violence between coworkers or workers and intimates is small, although these incidents do get high visibility. Therefore, exclusion of these small number of cases will have little effect on statistical measures.

Some commenters urged OSHA to place some restrictions on the proposed exception. For example, two commenters argued that cases involving violence should only be recorded for occupations where there is a reasonable potential of encountering violence (Exs. 15: 335, 409). The American Automobile Manufacturers Association (AAMA) stated that:

> Workplace violence as a reasonable function of an employee's employment should be recorded, for example: a cashier injured in a robbery attempt at a 24-hour retail establishment. An example of ''unreasonable'' recordable workplace violence that should not be recordable (i.e., where an employee was simply ''in the wrong place at the wrong time'') would be a flight crew that perishes mid-flight from a terrorist's bomb. These cases have nothing to do with the individual's employer, only that they happened to be victims at the employer's place of employment. It is AAMA's understanding that the purpose of the subject standard is to collect information pertaining to injuries and illnesses that arise out of conditions in the workplace, with the end objective being to use that information to correct or mitigate these conditions so as to prevent additional injuries or illnesses.

Caterpillar Inc. (Ex. 15: 201) suggested that ''a predominant contributor concept, similar to that being proposed to help establish work-relatedness, could be utilized in cases where the clear cause of violence is not readily apparent.''

In the final rule, OSHA has decided not to exclude from recording those injury and illness cases involving acts of violence against employees by family members or ex-spouses that occur in the work environment or cases involving other types of violence-related injuries and illnesses. The final rule does exempt from recording those cases resulting from intentionally self-inflicted injuries and illnesses; these cases represent only a small fraction of the total number of workplace fatalities (three percent of all 1997 workplace violence fatalities) (BLS press release USDL 98–336, August 12, 1998). OSHA believes that injuries and illnesses resulting from acts of violence against employees at work are work-related under the positional theory of causation. The causal connection is usually established by the fact that the assault or other harmful event would not have

occurred had the employee not, as a condition of his or her employment, been in the position where he or she was victimized. Moreover, occupational factors are directly involved in many types of workplace violence, such as assaults engendered by disputes about working conditions or practices, or assaults on security guards or cashiers and other employees, who face a heightened risk of violence at work. Accordingly, OSHA does not accept the premise, advanced by some commenters, that workplace violence is outside the purview of the statute.

In some cases, acts of violence committed by a family member or ex-spouse at the workplace may be prevented by appropriate security measures enforced by employers. Moreover, information about workplace injuries due to assaults by family members or ex-spouses is relevant and should be included in the overall injury and illness data for statistical and research purposes. Omitting the proposed exception also obviates the need for employers to make distinctions among various degrees of personal relationships. Accordingly, the final rule does not allow employers to exclude injuries and illnesses resulting from violence occurring in the workplace from their Logs. However, some cases of violence will be excluded under § 1904.5(b)(2)(v), which exempts an injury or ilness that is solely the result of an employee doing personal tasks (unrelated to their employment) at the establishment outside of the employee's assigned working hours. For example, if an employee arrives at work early to use a company conference room for a civic club meeting, and is injured by some violent act, the case would not be considered work related.

OSHA has decided to maintain the exclusion for intentionally self-inflicted injuries that occur in the work environment in the final rule. The Agency believes that when a self-inflicted injury occurs in the work environment, the case is analogous to one in which the signs or symptoms of a pre-existing, non-occupational injury or illness happen to arise at work, and that such cases should be excluded for the same reasons. (see paragraph 1904.5(b)(2)(ii)). The final rule at paragraph 1904.5(b)(2)(vi) therefore includes that the part of exception proposed that applied to injuries and illnesses that are intentionally self-inflicted.

Proposed Exception B–7. Parking Lots and Access Roads. This proposed exception, which in effect would have narrowed the definition of ''establishment'' to exclude company parking lots, had approximately equal numbers of commenters in favor and opposed. The final rule includes some aspects of the proposed exemption. In favor of recording injuries in parking lots and on access roads were the commenters represented by Exs. 24, 15: 41, 72, 310, 362. Typical of the views of this group was that of the Association of Operating Room Nurses (AORN) (Ex. 15: 72), which noted that:

> [e]mployee parking lots should be included in defining ''work-related.'' Perioperative nurses and other surgical service providers may be required on a ''call'' basis during the night hours. Consequently they enter and leave parking lots at unusual times when traffic in the lots is minimal. These providers may be at increased risk for random violence. Absent the ''call'' requirement, the employee would not be in the parking lot at the time of the injury. Further, if the employee is paid for travel time to and/or from the facility, injuries occurring during that period should be considered ''work-related.''

The AFL-CIO (Ex. 15: 362) added that employers may be less likely to provide lighting, security and other controls that could prevent violent assaults in parking lots and access roads if injuries occurring there are not recordable.

The opposite view, in support of the proposed exception for parking lots, was expressed by several employers (see, *e.g.*, Exs. 15: 27, 45, 176, 185, 195, 231, 248, 249, 250, 273, 289, 301, 304, 341, 363). The National Wholesale Druggists Association (NWDA) (Ex. 15: 185) supported the proposed exclusion:

> [i]nevitably, activities that take place in the company parking lot or on the company access road are not only outside of the employer's dominion and control but also are most often not related in any way to the employee's work. Including injuries that occur in these locations as part of the OSHA log would lead to an inaccurate reflection of injury data as a whole. OSHA should retain this exemption. An employer has no control over an employee's commute to and from the workplace, with the exception of arrival and departure times for the work day. If OSHA requires the reporting of injuries that occur during the employee's commute, the number of injuries reported would increase dramatically.

The National Federation of Independent Business (Ex. 15: 304) stated that the proposed exception would be consistent with workers' compensation rules.

OSHA has concluded that a limited exception for cases occurring on parking lots is appropriate but that the broader exception proposed is not. The final rule thus provides an exception for motor vehicle injury cases occurring when employees are commuting to and from work. As discussed in the preamble that accompanies the definition of ''establishment'' (see Subpart G of the final rule), OSHA has decided to rely on activity-based rather than location-based exemptions in the final rule. The parking lot exception in the final rule applies to cases in which employees are injured in motor vehicle accidents commuting to and from work and running personal errands (and thus such cases are not recordable), but does not apply to cases in which an employee slips in the parking lot or is injured in a motor vehicle accident while conducting company business (and thus such cases are recordable). This exception is codified at paragraph 1904.5(b)(2)(vii) of the final rule.

Proposed Exception B–8. Never Engaged in an Activity That Could Have Placed Stress On the Affected Body Part. This proposed exception would have allowed employers not to record cases if no aspect of the worker's job placed stress on the affected body part or exposed the worker to any chemical or physical agent at work that could be associated with the observed injury or illness. This proposed exception received support from a number of employers (see, *e.g.*, Exs. 15: 176, 185, 231, 273, 301, 341, 359, 406). For example, the National Wholesale Druggists' Association stated that ''Such injuries or illnesses are obviously not caused by any work-related activities and should therefore be excluded from any reporting and recording requirements' (Ex. 15: 185).

Deleting the word ''never'' from the proposed exception was also supported by many respondents (see, *e.g.*, Exs. 15: 146, 279, 304, 335, 374, 392, 395, 430, 431, 442). Representative of the latter group is the following comment by the BF Goodrich Company (Ex. 15: 146):

> The use of the term ''never'' in this exemption requires too harsh a test for case evaluation. A back injury should not be recordable because the employee lifted a box 10 years previous to the injury. A more reasonable evaluation criteria meeting the same intent could be stated as below: The injury or illness is not work-related if it cannot be associated with the employee's duties or exposures at work.

Taking an opposing view to the proposed exception were the AFL-CIO (Ex. 15: 418), the United Steelworkers of America (Ex. 15: 429), and the United Brotherhood of Carpenters Health and Safety Fund of North America (Ex. 15: 350). The AFL-CIO stated that:

> We believe when evaluating injuries this approach could logically work in most cases, but in cases of chemical exposures and musculoskeletal disorders this logic does not hold merit. If the Agency attempts to apply this approach to the aforementioned types of cases, the employer will have to become an

epidemiologist, ergonomist or toxicologist to determine if these cases meet the recordability criteria set forth in this proposal . . . . We encourage the Agency to omit this provision from the final standard. Because of the increasing numbers of workers being medically diagnosed for multiple chemical sensitivity and the exposures some workers receive without any knowledge until years after the incident, the Agency must carefully think about the inclusion of this provision to the final standard.

Similarly, the Carpenters Fund (UBC H&SF) argued that:

[T]his [exception] would exclude those cases where symptoms arise at work, but are caused by accidents or exposures away from work. The UBC H&SF agrees with the theory of this provision, but emphasizes that the task placed on employers to determine causation by exposures away from work would in many cases be impossible. Also the apportionment of causation is not discussed in this analysis and would allow some to record cases .01 percent caused by work and others to not record cases 99 percent caused by work. For the foregoing reasons, that this requirement is unworkable, we urge it be dropped from the final rule.

Based on a review of the record on this issue, OSHA has decided not to include this proposed exception in the final rule. On reflection, the proposed language is confusing and would be difficult to apply. The underlying concept, to the extent it has merit, is better covered in the exemption paragraph 1904.5(b)(2)(ii). As discussed in preceding sections of this summary and explanation for section 1904.5, there are sound legal and policy justifications for defining work-relationship broadly to include injuries and illnesses that result from events or exposures in the work environment. The proposed exception would effectively ''swallow'' the geographic presumption theory of causation underpinning the rule by shifting the focus of enquiry in every case to the employee's specific job duties. As OSHA has noted, the geographic presumption includes some cases in which the illness or injury cannot be directly linked to the stresses imposed by job duties. For example, if an employee trips while walking on a level factory floor and breaks his arm, the injury should be recordable. The comments supporting the proposed exemption do not, in OSHA's view, provide a basis for excluding these types of cases from recording on the Log.

Proposed Exception B–9. Voluntary Community Activities Away From The Employer's Establishment. This proposed exemption drew two comments supporting it as written (Exs. 15: 78, 304), and several other participants recommended that it be expanded to exclude injuries and illnesses that arise from voluntary community activities wherever they occur (see, *e.g.*, Exs. 15: 146, 184, 272, 303, 359). Typical of these comments is one from U.S. West (Ex. 15: 184), which stated that ''[e]mphasis should be on the activity that occurred, not the location of the activity.''

The United Brotherhood of Carpenters, Health & Safety Fund of North America (Ex. 15: 350) agreed with the proposed exception, except for cases where the employee is present as a condition of employment or in the employer's interest. It commented:

[A]t the surface this exception seems to make perfect sense. However, real employment relationships and real employer-community relationships do not fit such clean characterizations. Many times employees are forced to become ''team players'' and volunteer for unpaid off-establishment activities. Many employers engage in community ''good will'' generating activities by having their employees volunteer. For the above reasons we urge that cases occurring away from the employer's establishment be considered work-related if the employee is engaged in any activity in the interest of the employer or is there as a condition of employment.

OSHA has decided not to include this proposed exception in the final rule because the final rule's overall definition of work-environment addresses this situation in a simple and straightforward way. If the employee is taking part in the activity and is either working or present as a condition of employment, he or she is in the work environment and any injury or illness that arises is presumed to be work-related and must then be evaluated for its recordability under the general recording criteria. Thus, if the employee is engaged in an activity at a location away from the establishment, any injury or illness occurring during that activity is considered work-related if the worker is present as a condition of employment (for example, the worker is assigned to represent the company at a local charity event). For those situations where the employee is engaged in volunteer work away from the establishment and is not working or present as a condition of employment, the case is not considered work-related under the general definition of work-relationship. There is thus no need for a special exception.

Proposed Exception B–10. The Case Results Solely From Normal Body Movements, not Job-Related Motions or Contribution from the Work Environment. This proposed exception generated some support (see, *e.g.*, Exs. 15: 107, 147, 173, 185, 341, 348, 373, 392) but also caused much confusion about the meaning of the phrases ''normal body movement'' and ''job-related'' (see, *e.g.*, Exs. 15: 80, 83, 89, 98, 146, 176, 225, 226, 231, 239, 273, 301, 304, 313, 352, 353, 355, 359, 406, 424). The following comment by the American Gas Association (Ex. 15: 225) is representative of those in this group:

'[N]ormal body movements' needs clarification since OSHA has not set forth any reasons for excluding it. OSHA's language states that there is an exclusion ''* * * provided that activity does not involve a job related motion and the work environment does not contribute to the injury or illness''. OSHA goes on to elaborate that illnesses or injuries should not be recorded if they are not related to an identifiable work activity. However, OSHA also states the exclusion would not apply if it involved repetitive motion or if the work environment either caused or contributed to the injury or illness. This language is ambiguous and redundant. Repetitive motion injury/illness conditions should be treated in the same way as any other condition. There should be a work-related exclusion if the work environment did not cause or contribute to the injury/illness.

LeRoy E. Euvard, Jr., Safety and Environmental Staff (Ex. 15: 80) added:

[T]he definition of work-related resulting from normal body movements is too broad. The definition excludes walking, talking, etc. 'provided the activity does not involve a job-related motion.' Does that mean that if an employee is walking to the rest room and becomes ill, the illness is not work-related, but, if he/she is walking from the rest room back to his/her work station, it is work-related? If the employee is engaged in social talk, the illness is not work-related, but, if he/she is engaged in a conversation regarding some aspect of work, the illness is work-related?

Other commenters objected to the concept of excluding cases resulting from normal body movements from the Log (Ex. 56X, pp. 51, 52; Ex. 15: 418). Walter Jones of the International Brotherhood of Teamsters used the following example:

We do take opposition to some of the exceptions. For cases that result in normal body movement, I'd like to just bring another example up. We have a member who after spending most of his morning sorting about 700 different boxes, on break in a normal, unencumbered motion, dropped his pencil and picked it up, had a back spasm and his back went out. And I know that according to the way the standard is written, or the regulation is written, that this can be attributed to work activity. But the reason we bring it up is we need to be careful in trying to be that exact because an employer will take an uninformed employee and may take liberties (Ex. 56X, pp. 51, 52).

OSHA has decided not to include a recordkeeping exception for injuries or illnesses associated with normal body movements in the final rule. The

proposed provision was intended to exclude the recording of cases that happened to occur in the work environment without any real work contribution. However, the comments on this issue have convinced OSHA that the proposed provision is unnecessary, would be unworkable, and would result in incomplete and inconsistent data. The case cited by the Teamsters is but one example of a legitimate work-related injury that could go unrecorded if OSHA were to adopt this provision in the final rule. Further, the final rule already makes clear that injuries and illnesses that result solely from non-work causes are not considered work-related and therefore are excluded from the Log, and establishes the requirements employers must follow to determine work-relationship for an injury or illness when it is unclear whether the precipitating event occurred in the workplace or elsewhere (see paragraph 1904.5(b)(3)). According to the requirements in that section, the employer must evaluate the employee's work duties and the work environment to decide whether it is more likely than not that events or exposures in the work environment either caused or contributed to the condition or significantly aggravated a pre-existing condition. If so, the case is work-related.

Additional Exemptions Suggested by Commenters but Not Adopted

In addition to commenting on the eleven proposed exceptions, interested parties suggested adding some exceptions to the final rule. This section contains a discussion of those additional exemptions suggested by commenters but not adopted in the final rule.

Acts of God: The International Dairy Foods Association (IDFA) suggested that OSHA exclude any injury or illness that was ''the result of an ''Act of God,'' such as, but not limited to, an earthquake or a tornado'' (Ex. 15: 203). OSHA has not adopted such an exception because doing so would not be in keeping with the geographic presumption underpinning this final rule, and would exclude cases that are in fact work-related. For example, if a worker was injured in a flood while at work, the case would be work-related, even though the flood could be considered an act of God. Accordingly, if workplace injuries and illnesses result from these events, they must be entered into the records (for a more detailed discussion of this point, see the Legal Authority section, above).

Phobias: The American Crystal Sugar Company (Ex. 15: 363) suggested that OSHA add an exception from recording for cases involving phobias:

> I would also like to suggest exempting an employee's loss of consciousness based on a fear-based phobia, i.e., fainting at the sight of blood. Occasionally an OSHA regulation may require blood tests, such as checking lead levels in blood. There are a few employees that will lose consciousness at the sight of a needle. These phobias are not limited to medical procedures, but may include spiders, snakes, etc. In several of our factories, the occupational health nurse will administer tetanus boosters as a service to our employees. Employees that have a phobia about injections can (and do) lose consciousness, which now makes what was intended as a service an OSHA recordable accident.

OSHA has not included an exception from recording in the final recordkeeping regulation for phobias or any other type of mental illness. The scenario described by the American Crystal Sugar Company, which involved fainting from fear of an injection offered as a service to employees, might be considered non-work-related under the exception codified at paragraph 1904.5(b)(2)(iii), Voluntary participation in a medical activity. OSHA also believes that it would be unreasonable to omit a case of loss of consciousness resulting from the administration of a blood test for lead exposure at work. These tests are necessitated by the employee's exposure to lead at work and are required by OSHA's lead standard (29 CFR 1910.1025). The other scenarios presented by these commenters, involving spiders, snakes, etc., would also be work-related under the geographic presumption.

Illegal activities and horseplay: Several commenters suggested an exception for an employee engaging in illegal activities, horseplay, or failing to follow established work rules or procedures (see, *e.g.*, Exs. 15: 49, 69, 117, 151, 152, 179, 180, 203, 368, 393). The comment of the American Network of Community Options and Resources (ANCOR) (Ex. 15: 393) is representative of those on this issue:

> Employees who fail to follow employer training and best practices or violate established policy present a threat not only to other employees and consumers/customers, but also to employers held responsible for the consequences of their actions. For example, ANCOR does not believe that employers should have to use these recording and reporting procedures when illnesses and injuries are a result of an employee engaged in illegal activities or fails/violates established procedures.

OSHA has not adopted any of these recommended exceptions in the final recordkeeping rule because excluding these injuries and illnesses would be inconsistent with OSHA's longstanding reliance on the geographic presumption to establish work-relatedness. Furthermore, the Agency believes that many of the working conditions pointed to in these comments involve occupational factors, such the effectiveness of disciplinary policies and supervision. Thus, recording such incidents may serve to alert both the employer and employees to workplace safety and health issues.

Non-occupational degenerative conditions: Two commenters also asked OSHA to include in the final rule a recording exception for non-occupational degenerative conditions (Exs. 15: 176, 248) such as high blood pressure, arthritis, coronary artery disease, heart attacks, and cancer that can develop regardless of workplace exposure. OSHA has not added such an exception to the rule, but the Agency believes that the fact that the rule expects employers confronted with such cases to make a determination about the extent to which, if at all, work contributed to the observed condition will provide direction about how to determine the work-relatedness of such cases. For example, if work contributes to the illness in some way, then it is work-related and must be evaluated for its recordability. On the other hand, if the case is wholly caused by non-work factors, then it is not work-related and will not be recorded in the OSHA records.

Determining Whether the Precipitating Event or Exposure Occurred in the Work Environment or Elsewhere

Paragraph 1904.5(b)(3) of the final rule provides guidance on applying the geographic presumption when it is not clear whether the event or exposure that precipitated the injury or illness occurred in the work environment or elsewhere. If an employee reports pain and swelling in a joint but cannot say whether the symptoms first arose during work or during recreational activities at home, it may be difficult for the employer to decide whether the case is work-related. The same problem arises when an employee reports symptoms of a contagious disease that affects the public at large, such as a staphylococcus infection (''staph'' infection) or Lyme disease, and the workplace is only one possible source of the infection. In these situations, the employer must examine the employee's work duties and environment to determine whether it is more likely than not that one or more events or exposures at work caused or contributed to the condition. If the employer determines that it is unlikely that the precipitating event or exposure

occurred in the work environment, the employer would not record the case. In the staph infection example given above, the employer would consider the case work-related, for example, if another employee with whom the newly infected employee had contact at work had been out with a staph infection. In the Lyme disease example, the employer would determine the case to be work-related if, for example, the employee was a groundskeeper with regular exposure to outdoor conditions likely to result in contact with deer ticks.

In applying paragraph 1904.5(b)(3), the question employers must answer is whether the precipitating event or exposure occurred in the work environment. If an event, such as a fall, an awkward motion or lift, an assault, or an instance of horseplay, occurs at work, the geographic presumption applies and the case is work-related unless it otherwise falls within an exception. Thus, if an employee trips while walking across a level factory floor, the resulting injury is considered work-related under the geographic presumption because the precipitating event—the tripping accident—occurred in the workplace. The case is work-related even if the employer cannot determine why the employee tripped, or whether any particular workplace hazard caused the accident to occur. However, if the employee reports an injury at work but cannot say whether it resulted from an event that occurred at work or at home, as in the example of the swollen joint, the employer might determine that the case is not work-related because the employee's work duties were unlikely to have caused, contributed to, or significantly aggravated such an injury.

Significant Workplace Aggravation of a Pre-existing Condition

In paragraph 1904.5(b)(4), the final rule makes an important change to the former rule's position on the extent of the workplace aggravation of a preexisting injury or illness that must occur before the case is considered work-related. In the past, any amount of aggravation of such an injury or illness was considered sufficient for this purpose. The final rule, however, requires that the amount of aggravation of the injury or illness that work contributes must be ''significant,'' *i.e.*, non-minor, before work-relatedness is established. The preexisting injury or illness must be one caused entirely by non-occupational factors.

A number of commenters on OSHA's proposed rule raised the issue of recording injuries that were incurred off the job and then were aggravated on the job (see, *e.g.*, Exs. 15: 60, 80, 95, 107, 176, 201, 204, 213, 281, 308, 313, 338, 368, 375, 395, 396, 406, 424, 427, 428, 441). The National Roofing Contractors Association (NRCA) commented that ''[t]his definition [includes] aggravating a pre-existing condition. While NRCA believes that the exemptions provided [in the proposed rule] are a step in the right direction, this provision could require that an employer record an injury that originally occurred outside the employer's workplace. The motion or activity that aggravated the injury may not represent any substantial hazard, yet would still be recorded'' (Ex. 15: 441). The United Parcel Service (Ex. 15: 424) objected to the inclusion of the concept of aggravation in the definition of work-relatedness:

> [a]nother flaw in the proposal arises from its proposed recording requirement in the case of ''aggravation'' of prior conditions. As drafted, the rule would require reporting as an occupational injury or illness a musculoskeletal condition arising away from work which becomes aggravated by performing job duties (i.e., the job increases discomfort), when accompanied by swelling or inflammation. Thus, an employee who hurts his wrist playing tennis on the weekend and who returns to his word processing job Monday would have a reportable MSD under the rule. With such criteria for recordation, reported occupational injuries and illnesses would skyrocket, and yet most often these reports would reflect conditions arising away from work.

The Food Distributors International (Ex. 15: 368) recommended:

> [i]t is very important that injuries that are not truly work-related not be the subject of mandatory recording. For example, if an employee were injured off the job and came to work to ''try it out'' (i.e., to see if he or she was capable of performing the normal job functions), resulting pain might be seen as ''aggravation'' and become recordable on that basis. The true source of injury, however, would be outside the workplace, and recording would produce an artificially inflated rate of injuries and illnesses, and a profile that was inaccurate.

Several commenters were concerned about the aggravation of preexisting injuries in the context of recurrences or new cases (see, *e.g.*, Exs. 15: 210, 204, 338) . For example, Caterpillar Inc. (Ex. 15: 201) stated that:

> [b]ack injuries, repetitive motion injuries, and other chronic conditions which have degenerative or aging causal factors often recur without a new work accident and further without a new work accident capable of causing the underlying condition. Even if a new work accident occurs, the accident should be serious enough to cause the underlying condition before the new case presumption is applicable. The effect of this would be to eliminate minor aggravation of preexisting conditions from consideration as new injuries.

LeRoy E. Euvard, Jr., of the Safety and Environmental Staff Company (Ex. 15: 80), suggested that:

> [a]ggravation of a pre-existing condition should not be recordable if normal body movements or events cause the aggravation. For example, a smoker with asthma or other obstructive airway disease may experience shortness of breath while climbing a flight of stairs. A person with degenerative disk disease may experience pain while lifting a normal bag of groceries. If performing similar activities at work likewise aggravates the condition, it should not be recordable.

As discussed above, OSHA agrees that non-work-related injuries and illnesses should not be recorded on the OSHA Log. To ensure that non-work-related cases are not entered on the Log, paragraph 1904.5(b)(2)(ii) requires employers to consider as non-work-related any injury or illness that ''involves signs or symptoms that surface at work but result solely from a non-work-related event or exposure that occurs outside the work environment.''

The Agency also believes that preexisting injury or illness cases that have been aggravated by events or exposures in the work environment represent cases that should be recorded on the Log, because work has clearly worsened the injury or illness. OSHA is concerned, however, that there are some cases where work-related aggravation affects the preexisting case only in a minor way, i.e., in a way that does not appreciably worsen the preexisting condition, alter its nature, change the extent of the medical treatment, trigger lost time, or require job transfer. Accordingly, the final rule requires that workplace events or exposures must ''significantly'' aggravate a pre-existing injury or illness case before the case is presumed to be work-related. Paragraph 1904.5(a) states that an injury or illness is considered work-related if ''an event or exposure in the work environment either caused or contributed to the resulting condition or *significantly aggravated* a pre-existing injury or illness.''

Paragraph 1904.5(b)(4) of the final rule defines aggravation as significant if the contribution of the aggravation at work is such that it results in tangible consequences that go beyond those that the worker would have experienced as a result of the preexisting injury or illness alone, absent the aggravating effects of the workplace. Under the final rule, a preexisting injury or illness will be considered to have been significantly aggravated, for the purposes of OSHA injury and illness recordkeeping, when an event or exposure in the work

environment results in: (i) Death, providing that the preexisting injury or illness would likely not have resulted in death but for the occupational event or exposure; (ii) Loss of consciousness, providing that the preexisting injury or illness would likely not have resulted in loss of consciousness but for the occupational event or exposure; (iii) A day or days away from work or of restricted work, or a job transfer that otherwise would not have occurred but for the occupational event or exposure; or (iv) Medical treatment where no medical treatment was needed for the injury or illness before the workplace event or exposure, or a change in the course of medical treatment that was being provided before the workplace event or exposure. OSHA's decision not to require the recording of cases involving only minor aggravation of preexisting conditions is consistent with the Agency's efforts in this rulemaking to require the recording only of non-minor injuries and illnesses; for example, the final rule also no longer requires employers to record minor illnesses on the Log.

Preexisting Conditions

Paragraph 1904.5(b)(5) stipulates that pre-existing conditions, for recordkeeping purposes, are conditions that resulted solely from a non-work-related event or exposure that occurs outside the employer's work environment. Pre-existing conditions also include any injury or illness that the employee experienced while working for another employer.

Off Premises Determinations

Employees may be injured or become ill as a result of events or exposures away from the employer's establishment. In these cases, OSHA proposed to consider the case work-related only if the employee was engaged in a work activity or was present as a condition of employment (61 FR 4063). In the final rule, (paragraph 1904.5(b)(1)) the same concept is carried forward in the definition of the work environment, which defines the environment as including the establishment and any other location where one or more employees are working or are present as a condition of their employment.

Thus, when employees are working or conducting other tasks in the interest of their employer but at a location away from the employer's establishment, the work-relatedness of an injury or illness that arises is subject to the same decision making process that would occur if the case had occurred at the establishment itself. The case is work-related if one or more events or exposures in the work environment either caused or contributed to the resulting condition or significantly aggravated a pre-existing condition, as stated in paragraph 1904.5(a). In addition, the exceptions for determining work relationship at paragraph 1904.5(b)(2) and the requirements at paragraph 1904.5(b)(3) apply equally to cases that occur at or away from the establishment.

As an example, the work-environment presumption clearly applies to the case of a delivery driver who experiences an injury to his or her back while loading boxes and transporting them into a building. The worker is engaged in a work activity and the injury resulted from an event—loading/unloading—occurring in the work environment. Similarly, if an employee is injured in an automobile accident while running errands for the company or traveling to make a speech on behalf of the company, the employee is present at the scene as a condition of employment, and any resulting injury would be work-related.

Employees on Travel Status

The final rule continues (at § 1904.5(b)(6)) OSHA's longstanding practice of treating injuries and illnesses that occur to an employee on travel status as work-related if, at the time of the injury or illness, the employee was engaged in work activities ''in the interest of the employer.'' Examples of such activities include travel to and from customer contacts, conducting job tasks, and entertaining or being entertained if the activity is conducted at the direction of the employer.

The final rule contains three exceptions for travel-status situations. The rule describes situations in which injuries or illnesses sustained by traveling employees are not considered work-related for OSHA recordkeeping purposes and therefore do not have to be recorded on the OSHA 300 Log. First, when a traveling employee checks into a hotel, motel, or other temporary residence, he or she is considered to have established a ''home away from home.'' At this time, the status of the employee is the same as that of an employee working at an establishment who leaves work and is essentially ''at home''. Injuries and illnesses that occur at home are generally not considered work related. However, just as an employer may sometimes be required to record an injury or illness occurring to an employee working in his or her home, the employer is required to record an injury or illness occurring to an employee who is working in his or her hotel room (see the discussion of working at home, below).

Second, if an employee has established a ''home away from home'' and is reporting to a fixed worksite each day, the employer does not consider injuries or illnesses work-related if they occur while the employee is commuting between the temporary residence and the job location. These cases are parallel to those involving employees commuting to and from work when they are at their home location, and do not have to be recorded, just as injuries and illnesses that occur during normal commuting are not required to be recorded.

Third, the employer is not required to consider an injury or illness to be work-related if it occurs while the employee is on a personal detour from the route of business travel. This exception allows the employer to exclude injuries and illnesses that occur when the worker has taken a side trip for personal reasons while on a business trip, such as a vacation or sight-seeing excursion, to visit relatives, or for some other personal purpose.

The final rule's travel-related provisions (at paragraph 1904.5(b)(6)) are essentially identical to those proposed (63 FR 4063), with only minor editorial changes, and are also parallel to those for determining the work-relationship of traveling employees under the former recordkeeping system (Ex. 2, pp. 36, 37). OSHA received various comments and suggestions about how best to determine work relationship for traveling employees. A few commenters endorsed OSHA's proposed approach (see, *e.g.*, Exs. 15: 199, 396, 406). Other commenters believe, however, that employer control of, or the authority to control, the work environment should be determinative because activities outside the employer's control fall outside the scope of the employer's safety and health program (see, *e.g.*, Exs. 15: 335, 396, 409, 424). The comments of the Dow Chemical Company (Ex. 15: 335) are typical of these views:

> [t]ravel on public carriers such as commercial airlines, trains, and taxi services or pre-existing conditions that are aggravated during normal unencumbered body motions, or injuries that occur off-the-job but do not impair someone until they arrive at work are all beyond the control of the employer and the scope of any safety and health program. The commercial plane that crashes while the employee was flying on company business or the taxi accident while the employee was trying to get to the airport to fly on company business are events which, while tragic, are beyond the scope of an employer's control and beyond the reasonable reach of that employer's safety and health program.

However, as discussed in the Legal Authority section and the introduction to the work-relationship section of the preamble, OSHA has decided not to limit the recording of occupational injuries and illnesses to those cases that are preventable, fall within the employer's control, or are covered by the employer's safety and health program. The issue is not whether the conditions could have, or should have, been prevented or whether they were controllable, but simply whether they are occupational, i.e., are related to work. This is true regardless of whether the employee is injured while on travel or while present at the employer's workplace. An employee who is injured in an automobile accident or killed in an airline crash while traveling for the company has clearly experienced a work-related injury that is rightfully included in the OSHA injury and illness records and the Nation's occupational injury and illness statistics. As the American Industrial Hygiene Association (Ex. 15: 153) remarked:

> The workforce is increasingly made up of service sector jobs. Computers, materials movement, travel, violence are all emerging and increasing sources of occupational injury and illness. Many of these newer trends in cases may not involve lost workdays, but are recordable and significant to the workforce none the less. Many of the clean, non-manufacturing employers who were traditionally exempt from recordkeeping have risk in these and other emerging areas about which OSHA should be collecting data.

Two commenters specifically objected to the inclusion of cases involving client entertainment (Ex. 15: 409, 424). The American Association of Automobile Manufacturers (AAMA) remarked:

> AAMA agrees with OSHA that injuries/illnesses to employees during travel status are work-related and recordable. However, AAMA takes strong exception to the inclusion of 'entertaining or being entertained for the purpose of transacting, discussing, or promoting business.' We find the notion of recording an illness for an employee, while he/she was engaged in a business related dinner, and subsequently suffering acute onset of diarrhea leading to hospitalization for gastroenteritis, to be inappropriate. OSHA needs to remove this obligation from the final rule. (Ex. 15: 409)

OSHA does not agree with this comment, because the Agency believes that employees who are engaged in management, sales, customer service and similar jobs must often entertain clients, and that doing so is a business activity that requires the employee to work at the direction of the employer while conducting such tasks. If the employee is injured or becomes ill while engaged in such work, the injury or illness is work-related and should be recorded if it meets one or more of the other criteria (death, medical treatment, etc.). The gastroenteritis example provided by the AAMA is one type of injury or illness that may occur in this situation, but employees are also injured in accidents while transporting clients to business-related events at the direction of the employer or by other events or exposures arising in the work environment.

On the other hand, not all injuries and illnesses sustained in the course of business-related entertainment are reportable. To be recordable, the entertainment activity must be one that the employee engages in at the direction of the employer. Business-related entertainment activities that are undertaken voluntarily by an employee in the exercise of his or her discretion are not covered by the rule. For example, if an employee attending a professional conference at the direction of the employer goes out for an evening of entertainment with friends, some of whom happen to be clients or customers, any injury or illness resulting from the entertainment activities would not be recordable. In this case, the employee was socializing after work, not entertaining at the direction of the employer. Similarly, the fact that an employee joins a private club or organization, perhaps to ''network'' or make business contacts, does not make any injury that occurs there work-related.

Two commenters recommended that OSHA eliminate the exceptions for determining work-relationship while employees are on travel and simply require all injuries and illnesses occurring while an employee is on travel status to be considered work-related (Exs. 15: 350, 418). For example, the AFL–CIO (Ex. 15: 418) suggested:

> We would also strongly encourage the Agency to re-evaluate [proposed] Appendix A Section C ''Travel Status''. The AFL–CIO believes that employees in ''travel status'' (*e.g.*, traveling on company business) should be considered engaged in work-related activities during ALL of their time spent on the trip. This includes all travel, job tasks, entertaining and other activities occurring during ''travel status.''

OSHA believes that expanding the concept of work-related travel to include all of the time the worker spends on a trip would be inconsistent with the tests of work-relationship governing the recording of other injuries and illnesses and would therefore skew the statistics and confuse employers. As the Dow Chemical Company (Ex. 15: 335) stated:

> While the employee is traveling for the benefit of the company, it cannot be said that 100% of their time is engaged in work-related activities. Employees engage in personal and social activities while traveling on company business that is not for the direct benefit of the company nor a condition of employment and which cannot be impacted by an employer's safety or health program. Often there is ''free time'' while traveling and employees engage in a myriad of activities such as shopping, sightseeing, dining out with friends or family that may be in the area, and the like. These are activities that do not benefit the company and are outside the company's control or reasonable reach of its safety and health programs. These are activities which, if the employee were engaged in them at their normal work location, would not be recordable; but just by the fact that they happen to be traveling for business purposes raises these otherwise non-recordable cases into those subject to the recordkeeping rule.

OSHA agrees with Dow that there are situations where an injury or illness case involving an employee who is on travel status should be excluded from the records. There is no value in recording injuries and illnesses that would not be recorded under non-travel circumstances. For example, there is no value to including in the statistics an injury sustained by an employee who slips and falls in a motel room shower or who is injured in an automobile accident while on personal business, or becomes the victim of random street violence while doing personal shopping on a business trip. OSHA is therefore continuing the Agency's practice of excluding certain cases while employees are in travel status and applying the exceptions to the geographic presumption in the final rule to those occurring while the worker is traveling.

The Department of Energy (Ex. 15: 163) expressed a concern about overseas travel, remarking ''For employees who travel in the U.S., the standard makes sense. For employees who travel out of the country, additional burdens to them are generally incurred. Travelers to tropical locations or other areas with different fauna and microbes may incur diseases that are not indigenous to the U.S.'' In response, OSHA notes that the recordkeeping regulation does not apply to travel outside the United States because the OSH Act applies only to the confines of the United States (29 U.S.C. § 652(4)) and not to foreign operations. Therefore, the OSHA recordkeeping regulation does not apply to non-U.S. operations, and injuries or illnesses that may occur to a worker traveling outside the United States need not be recorded on the OSHA 300 Log.

Working at Home

The final rule also includes provisions at § 1904.5(b)(7) for

determining the work-relatedness of injuries and illnesses that may arise when employees are working at home. When an employee is working on company business in his or her home and reports an injury or illness to his or her employer, and the employee's work activities caused or contributed to the injury or illness, or significantly aggravated a pre-existing injury, the case is considered work-related and must be further evaluated to determine whether it meets the recording criteria. If the injury or illness is related to non-work activities or to the general home environment, the case is not considered work-related.

The final rule includes examples to illustrate how employers are required to record injuries and illnesses occurring at home. If an employee drops a box of work documents and injures his or her foot, the case would be considered work-related. If an employee's fingernail was punctured and became infected by a needle from a sewing machine used to perform garment work at home, the injury would be considered work-related . If an employee was injured because he or she tripped on the family dog while rushing to answer a work phone call, the case would not be considered work-related. If an employee working at home is electrocuted because of faulty home wiring, the injury would not be considered work-related.

This provision is consistent with longstanding Agency practice under the former recordkeeping system. It was also included in the proposed rule (63 FR 4063), which read ''An injury or illness will be considered work-related if it occurs while the employee is performing work for pay or compensation in the home, if the injury or illness is directly related to the performance of work rather than the general home environment or setting.''

A number of commenters supported OSHA's proposed approach to recording the injuries and illnesses of employees who work at home (see, *e.g.*, Exs. 15: 31, 146, 176, 231, 273, 301, 336, 348, 375, 406, 409, 413, 427, 429). The comments of the Council of Community Blood Centers (CCBC) (Ex. 15: 336) are typical of the views of these participants:

> CCBC believes this is a good rule and should stay on the books. Accident or illness should be work-related if it occurs at home and is related to performance of the work, not the general home environment or setting. Workers often are off the premises in a variety of situations, such as travel, providing repair services, or consultation. Just as injuries in these situations are reportable, so should those during work at home, if authorized by the employer.

A large number of commenters objected to the proposed approach, however (see, *e.g.*, Exs. 65, 66, 78, 89, 105, 111, 123, 194, 200, 225, 239, 260, 262, 265, 277, 288, 330, 335, 341, 345, 360, 387, 393, 401, 406, 409, 430, 434, 440). Most of these commenters objected because of the employer's perceived inability to control working conditions in the home environment (see, *e.g.*, Exs. 15: 89, 163, 194, 239, 262, 288, 330, 345, 360). For example, the Fort Howard Corporation commented:

> Fort Howard strongly opposes OSHA's proposal to consider any injuries and illnesses as ''work-related'' if it occurs while the employee is performing work for pay or compensation in the home if the injury or illness is directly related to the performance of the work. Employers have absolutely no control over employees' homes. They cannot oversee employees who are doing the work nor can they effectively monitor the manner the work is conducted or the environment in which it is conducted. OSHA's proposal could place employers in the role of insuring the home as a safe work environment. (Ex. 15: 194)

Again, as discussed above, OSHA is concerned that all non-minor work-related cases be recorded on the Log and become part of the national statistics, both because these injuries and illnesses provide information about the safety and health of the work environment to employers, employees, and safety and health professionals and because collecting them may allow previously obscured safety and health issues to be identified. Injuries and illnesses occurring while the employee is working for pay or compensation at home should be treated like injuries and illnesses sustained by employees while traveling on business. The relevant question is whether or not the injury or illness is work-related, not whether there is some element of employer control. The mere recording of these injuries and illnesses as work-related cases does not place the employer in the role of insuring the safety of the home environment.

The law firm of Leonard, Ralston, Stanton & Remington, Chartered (Ex. 15: 430) raised questions about OSHA's role when employees perform office work activities in a home office:

> The increasing incidence of home work (or ''telecommuting'') raises some interesting issues. For example, does OSHA assume that its right of inspection extends to an employee's private home? If so, has the Agency examined the constitutionality of this position? What control does the Agency assume an employer has over working conditions in a private home? Does the Agency expect the employer to inspect its employees' homes to identify unsafe conditions? Must the employer require an employee to correct unsafe conditions in the home (*e.g.*, frayed carpet which presents a tripping hazard; overloaded electrical wiring or use of extension cords; etc.) as a condition of employment? If so, who must pay the cost of necessary home improvements?

OSHA has recently issued a compliance directive (CPL 2–0.125) containing the Agency's response to many of the questions raised by this commenter. That document clarifies that OSHA will not conduct inspections of home offices and does not hold employers liable for employees' home offices. The compliance directive also notes that employers required by the recordkeeping rule to keep records ''will continue to be responsible for keeping such records, regardless of whether the injuries occur in the factory, in a home office, or elsewhere, as long as they are work-related, and meet the recordability criteria of 29 CFR Part 1904.''

With more employees working at home under various telecommuting and flexible workplace arrangements, OSHA believes that it is important to record injuries and illnesses attributable to work tasks performed at home. If these cases are not recorded, the Nation's injury and illness statistics could be skewed. For example, placing such an exclusion in the final rule would make it difficult to determine if a decline in the overall number or rate of occupational injuries and illnesses is attributable to a trend toward working at home or to a change in the Nation's actual injury and illness experience. Further, excluding these work-related injuries and illnesses from the recordkeeping system could potentially obscure previously unidentified causal connections between events or exposures in the work environment and these incidents. OSHA is unwilling to adopt an exception that would have these potential effects. As the BF Goodrich Company (Ex. 15: 146) said, ''[s]pecific criteria to address employee work-at-home situations is appropriate to assure consistent reporting in our changing work environment.''

Section 1904.6 Determination of New Cases

Employers may occasionally have difficulty in determining whether new signs or symptoms are due to a new event or exposure in the workplace or whether they are the continuation of an existing work-related injury or illness. Most occupational injury and illness cases are fairly discrete events, i.e., events in which an injury or acute illness occurs, is treated, and then resolves completely. For example, a worker may suffer a cut, bruise, or rash from a clearly recognized event in the

workplace, receive treatment, and recover fully within a few weeks. At some future time, the worker may suffer another cut, bruise or rash from another workplace event. In such cases, it is clear that the two injuries or illnesses are unrelated events, and that each represents an injury or illness that must be separately evaluated for its recordability.

However, it is sometimes difficult to determine whether signs or symptoms are due to a new event or exposure, or are a continuance of an injury or illness that has already been recorded. This is an important distinction, because a new injury or illness requires the employer to make a new entry on the OSHA 300 Log, while a continuation of an old recorded case requires, at most, an updating of the original entry. Section 1904.6 of the final rule being published today explains what employers must do to determine whether or not an injury or illness is a new case for recordkeeping purposes.

The basic requirement at § 1904.6(a) states that the employer must consider an injury or illness a new case to be evaluated for recordability if (1) the employee has not previously experienced a recorded injury or illness of the same type that affects the same part of the body, or (2) the employee previously experienced a recorded injury or illness of the same type that affected the same part of the body but had recovered completely (all signs and symptoms of the previous injury or illness had disappeared) and an event or exposure in the work environment caused the injury or illness, or its signs or symptoms, to reappear.

The implementation question at § 1904.6(b)(1) addresses chronic work-related cases that have already been recorded once and distinguishes between those conditions that will progress even in the absence of workplace exposure and those that are triggered by events in the workplace. There are some conditions that will progress even in the absence of further exposure, such as some occupational cancers, advanced asbestosis, tuberculosis disease, advanced byssinosis, advanced silicosis, etc. These conditions are chronic; once the disease is contracted it may never be cured or completely resolved, and therefore the case is never ''closed'' under the OSHA recordkeeping system, even though the signs and symptoms of the condition may alternate between remission and active disease.

However, there are other chronic work-related illness conditions, such as occupational asthma, reactive airways dysfunction syndrome (RADs), and sensitization (contact) dermatitis, that recur if the ill individual is exposed to the agent (or agents, in the case of cross-reactivities or RADs) that triggers the illness again. It is typical, but not always the case, for individuals with these conditions to be symptom-free if exposure to the sensitizing or precipitating agent does not occur.

The final rule provides, at paragraph (b)(1), that the employer is not required to record as a new case a previously recorded case of chronic work-related illness where the signs or symptoms have recurred or continued in the absence of exposure in the workplace. This paragraph recognizes that there are occupational illnesses that may be diagnosed at some stage of the disease and may then progress without regard to workplace events or exposures. Such diseases, in other words, will progress without further workplace exposure to the toxic substance(s) that caused the disease. Examples of such chronic work-related diseases are silicosis, tuberculosis, and asbestosis. With these conditions, the ill worker will show signs (such as a positive TB skin test, a positive chest roentgenogram, etc.) at every medical examination, and may experience symptomatic bouts as the disease progresses.

Paragraph 1904.6(b)(2) recognizes that many chronic occupational illnesses, however, such as occupational asthma, RADs, and contact dermatitis, are triggered by exposures in the workplace. The difference between these conditions and those addressed in paragraph 1904.6(b)(1) is that in these cases exposure triggers the recurrence of symptoms and signs, while in the chronic cases covered in the previous paragraph, the symptoms and signs recur even in the absence of exposure in the workplace. This distinction is consistent with the position taken by OSHA interpretations issued under the former recordkeeping rule (see the *Guidelines* discussion below). The Agency has included provisions related to new cases/continuations of old cases in the final rule to clarify its position and ensure consistent reporting.

Paragraph 1904.6(b)(3) addresses how to record a case for which the employer requests a physician or other licensed health care professional (HCP) to make a new case/continuation of an old case determination. Paragraph (b)(3) makes clear that employers are to follow the guidance provided by the HCP for OSHA recordkeeping purposes. In cases where two or more HCPs make conflicting or differing recommendations, the employer is required to base his or her decision about recordation based on the most authoritative (best documented, best reasoned, or most persuasive) evidence or recommendation.

The final rule's provisions on the recording of new cases are nearly identical to interpretations of new case recordability under the former rule. OSHA has historically recognized that it is generally an easier matter to differentiate between old and new cases that involve injuries than those involving illnesses: the *Guidelines* stated that ''the aggravation of a previous injury almost always results from some new incident involving the employee * * * [w]hen work-related, these new incidents should be recorded as new cases on the OSHA forms, assuming they meet the criteria for recordability * * *'' (Ex. 2, p. 31). However, the *Guidelines* also stated that ''certain illnesses, such as silicosis, may have prolonged effects which recur over time. The recurrence of these symptoms should not be recorded as a new case on the OSHA forms. * * * Some occupational illnesses, such as certain dermatitis or respiratory conditions, may recur as the result of new exposures to sensitizing agents, and should be recorded as new cases.''

OSHA developed and included specific guidance for evaluating when cumulative trauma disorders (CTDs) (ergonomic injuries and illnesses, now known as musculoskeletal disorders, or MSDs) should be recorded as new cases in the *Ergonomics Program Management Guidelines For Meatpacking Plants* (Ex. 11, p. 15) which were published in 1990. These *Guidelines* provided:

> If and when an employee who has experienced a recordable CTD becomes symptom free (including both subjective symptoms and physical findings), any recurrence of symptoms establishes a new case. Furthermore, if the worker fails to return for medical care within 30 days, the case is presumed to be resolved. Any visit to a health care provider for similar complaints after the 30-day interval ''implies reinjury or reexposure to a workplace hazard and would represent a new case.''

Thus, the former rule had different ''new case'' criteria for musculoskeletal disorders than for other injuries and illnesses. (For the final rule's recording criteria for musculoskeletal disorders, see Section 1904.12.)

OSHA's recordkeeping NPRM proposed a single approach to the identification of new cases for all injuries and illnesses, including musculoskeletal disorders. The proposal would have required the recurrence of a pre-existing injury or illness to be considered a new case to evaluate for recordability if (1) it resulted from a

new work event or exposure, or (2) 45 days had elapsed since medical treatment, work restriction, or days away from work had ceased, and the last sign or symptom had been experienced. The proposed approach would, in effect, have extended the recurrence criteria for musculoskeletal disorders to all injury and illness cases, but would have increased the no-medical-intervention interval from 30 to 45 days. A recurrence of a previous work-related injury or illness would have been presumed, under the proposed approach, to be a new case if (1) it resulted from a new work accident or exposure, or (2) 45 days had elapsed since medical treatment had been administered or restricted work activity or days away had occurred and since the last sign or symptom had been experienced. This proposed presumption would have been rebuttable if there was medical evidence indicating that the prior case had not been resolved. In the proposal, OSHA also asked for input on the following questions related to new case recording:

> OSHA solicits comment on the appropriateness of the 45-day interval. Is 45 days too short or long of a period? If so, should the period be 30 days? 60 days? 90 days? or some other time period? Should different conditions (*e.g.* back cases, asthma cases etc.) have different time intervals for evaluating new cases?
>
> OSHA is also seeking input for an improved way to evaluate new cases. Should a new category of cases be created to capture information on recurring injuries and illnesses? One option is to add an additional ''check box'' column to the proposed OSHA Form 300 for identifying those cases that are recurrences of previously recorded injuries and illnesses. This would allow employers, employees and OSHA inspectors to differentiate between one time cases and those that are recurrent, chronic conditions. This approach may help to remove some of the stigma of recording these types of disorders and lead to more complete records. OSHA solicits input on this approach. Will a recurrence column reduce the stigma of recording these types of cases? Should recurrences be included in the annual summaries? Should a time limit be used to limit the use of a recurrence column?

In response to the views and evidence presented by commenters to the record, OSHA has decided not to adopt the proposed approach to the recording of new/recurring cases in the final rule. Commenters expressed a wide variety of views about the recording of recurring injury and illness cases. Some commenters favored the proposed approach as drafted. Others, however, objected to it on many grounds: (1) the time limit should be longer or shorter than the 45 days proposed; (2) the proposed approach would result in under- or overreporting; (3) it would conflict with workers' compensation requirements; (4) it was too restrictive (5) it would encourage excessive use of the health care system; and (6) it should be replaced by a physician or other licensed health care professional's opinion.

A number of commenters supported OSHA's proposed approach (see, *e.g.*, Exs. 15: 27, 65, 70, 151, 152, 154, 179, 180, 181, 185, 186, 188, 214, 331, 332, 336, 359, 387, 396, 424, 428). Representative of these comments was one from The Fertilizer Institute (TFI):

> TFI agrees with OSHA's proposed 45 day criterion for the recording of new cases. Concerning OSHA's solicitation of comments on whether different conditions should have different evaluation periods, TFI encourages OSHA to adopt a single time period for all conditions. Different evaluation periods for different conditions will lead to complexity and confusion without any resulting benefit to recordkeeping (Ex. 15: 154).

Other commenters supported the concept of using a time limit for determining new cases, but thought the number of days should be higher (see, *e.g.*, Exs. 15: 45, 49, 61, 82, 89, 131, 147, 184, 235, 331, 389). Some commenters generally opposed the time limit concept but made recommendations for longer time periods if OSHA decided in the final rule to adopt a time limit (see, *e.g.*, Exs. 15: 38, 79, 89, 111, 136, 137, 141, 194, 224, 246, 266, 278, 288, 299, 313, 335, 352, 353, 430). The longer intervals suggested by commenters included 60 days (see, *e.g.*, Exs. 15: 82, 389); 90 days (see, *e.g.*, Exs. 15: 38, 49, 79, 147, 184, 246, 299, 313, 331, 335, 352, 353, 430); 120 days (Ex. 15: 194); 180 days (see, *e.g.*, Exs. 15: 61, 111, 136, 137, 141, 224, 266, 278, 288); one year (Ex. 15: 131); and five years (Ex. 15: 89).

A large number of commenters opposed the proposed approach for identifying new cases that would then be tested for their recordability (see, *e.g.*, Exs. 15: 33, 38, 39, 41, 78, 79, 89, 95, 102, 107, 111, 119, 127, 133, 136, 137, 141, 153, 171, 176, 194, 199, 203, 224, 225, 231, 246, 266, 273, 278, 281, 288, 289, 299, 301, 305, 307, 308, 313, 335, 337, 341, 346, 348, 352, 353, 375, 395, 405, 410, 413, 424, 425, 428, 430, 440). Some commenters argued that the proposed 45-day interval was arbitrary (see, *e.g.*, Exs. 15: 119, 203, 289, 313, 352, 353, 395), that it conflicted with workers' compensation new case determinations (see, *e.g.*, Exs. 15: 38, 119, 136, 137, 141, 224, 266, 278), that the approach would not work in the case of chronic injury (see, *e.g.*, Exs. 33; 15: 176, 199, 231, 273, 299, 301, 305, 308, 337, 346, 348, 375), or that the proposed 45-day rule would result in over-reporting of occupational injuries and illnesses (see, *e.g.*, Exs. 15: 119, 127, 136, 137, 141, 171, 199, 224, 266, 278, 305, 337, 424, 425). The comments of the NYNEX Corporation (Ex. 15: 199) illustrate the general concerns of these commenters:

> We do not agree, however, with the second criterion of a symptom free 45 day period following medical treatment, restriction, or days away from work. This criterion fails to take into account the persistent nature of many chronic or recurring conditions, i.e., back strains, musculoskeletal disorders, where the symptoms may disappear for a period of time, but the underlying conditions are still present. If adopted, this criterion could cause injury and illness data to be artificially inflated with the onset of ''new'' cases, which in fact are recurrences of existing conditions. This in turn could lead to false epidemics and a diversion of resources from more legitimate workplace concerns.

On the other hand, William K. Principe of Constangy, Brooks & Smith, LLC (Ex. 15: 428) was concerned that the proposed method would result in fewer recordable cases:

> Since many employees will report that they continued to experience symptoms or that they continue to have good days and bad days, the new rule will result in many fewer recordable CTD [cumulative trauma disorder] cases. In fact, at some hand-intensive manual operations, the number of CTD cases should be drastically reduced under the proposal that 45 days must elapse since the last symptom. There is something fundamentally wrong with a recordkeeping system that one year shows a high incidence of CTDs and the next shows a dramatic decline, when the underlying conditions remain virtually identical.

United Parcel Service (Ex. 15: 424) stated that there should be no time limit to determining whether or not a case is a recurrence:

> In UPS's experience, however, it is a simple process to determine, by medical referral or by examining prior medical history, whether a condition is a recurrence. This has long been the practice, and indeed the [proposal] contemplates it will remain the practice through the first 44 days. It does not become any more complex on the 45th, 50th, or 100th day; and if in an individual employer's judgment it does, then the employer may of course report the condition as a new injury.

Three commenters disapproved of OSHA's approach because it would have been applicable to all recurrences and they believe that each case must be evaluated on its own merits (Exs. 15: 78, 184, 203). The International Dairy Foods Association (IDFA) described this concern succinctly: ''Each injury has its own resolution based on the injury, illness, degree, and numerous other factors that are characteristic of the

individual. As such, it is impossible for OSHA or anyone else to set a valid number of days even if the resolution period is set on the basis of the type of illness/injury'' (Ex. 15: 203).

In addition, the proposed 45-day approach was interpreted differently by different commenters. For example, David E. Jones of the law firm Ogletree, Deakins, Nash, Smoak & Stewart (ODNSS) suggested:

> The words ''either'' and ''or'' * * * should be deleted because an aggravation of the previously recorded injury or illness brought about within the 45-day period would require the entry of a new case at that time, thus negating the 45-day rule, leading to the adverse result that the 45-day rule otherwise would rectify. Accordingly, ODNSS recommends * * * ''A recurrence of a previous work-related injury or illness is a new case when it (1) results from a new work event or exposure *and* (2) 45 days have elapsed since medical treatment, restricted work activity, or days away from work (as applicable) were discontinued and the employee has been symptom-free (including both subjective symptoms and physical findings) (emphasis added) (Ex. 15: 406).

In the final rule, OSHA has decided against the proposed approach of determining case resolution based on a certain number of days during which the injured or ill employee did not lose time, receive treatment, have signs or symptoms, or be restricted to light duty. OSHA agrees with those commenters who argued that the proposed approach was too prescriptive and did not allow for the variations that naturally exist from one injury and illness case to the next. Further, the record contains no convincing evidence to support a set number of days as appropriate. OSHA thus agrees with those commenters who pointed out that adoption of a fixed time interval would result in the overrecording of some injury and illness cases and the underrecording of others, and thus would impair the quality of the records.

Further, OSHA did not intend to create an ''injury free'' time zone during which an injury or illness would not be considered a new case, regardless of cause, as ODNSS suggested. Instead, OSHA proposed that a case be considered a new case if *either* condition applied: the case resulted from a new event or exposure *or* 45 days had elapsed without signs, symptoms, or medical treatment, restricted work, or days away from work. There are clearly cases where an event or exposure in the workplace would be cause for recording a new case. A new injury may manifest the same signs and symptoms as the previous injury but still be a new injury and not a continuation of the old case if, for example, an employee sustains a fall and fractures his or her wrist, and four months later falls again and fractures the wrist in the same place. This occurrence is not a continuation of the fracture but rather a new injury whose recordability must be evaluated. The final rule's approach to recurrence/new case determinations avoids this and other recording problems because it includes no day count limit and relies on one of the basic principles of the recordkeeping system, i.e., that injuries or illnesses arising from events or exposures in the workplace must be evaluated for recordability.

In response to those commenters who raised issues about inconsistency between the OSHA system and workers' compensation, OSHA notes that there is no reason for the two systems, which serve different purposes (recording injuries and illnesses for national statistical purposes and indemnifying workers for job-related injuries and illnesses) to use the same definitions. Accordingly, the final rule does not rely on workers' compensation determinations to identify injuries or illness cases that are to be considered new cases for recordkeeping purposes.

Another group of commenters argued that the 45-day recording requirement would lead employers to spend money on unnecessary and costly health care (see, *e.g.*, Exs. 15: 136, 137, 141, 224, 266, 278, 305, 346, 348, 375). The views of the American Petroleum Institute (API) are representative: ''OSHA's proposal would also add substantially to employers' costs since it could require employees to make frequent trips to a health care professional, even if symptom free, just to avoid being recorded repeatedly on the OSHA log as new cases'' (Ex. 15: 375). Union Carbide Corporation (Ex. 15: 396) also remarked on the proposed approach's potential incentive for medical follow-up, but viewed such an incentive as a positive phenomenon, stating ''One benefit [of the proposed approach] is that it encourages medical follow-up for the employee.'' Although the proposed approach would not have ''required'' an employer to send a worker to a physician or other licensed health care professional, and OSHA is not persuaded that employers would choose to spend money in this way merely to avoid recording an occasional case as a new case, elimination of any set day-count interval from the final rule will also have made the concerns of these commenters moot.

OSHA also received a number of suggestions about the role of physicians and other licensed health care professionals (HCP) in new case determinations. A number of commenters recommended that the decision to record should be based solely on the opinions of a physician or other licensed health care professional (see, *e.g.*, Exs. 33: 15: 39, 95, 107, 119, 127, 133, 225, 289, 332, 335, 341, 387, 424, 440). The National Grain and Feed Association, the National Oilseed Processors Association, and the Grain Elevator and Processing Society (Ex. 15: 119) commented as a group and recommended that ''[r]elying on a physician's opinion rather than an arbitrary timeframe would simplify recordkeeping and help ensure that the records are consistent with existing and accepted workers' compensation plans.''

Other commenters recommended that, if OSHA adopted a day count time limit, the rule should specifically allow a physician's opinion to be used to refute a new case determination (see, *e.g.*, Exs. 15: 65, 181, 184, 203). Several others simply asked OSHA to provide more guidance on what type of medical evidence could be used in new case determinations (see, *e.g.*, Exs. 15: 176, 231, 273, 301, 430). The National Wholesale Druggists' Association (NWDA) suggested that ''OSHA should also include a provision that the employee obtain written approval from a doctor that the employee's condition has been resolved before going back to work. Determining the end of treatment should be left in the hands of a medical professional and OSHA should require some type of documentation to that effect'' (Ex. 15: 185).

OSHA has not included any provisions in the final rule that require an employer to rely on a physician or other licensed health care professional or that tell a physician or other licensed health care professional how to treat an injured or ill worker, or when to begin or end such treatment. In the final rule OSHA does require the employer to follow any determination a physician or other licensed health care professional has made about the status of a new case. That is, if such a professional has determined that a case is a new case, the employer must record it as such. If the professional determines that the case is a recurrence, rather than a new case, the employer is not to record it a second time. In addition, the rule does not require the employee, or the employer, to obtain permission from the physician or other licensed health care professional before the employee can return to work. OSHA believes that the employer is capable of, and often in the best position to, make return-to-work decisions.

Southern California Edison (Ex. 15: 111) expressed concern that imposing a day limit would not take differences

between types of injuries and illnesses into account, stating ''A recurrence of a previous work-related injury or illness should only be considered a new case when the injury or illness has completely healed. Severe muscle and nerve damage can take many weeks or months to properly heal.'' The final rule takes such differences into account, as follows. If the previous injury or illness has not healed (signs and symptoms have not resolved), then the case cannot be considered resolved. The employer may make this determination or may rely on the recommendation of a physician or other licensed health care professional when doing so. Clearly, if the injured or ill employee is still exhibiting signs or symptoms of the previous injury or illness, the malady has not healed, and a new case does not have to be recorded. Similarly, if work activities aggravate a previously recorded case, there is no need to consider recording it again (although there may be a need to update the case information if the aggravation causes a more severe outcome than the original case, such as days away from work).

The Quaker Oats Company (Ex. 15: 289) suggested that employers should be permitted by the rule to decide whether a given case was a new case or not, without requirements in the rule:

> The 45 day interval on determining if a case is a new one or should be counted under a previous injury should be left to the discretion of the employer. They have the most intimate knowledge of the work environment, medical treatment of the affected employee and the status of their work-related injury or illness. I will agree that it is a difficult matter to decide and to assure consistency throughout industry * * * I believe that any number of days would simply be an arbitrary attempt at quantifying something that is best left to the medical judgment of a healthcare professional.

Under the OSHA recordkeeping system, the employer is always the responsible party when it comes to making the determination of the recordability of a given case. However, if OSHA did not establish consistent new case determination criteria, a substantial amount of variability would be introduced into the system, which would undermine the Agency's goals of improving the accuracy and consistency of the Nation's occupational injury and illness data. Accordingly, OSHA has not adopted this suggested approach in the final rule.

A number of commenters argued that the occurrence of a new event, exposure, or incident should be required to trigger the recording of a new case (see, *e.g.*, Exs. 33, 15: 102, 171, 176, 231, 273, 301, 307, 308, 405, 410, 413, 425). Representative of these comments was one from the Voluntary Protection Programs Participants' Association (VPPPA), which recommended that OSHA ''adopt a definition for new case that requires the occurrence of a new work-related event to trigger a new case. In the absence of this, the case would be considered recurring'' (Ex. 15: 425). OSHA agrees with the VPPPA that if no further event or exposure occurs in the workplace to aggravate a previous injury or illness, a new case need not be recorded. However, if events or exposures at work cause the same symptoms or signs to recur, the final rule requires employers to evaluate the injury or illness to see if it is a new case and is thus recordable.

The OSHA statistical system is designed to measure the incidence, rather than prevalence, of occupational injury and illness. Incidence measures capture the number of new occupational injuries and illnesses occurring in a given year, while prevalence measures capture the number of such cases existing in a given year (prevalence measures thus capture cases without regard to the year in which they onset). Prevalence measures would therefore capture all injuries and illnesses that occurred in a given year as well as those unresolved injuries and illnesses that persist from previous years. The difference is illustrated by the following cases: (1) A worker experiences a cut that requires sutures and heals completely before the year ends; this injury would be captured both by an incidence or prevalence measure for that particular year. (2) Another worker retired last year but continues to receive medical treatment for a work-related respiratory illness that was first recognized two years ago. This case would be captured in the year of onset and each year thereafter until it resolves if a prevalence measure is used, but would be counted only once (in the year of onset) if an incidence measure is used.

Because the OSHA system is intended to measure the incidence of occupational injury and illness, each individual injury or illness should be recorded only once in the system. However, an employee can experience the same type of injury or illness more than once. For example, if a worker cuts a finger on a machine in March, and is then unfortunate enough to cut the same finger again in October, this worker has clearly experienced two separate occupational injuries, each of which must be evaluated for its recordability. In other cases, this evaluation is not as simple. For example, a worker who performs forceful manual handling injures his or her back in 1998, resulting in days away from work, and the case is entered into the records. In 1999 this worker has another episode of severe work-related back pain and must once again take time off for treatment and recuperation. The question is whether or not the new symptoms, back pain, are continuing symptoms of the old injury, or whether they represent a new injury that should be evaluated for its recordability as a new case. The answer in this case lies in an analysis of whether or not the injured or ill worker has recovered fully between episodes, and whether or not the back pain is the result of a second event or exposure in the workplace, *e.g.*, continued manual handling. If the worker has not fully recovered and no new event or exposure has occurred in the workplace, the case is considered a continuation of the previous injury or illness and is not recordable.

One reason for the confusion that is apparent in some of the comments on the proposal's approach to the recording of recurrences may be the custom that developed over the years of referring to recordable recurrences of work-related injuries and illnesses as ''new cases.'' See for example, 61 FR 4037/1 (''employers may be dealing with a re-injury or recurrence of a previous case and must decide whether the recurrence is a ''new case'' or a continuation of the original case.'') The term ''new case'' tends to suggest to some that the case is totally original, when in fact new cases for OSHA recordkeeping purposes include three categories of cases; (1) totally new cases where the employee has never suffered similar signs or symptoms while in the employ of that employer, (2) cases where the employee has a preexisting condition that is significantly aggravated by activities at work and the significant aggravation reaches the level requiring recordation, and (3) previously recorded conditions that have healed (all symptoms and signs have resolved) and then have subsequently been triggered by events or exposures at work.

Under the former rule and the final rule, both new injuries and recurrences must be evaluated for their work-relatedness and then for whether they meet one or more of the recording criteria; when these criteria are met, the case must be recorded. If the case is a continuation of a previously recorded case but does not meet the ''new case'' criteria, the employer may have to update the OSHA 300 Log entry if the original case continues to progress, i.e., if the status of the case worsens. For example, consider a case where an

employee has injured his or her back lifting a heavy object, the injury resulted in medical treatment, and the case was recorded as a case without restricted work or days away. If the injury does not heal and the employer subsequently decides to assign the worker to restricted work activity, the employer is required by the final rule to change the case classification and to track the number of days of restricted work. If the case is a previous work-related injury that did not meet the recording criteria and thus was not recorded, future developments in the case may require it to be recorded. For example, an employee may suffer an ankle sprain tripping on a step. The employee is sent to a health care professional, who does not recommend medical treatment or restrictions, so the case is not recorded at that time. If the injury does not heal, however, and a subsequent visit to a physician results in medical treatment, the case must then be recorded.

OSHA and employers and employees need data on recurring cases because recurrence is an important indicator of severity over the long term. Just as the number of days away is a useful indicator of health and safety risk at a particular establishment, so is the total number of injury and illness events and of exposures resulting in health consequences that occur in an establishment or industry. Further, any realistic assessment of occupational safety and health conditions should reflect the fact that some but not all injuries and illnesses have long-term consequences. In other words, a safety and health analysis should give less weight to an injury or illness that has a clear and relatively quick recovery without impairment of any kind and an injury or illness that is chronic in nature or one that involves recurring episodes that are retriggered by workplace events or exposures.

Ignoring the fact that an occupational injury or illness is a recurrence occasioned by an event or exposure in the workplace would result in an underestimate of the true extent of occupational injury and illness and deprive employers, employees, and safety and health professionals of essential information of use in illness prevention. The other extreme, requiring employers to record on-going signs or symptoms repeatedly, even in the absence of an event or exposure in the workplace, would result in overstating the extent of illness. In terms of the recordkeeping system, deciding how most appropriately to handle new cases requires a balanced approach that minimizes both overrecording and underrecording. OSHA has dealt with this problem in the final rule by carefully defining the circumstances under which a chronic and previously recorded injury or illness must be considered closed and defining the circumstances under which a recurrence is to be considered a new case and then evaluated to determine whether it meets one or more of the recordability criteria.

OSHA's proposal to apply a single criterion to the determination of the recordability of all recurrences of previously recorded injuries and illnesses received support from several commenters (see, *e.g.*, Exs. 15: 31, 61, 70, 154, 203, 396). The final rule uses one set of criteria for determining whether any injury or illness, including a musculoskeletal disorder, is to be treated as a new case or as the continuation of an ''old'' injury or illness. First, if the employee has never had a recorded injury or illness of the same type and affecting the same part of the body, the case is automatically considered a new case and must be evaluated for recordability. This provision will handle the vast majority of injury and illness cases, which are new cases rather than recurrences or case continuations. Second, if the employee has previously had a recorded injury or illness of the same type and affecting the same body part, but the employee has completely recovered from the previous injury or illness, and a new workplace event or exposure causes the injury or illness (or its signs or symptoms) to reappear, the case is a recurrence that the employer must evaluate for recordability.

The implementation section of § 1904.6 describes these requirements and includes explanations applying to two special circumstances. In the first case, paragraph 1904.6(b)(1) the employee has experienced a chronic injury or illness of a type that will progress regardless of further workplace exposure. Cases to which this provision applies are serious, chronic illness conditions such as occupational cancer, asbestosis, silicosis, chronic beryllium disease, etc. These occupational conditions generally continue to progress even though the worker is removed from further exposure. These conditions may change over time and be associated with recurrences of symptoms, or remissions, but the signs (*e.g.*, positive chest roentgenogram, positive blood test) generally continue to be present throughout the course of the disease.

The second kind of case, addressed in paragraph 1904.6(b)(b)(2), requires employers to record chronic illness cases that recur as a result of exposures in the workplace. These conditions might include episodes of occupational asthma, reactive airways dysfunction syndrome (RADS), or contact allergic dermatitis, for example.

Paragraph 1904.6(b)(3) recognizes the role of physicians and other licensed health care professionals that the employer may choose to rely on when tracking a ''new case'' or making a continuation of an old case determination. If a physician or other licensed health care professional determines that an injury or illness has been resolved, the employer must consider the case to be resolved and record as a new case any episode that causes the signs and symptoms to recur as a result of exposure in the workplace. On the other hand, if the HCP consulted by the employer determines that the case is a chronic illness of the type addressed by paragraph 1904.6(b)(1), the employer would not record the case again. In either case, the employer would evaluate it for work-relatedness and then determine whether the original entry requires updating or the case meets the recording criteria. Paragraph (b)(3) also recognizes that the employer may ask for input from more than one HCP, or the employer and employee may each do so, and in such cases, the rule requires the employer to rely on the one judged by the employer to be most authoritative.

Adding a Recurrence Column to the OSHA 300 Log

In the proposal, OSHA asked commenters whether the Log should include a column with a check-box that could be marked if a case was a recurrence of a pre-existing condition (61 FR 4037). Some commenters supported the proposed approach (see, *e.g.*, Exs. 15: 27, 39, 61, 65, 89, 154, 186, 214, 235, 277, 299, 305, 332, 336). For example, the National Association of Manufacturers (NAM) suggested that, in lieu of adopting a 45-day time limit, OSHA should add a column to the Log: ''If the Agency believes there is a need to track the number of recurring cases, we believe the better approach would be to add a column to the log which would permit the original entry for each injury or illness to be updated in the event of a recurrence'' (Ex. 15: 305). The American Association of Homes and Services for the Aging (AAHSA) agreed:

> [t]here should be a column on the injury and illness log for employers to check for reoccurring injuries. This addition would help the employer to identify possible patterns or problems associated with a specific job and find solutions. Recommendation: Add a column to the injury and illness log allowing the employer

to check when an employee is having a repetitive injury or illness (Ex. 15: 214).

Other commenters did not support the proposal's approach to tracking recurrences (see, *e.g.*, Exs. 15: 70, 78, 136, 137, 141, 151, 152, 179, 180, 194, 224, 266, 278). The comments of Kathy Lehrman, RN, Occupational Health Nurse (Ex. 15: 136) are representative of these comments:

> The addition of a column to record recurrent conditions would not reduce the stigma and would lead to increased health care provider visits to avoid having an ongoing case labeled as a new case. * * * I do not see the value of including a new category of case designation. This runs counter to the simplification objective.

After a review of the comments on this issue, OSHA has decided not to include such a check-box on the Log. The final rule adds several columns to the OSHA 300 form to collect data on the number of restricted workdays and on various types of occupational injuries and illnesses. The addition of these columns, and the decision to provide more space on the Log to add information on the case, has used up the available space on the form. Requiring employers to record recurrences would also be burdensome and make the rule more complex. Further, OSHA did not propose such a requirement, and this issue raises questions not adequately aired in the record. For example, if an employee has recurring episodes of low back pain, should the employer be required to record each day the employee experiences such pain as a recurring injury? OSHA is also unsure how recurrence data should be captured and used in the Nation's injury and illness statistics. For example, would a separate data set on recurrences, similar to data on injuries and illnesses, be produced by the BLS?

OSHA has therefore decided that it is not appropriate to add a column to the Log to capture data on recurring injuries and illnesses. However, OSHA recognizes that data on injury and illness recurrence may be useful to employers and employees at individual worksites and encourages employers who wish to collect this additional information to do so; however, the final rule does not require employers to provide recurrence data on the Log.

Section 1904.7 General Recording Criteria

Section 1904.7 contains the general recording criteria for recording work-related injuries and illnesses. This section describes the recording of cases that meet one or more of the following six criteria: death, days away from work, restricted work or transfer to another job, medical treatment beyond first aid, loss of consciousness, or diagnosis as a significant injury or illness by a physician or other licensed health care professional.

Paragraph 1904.7(a)

Paragraph 1904.7(a) describes the basic requirement for recording an injury or illness in the OSHA recordkeeping system. It states that employers must record any work-related injury or illness that meets one or more of the final rule's general recording criteria. There are six such criteria: death, days away from work, days on restricted work or on job transfer, medical treatment beyond first aid, loss of consciousness, or diagnosis by a physician or other licensed heath care professional as a significant injury or illness. Although most cases are recorded because they meet one of these criteria, some cases may meet more than one criterion as the case continues. For example, an injured worker may initially be sent home to recuperate (making the case recordable as a ''days away'' case) and then subsequently return to work on a restricted (''light duty'') basis (meeting a second criterion, that for restricted work). (see the discussion in Section 1904.29 for information on how to record such cases.)

Paragraph 1904.7(b)

Paragraph 1904.7(b) tells employers how to record cases meeting each of the six general recording criteria and states how each case is to be entered on the OSHA 300 Log. Paragraph 1904.7(b)(1) provides a simple decision table listing the six general recording criteria and the paragraph number of each in the final rule. It is included to aid employers and recordkeepers in recording these cases.

1904.7(b)(2) Death

Paragraph 1904.7(b)(2) requires the employer to record an injury or illness that results in death by entering a check mark on the OSHA 300 Log in the space for fatal cases. This paragraph also directs employers to report work-related fatalities to OSHA within 8 hours and cross references the fatality and catastrophe reporting requirements in § 1904.39 of the final rule, Reporting fatalities and multiple hospitalizations to OSHA.

Paragraph 1904.7(b)(2) implements the OSH Act's requirements to record all cases resulting in work-related deaths. There were no comments opposing the recording of cases resulting in death. However, there were several comments questioning the determination of work-relatedness for certain fatality cases and the appropriateness of reporting certain kinds of fatalities to OSHA. These comments are addressed in the sections of this preamble devoted to work-relationship and fatality reporting (sections 1904.5 and 1904.39, respectively).

Paragraph 1904.7(b)(3) Days Away From Work

Paragraph 1904.7(b)(3) contains the requirements for recording work-related injuries and illnesses that result in days away from work and for counting the total number of days away associated with a given case. Paragraph 1904.7(b)(3) requires the employer to record an injury or illness that involves one or more days away from work by placing a check mark on the OSHA 300 Log in the space reserved for day(s) away cases and entering the number of calendar days away from work in the column reserved for that purpose. This paragraph also states that, if the employee is away from work for an extended time, the employer must update the day count when the actual number of days away becomes known. This requirement continues the day counting requirements of the former rule and revises the days away requirements in response to comments in the record.

Paragraphs 1904.7(b)(3)(i) through (vi) implement the basic requirements. Paragraph 1904.7(b)(3)(i) states that the employer is not to count the day of the injury or illness as a day away, but is to begin counting days away on the following day. Thus, even though an injury or illness may result in some loss of time on the day of the injurious event or exposure because, for example, the employee seeks treatment or is sent home, the case is not considered a days-away-from-work case unless the employee does not work on at least one subsequent day because of the injury or illness. The employer is to begin counting days away on the day following the injury or onset of illness. This policy is a continuation of OSHA's practice under the former rule, which also excluded the day of injury or onset of illness from the day counts.

Paragraphs 1904.7(b)(3)(ii) and (iii) direct employers how to record days-away cases when a physician or other licensed health care professional (HCP) recommends that the injured or ill worker stay at home or that he or she return to work but the employee chooses not to do so. As these paragraphs make clear, OSHA requires employers to follow the physician's or HCP's recommendation when recording the case. Further, whether the employee works or not is in the control of the

employer, not the employee. That is, if an HCP recommends that the employee remain away from work for one or more days, the employer is required to record the injury or illness as a case involving days away from work and to keep track of the days; the employee's wishes in this case are not relevant, since it is the employer who controls the conditions of work. Similarly, if the HCP tells the employee that he or she can return to work, the employer is required by the rule to stop counting the days away from work, even if the employee chooses not to return to work. These policies are a continuation of OSHA's previous policy of requiring employees to follow the recommendations of health care professionals when recording cases in the OSHA system. OSHA is aware that there may be situations where the employer obtains an opinion from a physician or other health care professional and a subsequent HCP's opinion differs from the first. (The subsequent opinion could be that of an HCP retained by the employer or the employee.) In this case, the employer is the ultimate recordkeeping decision-maker and must resolve the differences in opinion; he or she may turn to a third HCP for this purpose, or may make the recordability decision himself or herself.

Paragraph 1904.7(b)(3)(iv) specifies how the employer is to account for weekends, holidays, and other days during which the employee was unable to work because of a work-related injury or illness during a period in which the employee was not scheduled to work. The rule requires the employer to count the number of calendar days the employee was unable to work because of the work-related injury or illness, regardless of whether or not the employee would have been scheduled to work on those calendar days. This provision will ensure that a measure of the length of disability is available, regardless of the employee's work schedule. This requirement is a change from the former policy, which focused on scheduled workdays missed due to injury or illness and excluded from the days away count any normal days off, holidays, and other days the employee would not have worked.

Paragraph 1904.7(b)(3)(v) tells the employer how to count days away for a case where the employee is injured or becomes ill on the last day of work before some scheduled time off, such as on the Friday before the weekend or the day before a scheduled vacation, and returns to work on the next day that he or she was scheduled to work. In this situation, the employer must decide if the worker would have been able to work on the days when he or she was not at work. In other words, the employer is not required to count as days away any of the days on which the employee would have been able to work but did not because the facility was closed, the employee was not scheduled to work, or for other reasons unrelated to the injury or illness. However, if the employer determines that the employee's injury or illness would have kept the employee from being able to work for part or all of time the employee was away, those days must be counted toward the days away total.

Paragraph 1904.7(b)(3)(vi) allows the employer to stop counting the days away from work when the injury or illness has resulted in 180 calendar days away from work. When the injury or illness results in an absence of more than 180 days, the employer may enter 180 (or 180+) on the Log. This is a new provision of the final rule; it is included because OSHA believes that the ''180'' notation indicates a case of exceptional severity and that counting days away beyond that point would provide little if any additional information.

Paragraph 1904.7(b)(3)(vii) specifies that employers whose employees are away from work because of a work-related injury or illness and who then decide to leave the company's employ or to retire must determine whether the employee is leaving or retiring because of the injury or illness and record the case accordingly. If the employee's decision to leave or retire is a result of the injury or illness, this paragraph requires the employer to estimate and record the number of calendar days away or on restricted work/job transfer the worker would have experienced if he or she had remained on the employer's payroll. This provision also states that, if the employee's decision was unrelated to the injury or illness, the employer is not required to continue to count and record days away or on restricted work/job transfer.

Paragraph 1904.(b)(3)(viii) directs employers how to handle a case that carries over from one year to the next. Some cases occur in one calendar year and then result in days away from work in the next year. For example, a worker may be injured on December 20th and be away from work until January 10th. The final rule directs the employer only to record this type of case once, in the year that it occurred. If the employee is still away from work when the annual summary is prepared (before February 1), the employer must either count the number of days the employee was away or estimate the total days away that are expected to occur, use this estimate to calculate the total days away during the year for the annual summary, and then update the Log entry later when the actual number of days is known or the case reaches the 180-day cap allowed in § 1904.7(b)(3)(v).

Comments on the Recording of Days Away From Work

OSHA received a large number of comments on how days away should be counted. The issues addressed by commenters included (1) whether to count scheduled workdays or calendar days, (2) whether the day counts should be ''capped,'' and, if so, at what level, (3) how to count days away or restricted when employees are terminated or become permanently disabled, and (4) how to handle cases that continue to have days away/restricted from one year to the next.

Scheduled or calendar work days. OSHA proposed to count scheduled workdays, consistent with its long-standing policy of excluding normal days off such as weekends, holidays, days the facility is closed, and prescheduled vacation days (61 FR 4033). The proposal asked the public for input on which counting method—calendar days or scheduled work days—would be better, stating that ''OSHA is considering a modification to the concept of days away from work to include days the employee would normally not have worked (*e.g.* weekends, holidays, etc.). OSHA believes this change to calendar days would greatly simplify the method of counting days away by eliminating the need to keep track of, and subtract out, scheduled days off from the total time between the employee's first day away and the time the employee was able to return to full duty'' (61 FR 4033). The proposal also discussed the potential benefits and pitfalls of counting calendar days:

> Another potential benefit of changing to calendar days would be that the day count would more accurately reflect the severity of the injury or illness. The day count would capture all the days the employee would not have been able to work at full capacity regardless of work schedules. For example, if an employee, who normally does not work weekends, is injured on a Friday and is unable to work until the following Tuesday, the ''days away from work'' would be three (3), using calendar days, rather than one (1) day, using work days. If the same injury occurred on a Monday, the day count would be three (3) using either calendar or workdays. Changing the day count to calendar days would eliminate discrepancies based upon work schedules. Thus, the day counts would be easier to calculate and potentially more meaningful.
>
> One of the potential problems with this change would be that economic information on lost work time as a measure of the impact of job related injuries and illnesses on work

life would no longer be available. Employers could, however, estimate work time lost by applying a work day/calendar day factor to the recorded day counts. OSHA solicits comment on the idea of counting calendar days rather than work days, in particular, what potential do these methods have for overstating (i.e. counting calendar days) or understating (i.e. counting work days) the severity of injuries and illnesses? (61 FR 4034)

OSHA received a large number of comments on the calendar day/scheduled day issue. Many commenters suggested that OSHA track days away from work using its former method of counting scheduled workdays (see, *e.g.*, Exs. 21; 30; 37; 15: 10, 16, 30, 42, 44, 48, 61, 66, 69, 78, 79, 89, 100, 107, 108, 119, 121, 122, 127, 130, 133, 146, 151, 152, 154, 159, 163, 170, 172, 179, 180, 200, 203, 204, 213, 214, 219, 226, 246, 260, 262, 265, 281, 287, 297, 299, 300, 304, 305, 307, 308, 341, 346, 356, 363, 364, 368, 373, 378, 384, 385, 387, 389, 390, 397, 401, 404, 410, 413, 414, 424, 426, 427, 431, 440, 443). Many commenters also suggested that OSHA use calendar days instead of scheduled workdays to track days away from work (see, *e.g.*, Exs. 19; 44; 15: 26, 27, 31, 34, 44, 71, 75, 82, 105, 111, 119, 127, 136, 137, 138, 141, 153, 181, 182, 188, 198, 205, 218, 224, 233, 242, 263, 266, 269, 270, 271, 278, 310, 316, 326, 337, 345, 347, 350, 359, 369, 377, 391, 396, 405, 407, 409, 415, 418, 423, 425, 428, 429, 434, 438). The arguments of each group fall loosely into two categories: which counting method provides the most meaningful data and which method is least burdensome.

Arguing against counting calendar days, a number of commenters stated that calendar days would overstate lost workdays and artificially inflate or distort severity rates (see, *e.g.*, Exs. 15: 10, 16, 42, 44, 69, 108, 119, 127, 130, 133, 146, 159, 163, 170, 195, 203, 213, 219, 281, 287, 297, 300, 304, 305, 307, 341, 356, 364, 373, 385, 389, 390, 397, 404, 410, 414, 424, 426, 431, 440, 443). Some commenters also argued that the information would be ''false and misleading'' (see, *e.g.*, Exs. 15: 287, 443), ''would not indicate true severity'' (Ex. 15: 108), or would make it difficult to compare data from the old rule with data kept under the new rules (see, *e.g.*, Exs. 37; 15: 44, 61, 130, 146, 226, 281, 297, 299, 300, 304, 341, 378, 384, 385, 397, 404, 426, 440). Typical of these views was the one expressed by the American Trucking Associations (Ex. 15: 397), which stated that:

> This provision serves no useful purpose. Its proponents exaggerate the difficulty in computing days away from work under the current regulation. Instead, it will only serve the purpose of artificially increasing incidence and severity rates which would falsely designate a given worksite as unsafe or delineate it as a high hazard workplace. This false delineation of high hazardousness would also result in the workplace being unfairly targeted by OSHA for enforcement activities. In addition, this change would make it difficult, if not impossible, for employers to compare previous lost work day incidence rates with current rates. Such trend data is invaluable to employers in tracking progress made in eliminating workplace injuries and illnesses.

Other commenters, however, argued that calendar days would be a better statistical measure (see, *e.g.*, Exs. 15: 71, 75, 347, 425, 434, 438). For example, the American Waterways Shipyard Conference (Ex. 15: 75) stated:

> AWSC would also urge that ''days away from work'' be counted by calendar days rather than work days. This would ease the burden on establishments in their recordkeeping and would also make the data more useful. For example, an employee injured on Friday who does not return to work until Tuesday is currently counted as one-day off the job. If ''days away from work'' are calculated by calendar days, then this same injury would be counted as three days. The three day injury ruling is a more accurate indicator of the seriousness of the injury.

The United Auto Workers (UAW) argued that: ''Calendar days are a much better measure of severity or disability than actual days which are adjusted for work schedule, vacations, layoffs and other extraneous disruptions. Frankly, counting actual days is a waste of effort, subject to manipulation and serves no public health purpose. It is relic and should be eliminated. The only reason some employers might wish to retain this measure is because they can generate a lower number'' (Ex. 15: 438).

Other commenters were concerned that the change to counting calendar days would have an unfair effect on firms that rely more heavily on part-time workers, use alternative schedules, and/or use planned plant shutdowns (see, *e.g.*, Exs. 15: 42, 96, 121, 159, 163, 213, 219, 200, 262, 281, 299). For example, Dayton Hudson Corporation (Ex. 15: 121) stated that:

> DHC questions the concept of counting calendar days versus the proposed scheduled work days in documenting days away from work. Both methods have their value and also potential problems. The calendar method would make it much easier for a company to record the severity of an accident. However, this method would have a significant effect on an industry such as retailing, since the majority of our work force is part-time. If OSHA decides to go with the calendar method, there needs to be clearly defined examples referenced in the standard dealing with part-time workers.

Northrop Grumman Corporation (Ex. 15: 42) asserted that: ''[c]ounting calendar days for days away from work would have an adverse impact on those companies, such as aerospace companies, which routinely have shut downs for one or more weeks at a time. Employees injured on the day prior to shut down would have to be recorded as being injured, off work, for the entire time of the shut down.'' The Texas Chemical Council (Ex. 15: 159) expressed concern about the impact the change to calendar days might have on day counts involving alternative schedules:

> We believe the value of the reduced burden is not worth the skewed data that may result. OSHA's proposal may yield accurate data and better reflect severity when applied to work schedules following an 8 hour day, Monday through Friday. However, many industries utilize a 12 hour shift that provides periods of time off longer than the normal two day weekends. The proposed method of counting days could, for example, turn an injury requiring two days recuperation time into a case requiring four or more days to be counted. This would skew severity analysis utilizing days off data.

However, the Eli Lilly Company (Ex. 15: 434) argued that calendar days would help equalize day counts: ''[a] calendar day count would ensure employer consistency and comparability even when employers have unique and variable shift works.''

Other commenters argued that scheduled workdays are a better measurement because they measure economic impact and lost productivity (see, *e.g.*, Exs. 15: 154, 172, 203, 204, 226, 262, 304, 341, 356, 364, 367, 397). The Fertilizer Institute (Ex. 15: 154) argued that: ''Although such a change might simplify the counting of days, it will make comparisons difficult for companies, trade and professional associations, and government agencies that are trying to measure the severity of injuries and illnesses in terms of productivity. In addition to the health and safety of its employees, industry is primarily concerned with the cost of work-related injuries and illnesses, as they relate to lost productivity. Thus, the basis of the lost work day, not the lost calendar day, is the most appropriate measurement to use.'' The Society of the Plastics Industry, Inc. (Ex. 15: 364) urged OSHA to retain the scheduled days system because of its usefulness in measuring the economic impact of job-related accidents and the incentive such information provides for prevention efforts.

In addition to arguments about the preferred way of counting days away, commenters discussed the issues of

simplification and the burden of counting days away from work with both methods. A number of commenters supported using calendar days because doing so would simplify the process and reduce burden (see, *e.g.*, Exs. 15: 71, 75, 82, 136, 137, 141, 224, 242, 263, 266, 269, 270, 278, 347, 377, 415, 418, 423, 434). Two commenters made the point that using calendar days would make it easier to use computer software to calculate days away from work (Exs. 15: 347, 423). Representative of the comments supporting the use of calendar days to reduce the recording burden was the view of the Ford Motor Company (Ex. 15: 347):

> The single most significant change that could be made to simplify and reduce the burden of the current recordkeeping system would be a change to a calendar count for days away from work. This would eliminate the need to keep track of and subtract out any scheduled days off from the time of the employee's first day away until the time the employee was able to return to work. Of additional importance, a calendar count approach would provide a more accurate reflection of the severity of injuries and illnesses.
>
> Currently, tracking days away from work is a particular problem in that many individuals no longer work a traditional eight hours a day, Monday through Friday. Some individuals work four days a week, ten hours a day, others work every Saturday and/or Sunday, and some individuals have their scheduled days off during the week. Different employees in the same establishment commonly have different work schedules. Different departments are commonly on ''down time'' while the rest of the establishment may be in full operation. A calendar count will simplify the calculation of days away from work for alternative work schedules.
>
> In comparison to the current system, a calendar count will provide meaningful, consistent, and useful data, as well as provide an accurate reflection of severity. The calendar day count will also enhance the ability to develop software to standardize the recordkeeping process.
>
> In addition, the change to a calendar day count would enable Ford Motor Company to free up highly trained personnel for more productive and effective pursuits rather than tracking lost workdays under the current system. The cost of these resources to track lost workdays cases exceeds one million dollars per year.

Even some of the commenters who argued against OSHA's adoption of a calendar day approach in the final rule acknowledged that counting calendar days would be simpler but emphasized that this added simplicity and reduction in burden would not offset the deleterious effect of this change on the data (see, *e.g.*, Exs. 15: 44, 61, 69, 121, 154, 159, 170, 195). The Institute for Interconnecting and Packaging Electronic Circuits (IPC) said that: ''According to IPC member companies, the potential simplification gains that may be achieved by this proposal would not outweigh the gross overreporting and, therefore, inaccurate data that would result'' (Ex. 15: 69).

Other commenters arguing against calendar days stated that counting scheduled workdays is not difficult or onerous (see, *e.g.*, Exs. 15: 107, 146, 387), that counting calendar days would not simplify the counting of lost workdays (see, *e.g.*, Exs. 15: 16, 119, 146, 281, 299, 304, 308, 341, 364, 367, 424), that counting calendar days would add to the administrative burden (see, *e.g.*, Exs. 15: 42, 146, 304, 308, 341, 364, 367, 431), that counting calendar days would add confusion (see, *e.g.*, Exs. 15: 204, 431), or that employers already report scheduled workdays to workers' compensation and thus this information is already available (see, *e.g.*, Exs. 15: 367, 384). Commenters also cited the need to change computer software systems if a shift to calendar days was made (Ex. 15: 122) and argued that retaining scheduled workdays would require less training than moving to calendar days (see, *e.g.*, Exs. 15: 37, 122, 133, 304, 384). The BF Goodrich Company (Ex. 15: 146) summed up these views:

> BF Goodrich's business systems are set up to count and track work days and work hours. We do not agree with the suggestion of counting calendar days rather than actual work days for Days Away From Work cases. Counting calendar days would improperly inflate the severity incidence rates which are calculated based on actual hours worked and defeat any efforts to perform trend analysis against previous years. Use of calendar days would also require unnecessary analysis of work capability for days that would not be worked anyway. There would be no reduction in burden in a calendar day system and there would be loss of severity trend analysis capability.

A number of commenters pointed to the difficulty of analyzing days away for injuries that occur just before scheduled time off, such as before the weekend (see, *e.g.*, Exs. 15: 16, 42, 44, 69, 79, 130, 179, 226, 281, 299, 341, 363, 389, 414, 424). The Institute for Interconnecting and Packaging Electronic Circuits (IPC) described the following scenario:

> [i]f a worker is injured on Friday, is sent home, and returns to work on Monday, the alternative [calendar day] proposal would require employers to count weekend days in the lost workday count. IPC believes that this alternative proposal would not accurately reflect the severity of the injury since, if the same injury had occurred on a Monday, the worker might have been able to return to work on Tuesday. (Ex. 15: 69)

United Parcel Service (UPS) was concerned about the accuracy of employee reporting of injuries and illnesses under the calendar day system:

> [t]he cessation of the effects of an employee's injury or illness cannot reliably be determined in the case of a worker who ''heals'' on the weekend. Thus, the number of days away from work and their impact on the perception of serious incidents will be substantially inflated. Indeed, it has been UPS's experience that a disproportionate number of injuries are reported on Friday and Monday; inclusion of claimed weekend injury, therefore, would greatly inflate OSHA statistics with factors that honest observers know to be linked, to some degree, with the universal attraction of an extended weekend. The risk, moreover, is not merely inflated numbers, but inflation of the apparent severity of those conditions that are difficult to verify and that are therefore the most likely resort of employees who would misreport a condition for time off (Ex. 15: 424).

Another issue noted by commenters was the difficulty of getting medical attention over the weekend. For example, the American Ambulance Association (Ex. 15: 226) cautioned that ''The common practice of a health care provider is to defer an employee's return to work until after a weekend or holiday, due to limited staff resources for evaluating employee status on those days,'' and the Sandoz Corporation (Ex. 15: 299) noted that ''This change [to calendar days] would lead to overstatement of the severity in cases of part-time employees due to the difficulty of getting return-to-work clearance from medical personnel.''

Two commenters (Exs. 15: 69, 15: 363) objected to counting calendar days based on a belief that counting these days would raise their workers' compensation insurance rates. For example, the Institute for Interconnecting and Packaging Electronic Circuits (IPC) stated that ''Lost time is a major factor in insurance premiums for facilities. As a result, a definition that would over-estimate lost time would significantly raise facility insurance costs'' (Ex. 15: 69).

Patrick R. Tyson, a partner in the law firm of Constangy, Brooks & Smith, LLC (Ex. 55X, pp. 99–100), strongly favored moving to a calendar-day-count system, for the following reason:

> [w]hat we've seen in some audits is companies that attempt to try to control the number of days that would be counted as lost work days by controlling the number of days that otherwise would be worked.* * *
>
> We * * * encountered one company that announced proudly in its newsletter that one particular employee should be congratulated because when she had to have surgery for carpal tunnel syndrome, clearly work related * * * she chose to have that surgery during

her vacation so that the company's million man hours of work without a lost time accident would not be interrupted. That doesn't make any sense where we encourage those kinds of things * * * We ought to consider a calendar count if only to address those kinds of situations. I understand that would cause problems with respect to those companies who use lost work days as a measure of the economic impact of injuries and illnesses in the workplace, but I suspect that a better measure of that would be worker's compensation. If it's a lost work day, you're going to pay comp on it. * * *

OSHA agrees with some of the points made by those in favor of, and those opposed to, changing over to calendar day counts. After a thorough review of the arguments for each alternative, however, OSHA has decided to require employers to count calendar days, both for the totals for days away from work and the count of restricted workdays. OSHA does not agree with those commenters who argued that the counting of calendar days away from work would be a significant burden. The Agency finds that counting calendar days is administratively simpler than counting scheduled days away and thus will provide employers who keep records some relief from the complexities of counting days away from work (and days of restricted work) under the old system. For the relatively simple injury or illness cases (which make up the great majority of recorded cases) that involve a one-time absence from work of several days, the calendar-day approach makes it much easier to compare the injury/illness date with the return-to-work date and compute the difference. This process is easier than determining each employee's normal schedule and adjusting for normal days away, scheduled vacations, and days the facility was not open. The calendar method also facilitates computerized day counts. OSHA recognizes that, for those injuries and illnesses that require two or more absences, with periods of work between, the advantages of the calendar day system are not as significant; OSHA notes, however, that injuries and illnesses following this pattern are not common.

Changing to a calendar day counting system will also make it easier to count days away or restricted for part-time workers, because the difficulties of counting scheduled time off for part-time workers will be eliminated. This will, in turn, mean that the data for part-time workers will be comparable to that for full-time workers, i.e., days away will be comparable for both kinds of workers, because scheduled time will not bias the counting method. Calendar day counts will also be a better measure of severity, because they will be based on the length of disability instead of being dependent on the individual employee's work schedule. This policy will thus create more complete and consistent data and help to realize one of the major goals of this rulemaking: to improve the quality of the injury and illness data.

OSHA recognizes that moving to calendar day counts will have two effects on the data. First, it will be difficult to compare injury and illness data gathered under the former rule with data collected under the new rule. This is true for day counts as well as the overall number and rate of occupational injuries and illnesses. Second, it will be more difficult for employers to estimate the economic impacts of lost time. Calendar day counts will have to be adjusted to accommodate for days away from work that the employee would not have worked even if he or she was not injured or ill. This does not mean that calendar day counts are not appropriate in these situations, but it does mean that their use is more complicated in such cases. Those employers who wish to continue to collect additional data, including scheduled workdays lost, may continue to do so. However, employers must count and record calendar days for the OSHA injury and illness Log.

Thus, on balance, OSHA believes that any problems introduced by moving to a calendar-day system will be more than offset by the improvements in the data from one case to the next and from one employer to another, and by the resulting improvements in year-to-year analysis made possible by this change in the future, i.e., by the improved consistency and quality of the data.

The more difficult problem raised by the shift to calendar days occurs in the case of the injury or illness that results on the day just before a weekend or some other prescheduled time off. Where the worker continues to be off work for the entire time because of the injury or illness, these days are clearly appropriately included in the day count. As previously discussed, if a physician or other licensed health care professional issues a medical release at some point when the employee is off work, the employer may stop counting days at that point in the prescheduled absence. Similarly, if the HCP tells the injured or ill worker not to work over the scheduled time off, the injury was severe enough to require days away and these must all be counted. In the event that the worker was injured or became ill on the last day before the weekend or other scheduled time off and returns on the scheduled return date, the employer must make a reasonable effort to determine whether or not the employee would have been able to work on any or all of those days, and must count the days and enter them on the Log based on that determination. In this situation, the employer need not count days on which the employee would have been able to work, but did not, because the facility was closed, or the employee was not scheduled to work, or for other reasons unrelated to the injury or illness.

Accordingly, the final rule adopts the counting of calendar days because this approach provides a more accurate and consistent measure of disability duration resulting from occupational injury and illness and thus will generate more reliable data. This method will also be easier and less burdensome for employers who keep OSHA records and make it easier to use computer programs to keep track of the data.

Capping the Count of Lost Workdays

OSHA proposed to limit, or cap, the total number of days away from work the employer would be required to record. This would have been a departure from OSHA's former guidance for counting both days away from work and restricted workdays. The former rule required the employer to maintain a count of lost workdays until the worker returned to work, was permanently reassigned to new duties, had permanent work restrictions, or was terminated (or retired) for reasons unrelated to the workplace injury or illness (Ex. 2, pp. 47–50).

OSHA's proposed regulatory text stated that ''[f]or extended cases that result in 180 or more days away from work, an entry of ''180'' or ''180+'' in the days away from work column shall be considered an accurate count'' (61 FR 4058). In the preamble to the proposal, OSHA explained that day counts of more than 180 days would add negligible information for the purpose of injury and illness case analysis but would involve burden when updating the OSHA records. The proposed preamble also asked several questions: ''Should the days away from work be capped? Is 180 days too short or long of a period? If so, should the count be capped at 60 days? 90 days? 365 days? or some other time period?'' (61 FR 4033)

A large number of commenters supported a cap on day counts (see, *e.g.*, Exs. 21; 27; 33; 51; 15: 26, 67, 72, 82, 85, 89, 95, 105, 108, 111, 119, 120, 121, 127, 132, 133, 136, 137, 141, 146, 153, 159, 170, 173, 176, 180, 182, 185, 188, 194, 195, 198, 199, 203, 205, 213, 224, 231, 233, 239, 242, 260, 262, 263, 265, 266, 269, 270, 271, 273, 278, 283, 287, 288, 289, 297, 298, 301, 304, 307, 310,

316, 317, 321, 332, 334, 335, 336, 341, 345, 346, 347, 348, 351, 368, 373, 374, 375, 377, 378, 384, 385, 387, 389, 390, 392, 397, 401, 404, 405, 434, 437, 440, 442). The most common argument was that capping the counts would reduce the burden on employers (see, *e.g.*, Exs. 21; 33; 15: 82, 95, 111, 146, 154, 159, 170, 176, 182, 188, 213, 231, 260, 262, 265, 273, 288, 289, 297, 301, 304, 305, 310, 341, 345, 346, 373, 389, 390, 401, 442) and simplify the OSHA recordkeeping system (see, *e.g.*, Exs. 21; 15: 188, 297, 373). Several commenters argued that such a change would produce a ''significant'' reduction in burden and cost (see, *e.g.*, Exs. 15: 154, 159, 203, 297). The Miller Brewing Company comment (Ex. 15: 442) was representative: ''We endorse this cap on the days away from work (DAFW) calculation. Once a case reaches 180 days, it is clearly recognized as a serious case. The requirement to calculate days away from work beyond 180 is a time consuming administrative exercise which provides no value-added information relative to the severity of a given case. Again, we support this rule change and OSHA's attempt to simplify the recordkeeping process.''

Commenters also pointed out that limiting the day counts would make it easier to count days for cases that span two calendar years (see, *e.g.*, Exs. 15: 153, 194, 195, 289). Other commenters stated that it was difficult to modify the former year's records (Ex. 15: 153) and that the day count cap would ease the burden of tracking cases that span two calendar years (Ex. 15: 289).

Several commenters stated that the benefits of recording extended day counts were insignificant (see, *e.g.*, Exs. 15: 111, 159, 176, 184, 260, 262, 265, 288, 297, 373, 401, 430, 434, 442), that they added negligible information for case analysis or safety and health program evaluation (Ex. 15: 434), and that there was no ''value added information'' from high day counts (see, *e.g.*, Exs. 15: 260, 262, 265, 401, 442). Others stated that capping the day counts would provide ''adequate data'' (see, *e.g.*, Exs. 15: 111, 159, 304, 345) and that there would be no loss of significant data for analysis (see, *e.g.*, Exs. 15: 170, 184, 297, 341, 373). The McDonnell Douglas Corporation (Ex. 15: 297) argued that a cap ''[w]ould allow industry to avoid the significant and costly paperwork burdens associated with tracking lost workdays, without any appreciable reduction in OSHA's ability to identify significant workplace injuries and illnesses or to assure continuing improvement in workplace safety and health.''

Support for capping the count of days away from work was not unanimous, and several commenters opposed a day count cap (see, *e.g.*, Exs. 15: 31, 62, 197, 204, 225, 277, 294, 302, 350, 359, 369, 379). The National Safety Council stated that ''[n]o cap on counting lost workdays is necessary provided that the count automatically ends with termination, retirement, or entry into long-term disability. Only a small proportion of cases have extended lost workday counts so there is little additional recordkeeping burden. The additional information gained about long-term lost workday cases is important and keeps employers aware of such cases'' (Ex. 15: 359). Other commenters stressed that it was important to obtain an accurate accounting of days away to assess the severity of the case (see, *e.g.*, Exs. 15: 294, 379, 429, 440), that the counts were needed to make these cases visible (see, *e.g.*, Exs. 15: 294, 440), and that the counts demonstrate the impact of long term absences (Ex. 15: 62). For example, the Boeing Company (Ex. 15: 294) argued that

> If the count is suspended after 180 days (or any other arbitrary number), an employer will lose valuable information regarding the true amount of lost work days and their associated costs. The experience of The Boeing Company indicates that there are a small number of cases that have many more than 180 days. The result is a disproportionate amount of total costs. Not having visibility of these cases would be a mistake.

The United Steelworkers of America (USWA) offered several reasons for not adopting a day count cap: ''The USWA also strongly opposes capping lost work day cases at 180. We believe that no cap is necessary or desirable. Only a very small proportion of cases have extended lost workdays recorded so there is little additional recordkeeping burden. The additional information gained about long-term lost workday cases is important in evaluating the severity of the injury and it keeps attention on such cases'' (Ex. 15: 429).

The International Brotherhood of Teamsters (IBT) opposed the capping of day counts on the basis that the OSH Act requires ''accurate'' records, stating that:

> The IBT opposes the elimination of counting the days of restricted work activity and opposes capping the count of ''days away from work'' at 180 days. The IBT uses the restricted work activity day count to gauge the severity of an injury or illness. We are supported by the OSH Act, section 24(a) ''the Secretary shall compile accurate statistics on work injuries and illnesses which shall include all disabling, serious, or significant injuries or illnesses. * * *. The International Brotherhood of Teamsters maintains that the recording of restricted work activity day counts and counting of days away from work enables OSHA to compile accurate data on serious and significant injuries. (Ex. 15: 369)

After a review of the evidence submitted to the record, OSHA has decided to include in the final rule a provision that allows the employer to stop counting days away from work or restricted workdays when the case has reached 180 days. OSHA's primary reason for this decision is that very few cases involve more than 180 days away or days of restricted work, and that a cap of 180 days clearly indicates that such a case is very severe. Continuing to count days past the 180-day cap thus adds little additional information beyond that already indicated by the 180-day cap.

Selection of the Day Count Cap

A large number of commenters specifically supported the 180 day cap proposed by OSHA (see, *e.g.*, Exs. 51; 15: 26, 27, 67, 70, 89, 111, 121, 127, 136, 137, 141, 153, 154, 159, 170, 176, 184, 224, 233, 242, 260, 262, 263, 265, 266, 269, 270, 278, 283, 288, 298, 316, 335, 341, 368, 377, 385, 401, 404, 423, 430, 437, 442). The Chemical Manufacturers Association (CMA) stated that ''CMA supports the use of a cap on the number of days away from work that must be counted. Once an employee misses more than 180 days from work * * * due a workplace injury or illness, the relative seriousness of the incident is determined and little benefit is derived from continuing to count the number of days for OSHA's recordkeeping system.'' The Fertilizer Institute (Ex. 15: 154) supported 180 days because it ''is consistent with most corporate long-term disability plans.''

Many commenters who supported a cap on counting days away recommended that OSHA adopt a number of days other than 180 (see, *e.g.*, Exs. 21; 37; 15: 60, 71, 75, 82, 85, 105, 108, 119, 122, 132, 180, 182, 185, 188, 194, 195, 198, 199, 203, 213, 239, 246, 271, 272, 287, 289, 297, 303, 304, 305, 307, 308, 317, 336, 347, 348, 351, 375, 378, 384, 385, 404, 405, 407, 409, 410, 414, 425, 431, 434). The most common argument against capping at 180 days was that a few very serious cases would skew the statistical data (see, *e.g.*, Exs. 15: 75, 180, 246, 271, 385, 409). Hoffman-La Roche, Inc. argued for 90 days on the grounds that ''90 days is more than sufficient to get a read on the severity of the injury/illness. This would enable employers to obtain meaningful data that is not skewed by one or two cases'' (Ex. 15: 271).

Commenters suggested a number of alternatives, including 30 days (see, *e.g.*, Ex. 15: 414); 60 days (see, *e.g.*, Exs. 15: 60, 108, 119, 194, 203, 246, 287, 405); 60 or 90 (Ex. 15: 407); 90 days (see, *e.g.*, Exs. 21; 15: 75, 85, 105, 132, 182, 185, 239, 271, 272, 289, 297, 303, 317, 336, 347, 378, 409, 410, 425, 431); 50 to 100 days (see, *e.g.*, Exs. 37; 15: 384); 90 to 120 days (Ex. 15: 71); 90 or 180 days (Ex. 15: 434); 120 days (Ex. 15: 198); the equivalent of six months (see, *e.g.*, Exs. 15: 82, 188, 199, 213, 304, 307, 308, 351, 375); one year (Ex. 15: 122); and 60 days after the beginning of the new year (see, *e.g.*, Ex. 15: 195).

The most common alternative recommended by commenters was 90 days (see, *e.g.*, Exs. 21; 15: 75, 85, 105, 132, 182, 185, 239, 271, 272, 289, 297, 303, 317, 336, 347, 378, 409, 410, 425, 431). These commenters argued that 90 days would reduce the burden without a loss of information (see, *e.g.*, Exs. 15: 75, 85, 239, 297, 425), that 90 days is sufficient to determine severity (see, *e.g.*, Exs. 15: 85, 105, 271 272, 289, 303, 410), that 90 days matches existing labor agreements (see, *e.g.*, Exs. 15: 378), and that 90 days limits the problems caused by a case that extends over 2 years (see, *e.g.*, Exs. 15: 407, 431).

NIOSH (Ex. 15: 407) commented that:

NIOSH agrees with OSHA that ''day counts greater than 180 days add negligible information while entailing significant burden on employers when updating OSHA records.'' Therefore, NIOSH agrees with the concept of capping the count of days away from work at a maximum of 180 days, and recommends that OSHA also consider caps of 60 or 90 days away from work.

Currently, the Annual Survey of Occupational Injuries and Illnesses reports distributional data for the number of days away from work and the median number of days away from work for demographic (age, sex, race, industry, and occupation) and injury/illness (nature, part of body, source, and event) characteristics. The largest category of days away from work reported by the BLS for days away from work is ''31 days or more.'' In 1992, the Annual Survey reported median days away from work that ranged from 1 day to 236 days [U.S. Department of Labor 1995]. For most demographic and injury/illness categories, capping the count of days away from work at 180 days will not alter the values for either the percent of injuries in the ''31 days or more'' category or median days away from work.

OSHA may wish to consider capping the count of days away from work at either the 60 or the 90 day level. Employers could be instructed to enter a value of 61+(or 91+) to indicate that the recorded injury or illness condition existed beyond the cap on the count of days away from were based on the 1992 Annual Survey data, no reported industry and only one reported occupation had a median of greater than 60 days (dental hygienist, median = 71). There was also a very small number of injury/illness characteristics with medians between 60 and 90 days or with medians exceeding 90 days. Eleven of the 13 instances in which the median exceeded 60 days away from work were based on distributions involving a small number of estimated cases i.e., only 100 to 400 nationally. Capping the count of days away from work at either 60 or 90 days would still allow the reporting of the proportion of cases involving days away from work in the ''31 days or more category'' that is currently being reported by the BLS. A minor limitation of capping the count of days away from work at 60 or 90 days is that for a very small number of characteristics, the median would have to be reported as exceeding the cap.

Two commenters suggested that OSHA use months instead of days as the measurement (Exs. 15: 304, 404), and a number of commenters pointed out that OSHA's proposed 180 days should be 125 if based on 6 months of actual workdays instead of calendar days (see, *e.g.*, Exs. 15: 199, 213, 307, 308, 348).

After careful consideration, OSHA has decided to cap the day counts at 180 days and to express the count as days rather than months. The calendar month is simply too large and unwieldy a unit of measurement for this purpose. The calendar-day method is the simplest method and will thus produce the most consistent data.

OSHA has decided to cap the counts at 180 days to eliminate any effect such capping might have on the median days away from work data reported by BLS. This cap will continue to highlight cases with long periods of disability, and will also reduce the burden on employers of counting days in excess of 180. Using a shorter threshold, such as 90 or even 120 days, could impact the injury and illness statistics published by the BLS, and could thus undermine the primary purpose of this regulation: to improve the quality and utility of the injury and illness data. Using a shorter time frame would also make it harder to readily identify injuries and illnesses involving very long term absences. The rule also does not require the employer to use the designation of 180+ or otherwise require cases extending beyond 180 days to be marked with an asterisk or any other symbol, as suggested by various commenters (see, *e.g.*, Exs. 15: 31, 62, 153, 289, 374, 407, 425). Employers who wish to attach such designations are free to do so, but OSHA does not believe such designations are needed.

Counting Lost Workdays When Employees Are No Longer Employed by the Company

The proposed rule contained a provision that would have allowed the employer to stop counting the days away from work when the worker was terminated for reasons unrelated to an injury or illness (61 FR 4058). This provision would have continued OSHA's former policy on this matter, which allowed the employer to stop counting days away or restricted workdays when the employee's employment was terminated by retirement, plant closings, or like events unrelated to the employee's work-related injury or illness (Ex. 2, pp. 49, 50). The final rule, at paragraph 1904.7(b)(3)(vii), permits employers to stop counting days away if an injured or ill employee leaves employment with the company for a reason unrelated to the injury or illness. Examples of such situations include retirement, closing of the business, or the employee's decision to move to a new job.

Paragraph 1904.7(b)(3)(vii) also requires employers whose employees have left the company because of the injury or illness to make an estimate of the total days that the injured or ill employee would have taken off work to recuperate. The provisions in paragraph 1904.7(b)(3)(vii) also apply to the counting of restricted or transferred days, to ensure that days are counted consistently and to provide the simplest counting method that will collect accurate data. OSHA's reasoning is that day counts continue to be relevant indicators of severity in cases where the employee was forced to leave work because of the injury or illness.

Handling Cases That Cross Over From One Year to the Next

A special recording problem is created by injury and illness cases that begin in one year but result in days away from work or days of restricted work in the next year. Under the former rule, the employer was to record the case once, in the year it occurred, and assign all days away and restricted days to that case in that year (Ex. 2, p. 48). Under the rule being published today, this policy still applies. If the case extends beyond the time when the employer summarizes the records following the end of the year as required by § 1904.32, the employer is required by paragraph 1904.7(b)(3)(viii) to update the records when the final day count is known. In other words, the case is entered only in the year in which it occurs, but the original Log entry must subsequently be updated if the day count extends into the following year.

In addition to the NIOSH (Ex. 15: 407) comments on the day counts summarized above, the Society for Human Resource Management (Ex. 15: 431) urged OSHA to adopt a lower day

count cap to limit the ''crossover'' problem. Two commenters urged OSHA to take a new approach to cases that extend over two or more years. Both the Laborers' Health & Safety Fund of North America (Ex. 15: 310) and the Service Employees International Union (Ex. 15: 379) recommended that these cases be recorded in each year, with the days for each year assigned to the appropriate case. The Laborers' Health & Safety Fund of North America (Ex. 15: 310) stated:

> One concern with a large number of days away from work is how to record the lost days which begin in one calendar year and end in a following calendar year. We suggest that it is best to record the number of days lost from the date of the injury to the end of the calendar year, and to enter the injury again on the following year's OSHA 300 with the remaining days of lost time up to the 180 day maximum. A box should be available to indicate that the entry is a continuation from the prior year.

As stated earlier, OSHA has decided on the 180 day cap for both days away and days of restricted work cases to ensure the visibility of work-related injuries and illnesses with long periods of disability. The final rule also requires the employer to summarize and post the records by February 1 of the year following the reference year. Therefore, there will be some cases that have not been closed when the records are summarized. Although OSHA expects that the number of cases extending over two years will be quite small, it does not believe that these cases warrant special treatment. A policy that would require the same case to be recorded in two years would result in inaccurate data for the following year, unless special instructions were provided. Accordingly, the final rule requires the employer to update the Log when the final day count is known (or exceeds 180 days), but to record the injury or illness case only once. This approach is consistent with OSHA's longstanding practice and is thus familiar to employers.

Miscellaneous Day Counting Issues

Two commenters provided additional comments for OSHA to consider on the issue of counting days away from work. The Laborers' Health & Safety Fund of North America (Ex. 15: 310) recommended that OSHA require employers to enter a count of 365 days away from work on the Log for any fatality case:

> In a recent project we used OSHA 200 data from road construction and maintenance employers to determine the causes and relative severities of serious injuries. The number of lost workdays plus restricted work activity days for an injury event or type was used as a measure of severity. In quite a few individual injury cases, the number of days away from work entry was not available because of the severity of the injury or because the injury resulted in a fatality. For recordkeeping purposes, we would suggest a maximum cap of 180 days for a non-fatal serious injury of long duration, and an automatic entry of 365 for fatalities. Using this method, the most severe cases would be weighted appropriately, with fatalities carrying the heaviest weight. Also, entering a lost workday number for fatalities would enable fatalities to count in a single and simple ''severity-weighted Lost Work Day Injury and Fatality (LWDIF) rate''.

OSHA has not adopted the Laborers' Health & Safety Fund of North America recommendation. OSHA believes that fatalities must be considered separately from non-fatal cases, however severe the latter may be. When an employee dies due to a work-related injury or illness, the outcome is so severe and so important that it must be treated separately. Merging the two types of cases would diminish the importance of fatality entries and make the days away data less useful for determining the severity of days away injury cases. Accordingly, the final rule being published today does not reflect this recommendation.

The Westinghouse Corporation (Ex. 15: 405) suggested that OSHA look at days of hospitalization as a measure of severity, stating ''[t]he number of days hospitalized does provide a more objective indication of the seriousness of injury or illness, if for no other reason than cost control by insurance companies. If OSHA can document a legitimate use for an indicator of the ''seriousness'' of an injury, it may want to consider hospital stay time.'' OSHA has considered the use of hospitalized days, but has rejected them as a measure of injury or illness severity. Although these day counts may be a reasonable proxy for severity, they are applicable only in a relatively small number of cases.

Paragraph 1904.7(b)(4) Restricted Work or Transfer to Another Job

Another class of work-related injuries and illnesses that Section 8(c) of the Act identifies as non-minor and thus recordable includes any case that results in restriction of work or motion[2] or transfer to another job. Congress clearly identified restricted work activity and job transfer as indicators of injury and illness severity.

In the years since OSHA has been enforcing the recordkeeping rule, however, there has been considerable misunderstanding of the meaning of the term ''restricted work,'' and, as a result, the recording of these cases has often been inconsistent. The Keystone Report (Ex. 5), which summarized the recommendations of OSHA stakeholders on ways to improve the OSHA recordkeeping system, noted that restricted work was perhaps the least understood of the elements of the system.

This section of the Summary and Explanation first discusses the former recordkeeping system's interpretation of the term restricted work, describes how the proposed rule attempted to revise that interpretation, and then summarizes and responds to the comments OSHA received on the proposed approach to the recording of work restriction and job transfer cases. Finally, this section explains the final rule's restricted work and job transfer requirements and OSHA's reasons for adopting them.

The Former Rule

The former recordkeeping rule did not include a definition of restricted work or job transfer; instead, the definition of these terms evolved on the basis of interpretations in the BLS *Guidelines* (Ex. 2, p. 48). The *Guidelines* stated that restricted work cases were those cases ''where, because of injury or illness, (1) the employee was assigned to another job on a temporary basis; or (2) the employee worked at a permanent job less than full time; or (3) the employee worked at his or her permanently assigned job but could not perform all the duties connected with it.'' The key concepts in this interpretation were that work was to be considered restricted when an employee experienced a work-related injury or illness and was then unable, as a result of that injury or illness, to work as many hours as he or she would have been able to work before the incident, or was unable to perform all the duties formerly connected with that employee's job. ''All duties'' were interpreted by OSHA as including any work activity the employee would have performed over the course of a year on the job.

OSHA's experience with recordkeeping under the former system indicated that employers had difficulty with the restricted work concept. They questioned the need for keeping a tally of restricted work cases, disagreed with the ''less than full time'' concept, or

[2] The term *restricted motion* has been interpreted to mean restricted work motion and to be essentially synonymous with *restricted work.* OSHA does not distinguish between the two terms. OSHA's former *Guidelines* (Ex. 2, p. 43) clearly stated that a restriction of work or motion, such as that resulting from a bandaged finger, that did not also impair work was not recordable, and that is also the interpretation of the final rule.

were unsure about the meaning of ''all the duties connected with [the job].'' (In OSHA's experience, employers have not generally had difficulty understanding the concept of temporary job transfer, which are treated in the same way as restricted work cases for recordkeeping purposes. The following discussion thus focuses on restricted work issues.) The changes OSHA proposed to make to the work restriction concept (61 FR 4033) were intended to address these employer concerns.

The Proposed Rule

The proposal would have changed restricted work recordkeeping practices markedly. For example, the proposal would have required employers to acknowledge that the case involved restricted work by placing a check in the restricted work column on the Log but would no longer have required them to count the number of restricted work days associated with a particular case. At the time of the proposal, OSHA believed that dropping the requirement to count restricted days was appropriate because the Agency lacked data showing that restricted work day counts were being used by employers in their safety and health programs. In addition, the proposal would have limited the work activities to be considered by the employer in determining whether the injured or ill worker was on restricted work. Under the former rule, employers had to consider whether an injured or ill employee was able to perform ''all the duties'' normally connected with his or her job when deciding if the worker's job was restricted; OSHA interpreted ''all the duties'' to include any work activity the employee performed at any time within a year. Under the proposal, the duties that the employer would have been required to consider were narrowed to include only (1) those work activities the employee was engaged in at the time of injury or illness onset, or (2) those activities the employee would have been expected to perform on that day (61 FR 4059). OSHA also requested comment in the proposal on the appropriateness of limiting the activities to be considered and on other definitions of work activities that should be considered, *e.g.*, would it be appropriate not to consider an employee to be on restricted work if he or she is able to perform any of his or her former job activities? (61 FR 4059).

Comments on the Proposed Rule's Restricted Work and Job Transfer Provisions

The comments OSHA received on these provisions were extensive. Commenters offered a wide variety of suggestions, including that OSHA eliminate restricted work activity cases from the recordkeeping system altogether, that the proposed definition of restricted work activity be changed, that the proposed approach be rejected, that it be adopted, and many other recommendations. These comments are grouped under topic headings and are discussed below.

Eliminate the Recording of Restricted Work Cases

Several commenters recommended that OSHA completely eliminate the recording of restricted work cases because, in the opinion of these commenters, the concept confused employers, created disincentives to providing light duty work or return-to-work programs, and provided no useful information (see, *e.g.*, Exs. 15: 119, 203, 235, 259, 336, 414, 427). For example, the American Bakers Association said, ''We believe that the concept and definitions of 'restricted work activity' should be eliminated. That term and its proposed definition is so ambiguous as to be unworkable, and information gleaned from that terminology would have little reliability or usefulness'' (Ex. 15: 427).

The National Grain and Feed Association agreed, arguing that the recording of restricted work cases should be eliminated on the following grounds:

> [w]e agree with the conclusion of the Keystone Report that ''the recording of restricted work is perhaps the least understood and least accepted concept in the recordkeeping system.'' We disagree with OSHA, however, that the concept of restricted work is meaningful. For example, there is a wide range of restrictions that may be placed on an injured employee's activity after returning to work depending on the nature of the injury (*e.g.*, the range of work possible for an employee who has experienced a slight sprain versus an employee with a broken bone). Additionally, the concept of restricted work is greatly dependent on individual employee motivation and job description. * * * Importantly, we believe the concepts embodied in the proposed restricted work definition run counter to modern work practices that encourage workers to return to productive work at the worksite. Workers who have experienced minor injuries on the job can return to productive work under employer ''return-to-work'' programs. For this reason, the concept of restricted work is arbitrary and ultimately of little use to either evaluating the effectiveness of an employer's safety and health programs or determining the exposure of workers to a hazard at a specific worksite. We, therefore, recommend that the Agency delete the category of restricted work injuries from the proposed changes to 29 CFR 1904. Removal of this section will simplify the recordkeeping system and make it more ''user friendly.'' We support deletion of this category of injury because we think it will make the system more complex and is inconsistent with current practices of returning employees back to productive work at the earliest date (Ex. 15: 119).

Revise the Proposed Definition of a Restricted Work Case

Most of the remaining comments recommended either that the definition of restricted work in the final rule be revised to include a more inclusive set of job activities or functions or a less inclusive set. For example, the Small Business Administration (Ex. 51) was concerned that:

> [t]he new definition for classifying ''restricted work activity'' could increase the number of cases that would be subject to this standard, and subsequently, classified as a recordable incident. Small businesses would face increased recordkeeping. Under the proposed definition, a case would be determined as a ''restricted work activity'' if the employee cannot perform what he or she was doing at the time of the illness or injury, or he or she could not perform the activities scheduled for that day. While this would be a very simple method, it would encompass more recordable incidents. Many workers have a myriad of tasks associated with their job. If an employee can return to work and perform functions within their job description, this should not be considered ''restricted work activity''. * * *

Several commenters recommended that OSHA rely on a definition of restricted work that would focus on ''non productive work'' and exclude the recording of any case where the employee was still productive (see, *e.g.*, Exs. 15: 9, 45, 46, 67, 80, 89, 247, 437). For example, Countrymark Cooperative, Inc. (Ex. 15: 9) stated:

> [w]e disagree with a portion of the definition for restricted work activity. We agree that this should include injuries or illnesses where the worker is not capable of performing at full capacity for a full shift. However, by addressing the task that they were engaged in at the time of the injury will create problems. Most employees today have numerous assignments and responsibilities. They move from one task to another during a given day and during a given week. What they are doing at the time they are injured may not be the assignment for the next day or the next week. In these cases, they may be back at work in a fully productive role, but not doing the same task as when they were hurt. If they are performing a fully productive role within the same job description, but cannot perform the role of the job they were doing at the time, they should not be penalized. In many cases, this job task may not be active at the time they return. * * * It should be very clear that the ability to return an employee to a productive role (whether 50% or 100%) is extremely important to any ''Return-to-Work'' Program. If that person is returned to work and is

performing at full capacity in a given task within their job description, this should not be recorded unless it meets other criteria such as medical treatment. If we return to the days of recording these and penalizing the employer, they may be inclined to return to the days of only allowing employees to return to work when they are 100% in all given tasks within their job description. If this occurs, we all lose. * * * We do agree that any time an employee is returned to work and is restricted to only perform certain jobs, can only return for a limited duration, or must be reassigned to another task, this should be recorded as a restricted work case (Ex. 15: 9).

Others recommended that OSHA adopt the Keystone Report's definition of restricted work (see, *e.g.*, Exs. 15: 123, 129, 145, 225, 359, 379, 418). For example, the National Safety Council recommended:

[t]he concept of restricted work activity as described on page 4046 [of the **Federal Register**] is one with which the Council concurs, but the specific wording in proposed section 1904.3 is less clear. The colon following the opening clause of the definition ''at full capacity for a full shift:'' seems to mean that the employee must be able to perform the task during which he/she was injured and the other tasks he/she performed or would have performed that day not only for the normal frequency or duration, but ''at full capacity for a full shift.'' For example, if the employee were required to open a valve at the start of a shift and close it at the end of the shift, the current wording seems to say that if the employee could not spend the entire shift opening and closing the valve, then his/her work activity is restricted. * * * The Council also believes that the concept of restricted work activity as formulated by the Keystone Report is appropriate in that it represents a consensus among the various stakeholder groups. For this reason, we also recommend that the task limitations refer to the week's activities rather than the day's activities (Ex. 15: 359).

The Union of Needletrades, Industrial and Textile Employees (UNITE) agreed with the National Safety Council that a different time period should be used in determining what job activities to consider. UNITE suggested that OSHA use the employee's monthly, rather than daily or weekly, duties to define restricted work activity (Ex. 15: 380).

A few commenters expressed concern that use of the proposed restricted work definition could lead employers to include unusual, extraordinary or rarely performed duties in the ''work activities'' to be considered when determining whether a case was a restricted work case (see, *e.g.*, Exs. 15: 80, 247). For example, the Arizona Public Service Company said:

[d]etermining restricted duty days should remain as it currently is in the Guidelines. The restriction should focus on the ability of the employee to perform all or any part of his or her normal job duties. Focusing on what specifically they were doing at the time of injury could incorrectly base this determination on an activity that is performed rarely. Also, focusing on what they were scheduled to do for that week would not be useful for those whose schedules can change daily (Ex. 15: 247).

Adopt the Americans With Disabilities Act Definition of Essential Duties

The Laboratory Corporation of America's comment (Ex. 15: 127) was typical of those of several commenters who suggested that OSHA use the concept of essential job duties that is also used for the administration of the Americans with Disabilities Act (ADA) (see, *e.g.*, Exs. 15: 127, 136, 137, 141, 224, 266, 278, 431):

[t]he definition used by the Americans with Disability Act (ADA) would be very useful here. That definition indicates that restricted work exists if an employee is unable to perform the essential functions of his/her job. Since these essential functions are identified in the employee's job description, the employer would have a consistent ''yardstick'' with which to make this determination for each employee.

Adoption of the Proposed Approach Will Lead to Underreporting

Some commenters, such as the AFL–CIO, opposed the proposed approach to restricted work on the grounds that it would result in underreporting:

[w]e believe this proposed provision would entice employers to manipulate records and lead to further under-reporting. We strongly suggest that the Agency adopt the Keystone Report recommendation of restricted work which requires an employer to record if the employee is (1) unable to perform the task he or she was engaged in at the time of injury or onset of illness (task includes all facets of the assignment the employee was to perform); or (2) unable to perform any activity that he or she would have performed during the week (Ex. 15: 418).

Other commenters agreed (see, *e.g.*, Exs. 20, 15: 17, 129, 418). For example, the United Brotherhood of Carpenters (UBC) Health & Safety Fund of North America argued in favor of a broader definition to avoid this problem:

[t]he majority of workers represented by the UBC, such as carpenters and millwrights, routinely perform a wide variety of tasks during their normal workdays in either construction or industrial settings. Therefore, OSHA should not limit the classification of ''restricted work activity'' to either ''the task he or she was engaged in at the time of the injury'' or his or her daily work activity (daily work activity includes all assignments the employee was expected to perform on the day of the injury or onset of illness)'' as proposed. The UBC feels that the current proposal would allow for manipulation of the records and will lead to serious under reporting. Many workplaces have armies of ''walking wounded'' rather than reporting lost or restricted work activity. OSHA should at the very least adopt the position of the Keystone Report which recommended that restricted work activity should be recorded if the employee is ''(1) unable to perform the task he or she was engaged in at the time of the injury or onset of illness, or (2) unable to perform any activity that he or she would have performed during the week.'' The UBC believes that the best definition of restricted work activity would be any illness or injury which inhibits, interferes with, or prevents a worker from performing any or all of the functions considered to be a normal part of his or her trade or occupation as defined in the applicable job description (Ex. 20).

Do Not Count Incidents Involving Only One or a Few Days as Restricted Work

A number of commenters recommended that restricted work activity involving only the day of injury/illness onset should not trigger an OSHA recordable case (see, *e.g.*, Exs. 15: 19, 44, 146, 154, 156, 198, 364, 374, 391). Typical of these comments is one from the Society of the Plastics Industry, Inc.:

[e]mployers have had problems with OSHA's definition of restricted work activity because OSHA's interpretation that having any work restriction, even one which lasts only for the remainder of the shift and which imposes no significant limitations on the employee's ability to perform his or her job, makes a case recordable. OSHA should adopt the administratively simple and common-sense rule that restricted work activity on the day of the case report does not make the case recordable. . . . The definition of ''restricted work activity'' should be clarified to state that the criteria apply only to days following the day of injury or onset of the illness. An employee's inability to work a full shift on the actual date of injury or onset of illness should not require recording as a restricted work case. As noted above, because OSHA's interpretation that having any work restriction, even one which lasts only for the remainder of the shift and which imposes no significant limitations on the employee's ability to perform his or her job, makes a case recordable, many non-serious, non-disabling cases are now recorded. Cases which do not otherwise meet the recordability criteria should not be recordable. Therefore, as recommended above, OSHA should eliminate the current requirement to record cases in which restricted work activity occurs only on the day of the case report (Ex. 15: 364).

The Kodak Company urged OSHA not to count cases involving restrictions lasting only for three days as restricted work cases on the grounds that such cases are ''minor'': ''Restricted work activity allows employers and employees to remain at work. This is a win-win situation for both. Kodak suggests restricted work activity be counted only if the restriction lasts

longer than 3 working days. Hence, only serious cases would be recorded'' (Ex. 15: 322).

Adopt the Proposed Approach

A large number of commenters supported OSHA's proposed definition, however (see, *e.g.*, Exs. 27, 15: 26, 61, 70, 133, 159, 171, 185, 199, 204, 242, 263, 269, 270, 272, 283, 303, 305, 307, 317, 318, 324, 334, 347, 351, 373, 375, 377, 378, 384, 390, 392, 405, 409, 413, 425, 430). Typical of these were comments from the New Jersey Department of Labor (Ex. 15: 70), which commented:

[p]roviding a clear definition of what constitutes restricted work and an item to indicate that an injured employee has been shifted to restricted work activity should improve the accuracy and completeness of case reporting. Identifying the actual number of cases in which employees are shifted to alternate work, which are thought to be under reported, and adding the date when the employee returned to his/her usual work will help to assess the impact of these incidents.

The American Petroleum Institute, which believed that the proposed definition would be easy to interpret and would therefore improve recording consistency, stated: ''API strongly supports OSHA's proposed definition of restricted activity. Because it is much more logical and easy to understand than the current definition, API believes it will lead to greater consistency'' (Ex. 15: 375).

Use Different Triggers Than Those Proposed

The Commonwealth Edison Company recommended that restricted work be defined only in terms of the hours the employee is able to work, not the functions the employee is able to perform:

[C]omEd disagrees with OSHA on its definition of ''restricted work activity''. We propose that OSHA consider that restricted work activity simply state ''Restricted work activity means the worker, due to his or her injury or illness, is unable to work a full shift.'' OSHA's proposed definition of restricted work activity is even more confusing than the current one. ComEd's proposed definition will allow quantifiable, direct cost tracking for this category of injury or illness. Workers will more than likely have some kind of meaningful work waiting for them if the injury is not disabling. If he or she is able to work the required normal shift hours, don't count the case as restricted. If they miss the entire shift, count is as a day away from work. If they miss part of the shift, count it as restricted (Ex. 15: 277).

Two commenters suggested that a case should only be considered restricted when it involves both medical treatment *and* work restrictions (Exs. 15: 9, 348). For example, the E. I. du Pont de Nemours & Company (DuPont) said that the

''Restricted Work Activity'' definition is a definite improvement over the current one. Suggest making treatment AND restriction the criteria. An insignificant injury can result in being told not to climb ladders. This does not negate the ability to do the job; it just limits the job to levels where ladder climbing is not required. * * * Restricted work activity is more dependent on timing and job than on injury severity. It doesn't necessarily focus on hazardous conditions. Certainly the definition in the proposed guidelines is far more specific and appropriate than the current one. We suggest consideration be given to dropping the Restricted category where medical treatment is not also given. For example, a slight muscle strain will result in advice not to climb ladders. The case would be in the restricted category although the treatment, if any, would be at the first aid level. Injury severity is the equivalent of a cut finger'' (Ex. 15: 348).

Other comments sought a broader, more inclusive definition of restricted work, one that relies on job descriptions (see, *e.g.*, Exs. 15: 41, 62, 198, 426). For example, Robert L. Rowan, Jr. stated:

[t]he definition of ''restricted work activity'' also concerns me and I believe it is unsuitable. The definition refers to an employee who is not capable of performing at full capacity for a full shift the ''task'' that he or she was engaged in at the time of the injury or onset of illness. The definition should include ''any and all tasks'' within the employee's clearly defined job description'' (Ex. 15: 62).

The Maine Department of Labor, however, preferred the former rule's interpretation, with some modifications:

[w]e agree that there should be no mention of ''normal'' duties in the definition. Include: temporary transfer to a position or department other than the position or department the worker was working at when he/she was injured. Some of these can be detected on payroll records; only being able to work part of their workday. Time forms could raise suspicion here; a health care provider puts the person on written restrictions unless the employer can show that the restrictions listed do not impact the employee's ability to do his or her scheduled job during the time period of the restrictions. Keep a copy of the restrictions in the file. The doctor's name on the OSHA 301 serves as another possible check (Ex. 15:41).

Miscellaneous Comments and Questions

There were also a variety of miscellaneous comments and questions about the proposed approach to the recording of restricted work cases. For example, Bob Evans Farms suggested that:

[w]hen considering this proposal, OSHA needs to keep in mind the special nature of the restaurant business. It is not uncommon for a cook to cut himself or herself, apply a Band-Aid, and then temporarily be reassigned to janitorial work for a day or two to keep the cut dry while it heals. This could be considered work duty modification and would then need to be reported to OSHA. As you can see, this type of minor occurrence would clog the system with needless paper (Exs. 15: 3, 4, 5, 6).

Phibro-Tech, Inc. offered this comment:

[a] factory employee who normally performs heavy labor may be assigned office work as a restricted work activity, and may not actually be contributing anything meaningful to the job. Will employers be required to limit what is considered ''light duty'' tasks? Will there be directives as to when an employee should really be off work or when he can be on ''light duty''? Occupational physicians all have different opinions as to when an employee can return for light or full duty. It would be helpful to have more direction on this issue so employees aren't sent back to work too soon or kept off on lost time too long (Ex. 15: 35).

The law firm of Constangy, Brooks & Smith, LLC, asked, ''[w]ould a restriction of piece rate or production rate be considered restricted duty under the proposed definition even though it is not considered restricted duty under the present guidelines?'' (Ex. 15: 428). Miller Brewing Company added, ''[w]ould also recommend that OSHA attempt to clarify whether a treating physician's [non-specific] return to work instructions such as ''8 hours only,'' ''self restrict as needed,'' and ''work at your own pace'' will constitute restricted work activity under the proposed recordkeeping rule'' (Ex. 15: 442).

The Pacific Maritime Association stated:

This is another example where the ILWU/PMA workforce does not fit into the proposed recordkeeping system. The regulation as written pertains to employers who assign their employees to work tasks. As previously mentioned, in our industry it is the employee who selects the job they will perform. This dispatch system, or job selection process, presents many problems when the maritime industry is required to conform to requirements established for traditional employee/employer relationships found in general industry. At the present time there is no method available to determine why an individual longshoreman selects a specific job. Therefore, the requirement to identify, track, and record ''restricted work activity'' may be impossible to accomplish [in the maritime industry] (Ex. 15: 95).

Preventive Job Transfers

Several commenters (see, *e.g.*, Exs. 25; 15: 69, 156, 406) urged OSHA to make some accommodation for ''preventive

transfers'' and medical removals. Many transfers and removals of this nature are related to work-related musculoskeletal disorders and are used to prevent minor musculoskeletal soreness from becoming worse. The following comments are representative of the views of these commenters. The Ogletree, Deakins, Nash, Smoak & Stewart (ODNSS) coalition commented:

[t]his definition [the proposed definition of restricted work] is overly broad, penalizes employers who have a light duty program in place, and fails to take into account that (1) today's employees increasingly are cross trained and perform varied tasks, and (2) the ability of an employee to perform alternative meaningful work mitigates the seriousness of the inability to perform work in the two categories set out in the definition as proposed. The ODNSS Coalition recommends curing these defects by adding the following proviso to the proposed definition: ''The case should be recorded as a restricted work case UNLESS the restrictive work activity is undertaken to relieve minor soreness experienced by a newly hired or transferred employee during a break-in phase to prevent the soreness from worsening, or the employee otherwise is able to perform other existing full-time duties.'' The appropriate nature of the recommended proviso is underscored by a baseball analogy where the right fielder and the center fielder change positions. They both continue to play on the same team and make substantial contributions, but the strain on the new right fielder is less because he doesn't have as much ground to cover (Ex. 15: 406).

The National Association of Manufacturers (NAM) summed up its views as follows:

[a] preventive or prophylactic measure such as medical removal (as opposed to a restorative or curative measure) is not and should not be deemed medical treatment, a job transfer or restricted activity for purposes of recordability, in the absence of a substantial impairment of a bodily function (Ex. 25).

Although Organization Resource Counselors (ORC) generally endorsed the proposed approach to the treatment of restricted work cases, it did express concern about how medical removal cases would be treated under the proposed definition:

[t]he proposed definition of restricted work is a significant improvement over the current [former] one, which was considered by many employers to be unfair and confusing. It is no secret that many employers did not understand the current restricted work rules and, as a result, did not follow them consistently. Additionally, the [proposed] elimination of the count of restricted workdays is appropriate and is a recognition by OSHA that the recording of this count is of little value to either the Agency or employers in program evaluation or program development. * * * Additionally, requirements for the recording of either voluntary or mandatory medical removals where no additional symptoms are present are examples of appropriate action taken by employers to prevent harm to employees and not of a recordable injury or illness. * * *'' (Ex. 15: 358).

Final Rule's Restricted Work and Job Transfer Provisions, and OSHA's Reasons for Adopting Them

Paragraph 1904.7(b)(4) contains the restricted work and job transfer provisions of the final rule. These provisions clarify the definition of restricted work in light of the comments received and continue, with a few exceptions, most of the former rule's requirements with regard to these kinds of cases. OSHA finds, based on a review of the record, that these provisions of the final rule will increase awareness among employers of the importance of recording restricted work activity and job transfer cases and make the recordkeeping system more accurate and the process more efficient.

OSHA believes that it is even more important today than formerly that the definition of restricted work included in the final rule be clear and widely understood, because employers have recently been relying on restricted work (or ''light duty'') with increasing frequency, largely in an effort to encourage injured or ill employees to return to work as soon as possible. According to BLS data, this category of cases has grown by nearly 70% in the last six years. In 1992, for example, 9% of all injuries and illnesses (or a total of 622,300 cases) recorded as lost workday cases were classified in this way solely because of restricted work days, while in 1998, nearly 18% of all injury and illness cases (or a total of 1,050,200 cases) were recorded as lost workday cases only because they involved restricted work [BLS Press Release 99–358, 12–16–99). The return-to-work programs increasingly being relied on by employers (often at the recommendation of their workers' compensation insurers) are designed to prevent exacerbation of, or to allow recuperation from, the injury or illness, rehabilitate employees more effectively, reintegrate injured or ill workers into the workplace more rapidly, limit workers' compensation costs, and retain productive workers. In addition, many employees are eager to accept restricted work when it is available and prefer returning to work to recuperating at home.

The final rule's requirements in paragraph 1904.10(b)(4) of the final rule state:

(4) How do I record a work-related injury or illness that involves restricted work or job transfer?

When an injury or illness involves restricted work or job transfer but does not involve death or days away from work, you must record the injury or illness on the OSHA 300 Log by placing a check mark in the space for job transfer or restricted work and entering the number of restricted or transferred days in the restricted work column.

(i) How do I decide if the injury or illness resulted in restricted work?

Restricted work occurs when, as the result of a work-related injury or illness:

(A) You keep the employee from performing one or more of the routine functions of his or her job, or from working the full workday that he or she would otherwise have been scheduled to work; or

(B) A physician or other licensed health care professional recommends that the employee not perform one or more of the routine functions of his or her job, or not work the full workday that he or she would otherwise have been scheduled to work.

(ii) What is meant by ''routine functions''?

For recordkeeping purposes, an employee's routine functions are those work activities the employee regularly performs at least once per week.

(iii) Do I have to record restricted work or job transfer if it applies only to the day on which the injury occurred or the illness began?

No. You do not have to record restricted work or job transfers if you, or the physician or other licensed health care professional, impose the restriction or transfer only for the day on which the injury occurred or the illness began.

(iv) If you or a physician or other licensed health care professional recommends a work restriction, is the injury or illness automatically recordable as a ''restricted work'' case?

No. A recommended work restriction is recordable only if it affects one or more of the employee's routine job functions. To determine whether this is the case, you must evaluate the restriction in light of the routine functions of the injured or ill employee's job. If the restriction from you or the physician or other licensed health care professional keeps the employee from performing one or more of his or her routine job functions, or from working the full workday the injured or ill employee would otherwise have worked, the employee's work has been restricted and you must record the case.

(v) How do I record a case where the worker works only for a partial work shift because of a work-related injury or illness?

A partial day of work is recorded as a day of job transfer or restriction for recordkeeping purposes, except for the day on which the injury occurred or the illness began.

(vi) If the injured or ill worker produces fewer goods or services than he or she would have produced prior to the injury or illness but otherwise performs all of the activities of his or her work, is the case considered a restricted work case?

No. The case is considered restricted work only if the worker does not perform all of the

routine functions of his or her job or does not work the full shift that he or she would otherwise have worked.

(vii) How do I handle vague restrictions from a physician or other licensed health care professional, such as that the employee engage only in ''light duty'' or ''take it easy for a week''?

If you are not clear about a physician or other licensed health care professional's recommendation, you may ask that person whether the employee can perform all of his or her routine job functions and work all of his or her normally assigned work shift. If the answer to both of these questions is ''Yes,'' then the case does not involve a work restriction and does not have to be recorded as such. If the answer to one or both of these questions is ''No,'' the case involves restricted work and must be recorded as a restricted work case. If you are unable to obtain this additional information from the physician or other licensed health care professional who recommended the restriction, record the injury or illness as a case involving job transfer or restricted work.

(viii) What do I do if a physician or other licensed health care professional recommends a job restriction meeting OSHA's definition but the employee does all of his or her routine job functions anyway?

You must record the injury or illness on the OSHA 300 Log as a restricted work case. If a physician or other licensed health care professional recommends a job restriction, you should ensure that the employee complies with that restriction. If you receive recommendations from two or more physicians or other licensed health care providers, you may make a decision as to which recommendation is the most authoritative, and record the case based upon that recommendation.

The concept of restricted work activity in the final rule falls somewhere between the commenters' broadest and narrowest definitions of the work activities that should be considered in determining whether a particular case involves work restriction. The final rule's concept of restricted work is based both on the type of work activities the injured or ill worker is able to perform and the length of time the employee is able to perform these activities. The term ''routine functions of the job'' in paragraphs 1904.7(b)(4)(i) and (b)(4)(ii) clarifies that OSHA considers an employee who is unable, because of a work-related injury or illness, to perform the job activities he or she usually performs to be restricted in the work he or she may perform. Use of the term ''routine functions of the job'' should eliminate the concern of some commenters who read the proposed definition as meaning that an employee had to be able to perform every possible work activity, including those that are highly unusual or performed only very rarely, in order for the employer to avoid recording the case as a restricted work case (see, *e.g.*, Exs. 15: 80, 247). In other words, OSHA agrees that it makes little sense to consider an employee who is prevented by an injury or illness from performing a particular job function he or she never or rarely performed to be restricted (see, *e.g.*, Exs. 15: 80, 247). For example, OSHA finds that, for the purposes of recordkeeping, an activity that is performed only once per month is not performed ''regularly.'' This approach is consistent with OSHA interpretations under the former rule. Limiting the definition to ''essential functions,'' the ADA term recommended by several commenters (see, *e.g.*, Exs. 15: 127, 136, 137, 141, 224, 266, 278, 431), would be inappropriate, because OSHA needs information on all restricted work cases, not just those that interfere with the essential functions of the job (29 U.S.C. 657(c)(2)).

On the other hand, OSHA agrees with those commenters who argued that the proposed definition, to limit the definition of restricted activity to the specific functions or tasks the employee was engaged in on the day of injury or onset of illness would be unsatisfactory, because doing so could fail to capture activities that an employee regularly performs (see, *e.g.*, Exs. 20; 15: 17, 129, 380, 418). In the final rule, OSHA has decided that defining restricted work as work that an employee would regularly have performed at least once per week is appropriate, i.e., OSHA believes that the range of activities captured by this interval of time will generally reflect the range of an employee's usual work activities. Activities performed less frequently than once per week reflect more uncommon work activities that are not considered routine duties for the purposes of this rule. However, the final rule does not rely on the duties the employee actually performed during the week when he or she was injured or became ill. Thus, even if an employee did not perform the activity within the last week, but usually performs the activity once a week, the activity will be included. OSHA believes that this change in definition will foster greater acceptance of the concept of restricted work among employers and employees because of its common sense approach.

Use of the term ''partial work shift'' in paragraph 1904.7(b)(4)(v) covers restrictions on the amount of time an employee is permitted to work because of the injury or illness. This interpretation of restricted work was not generally disputed by commenters, although some argued that the restriction on the hours worked should last for a specific number of days before the case becomes recordable as a restricted work case (see, *e.g.*, Exs. 15: 19, 44, 146, 154, 156, 198, 364, 374, 391).

The final rule's restricted work provisions also clarify that work restriction must be imposed by the employer or be recommended by a health care professional before the case is recordable. Only the employer has the ultimate authority to restrict an employee's work, so the definition is clear that, although a health care professional may recommend the restriction, the employer makes the final determination of whether or not the health care professional's recommended restriction involves the employee's routine functions. Restricted work assignments may involve several steps: an HCP's recommendation, or employer's determination to restrict the employee's work, the employers analysis of jobs to determine whether a suitable job is available, and assignment of the employee to that job. All such restricted work cases are recordable, even if the health care professional allows some discretion in defining the type or duration of the restriction, an occurrence noted by one commenter (Ex. 15:442). However, the final rule's provisions make it clear that the employee is not the person making the determination about being placed on restricted work, as one commenter (Ex. 15: 97) feared.

A number of commenters suggested that OSHA cease to require the recording of restricted work cases entirely (see, *e.g.*, Exs. 15: 119, 427). However, the Congress has directed that the recordkeeping system capture data on non-minor work-related injuries and illnesses and specifically on restricted work cases, both so that the national statistics on such injuries and illnesses will be complete and so that links between the causes and contributing factors to such injuries and illnesses will be identified (29 U.S.C. 651(b)). Days away and restricted work/job transfer cases together constitute two of the most important kinds of job-related injuries and illnesses, and it would be inappropriate not to record these serious cases. OSHA also cannot narrow the definition of restricted work to those cases where the employee is at work but cannot do productive work, as several commenters suggested (see, *e.g.*, Exs. 15: 9, 45, 46, 89, 437), because the Congress clearly intended that workers whose work-related injuries and illnesses were so severe as to prevent them from doing their former work or from working for a full shift had experienced an injury or illness that was non-minor and thus worthy of being recorded. OSHA does not believe that requiring employers to record such injuries and illnesses as

restricted work cases will in any way discourage the use of restricted work or return-to-work programs, and the marked shift in the number of restricted work cases reported to the BLS in the last few years bears this out. It would also not be appropriate for OSHA to require that employers only record as restricted work cases those cases in which the injured or ill worker requires medical treatment *and* is placed on restricted work, as some commenters suggested (see, *e.g.*, Exs. 15: 9, 348). The OSH Act clearly requires the recording of all work-related cases that require either medical treatment or restricted work.

Under the final rule, employers are not required to record a case as a restricted work case if the restriction is imposed on the employee only for the day of the injury or onset of illness. OSHA thus agrees with a number of commenters (see, *e.g.*, Exs. 15: 19, 44, 146, 154, 156, 198, 364, 374, 391) that restricted activity only on the day the injury occurred or the illness began does not justify recording. This represents a change in the treatment of restricted work cases from OSHA's practice under the former rule. OSHA has made this change to bring the recording of restricted work cases into line with that for days away cases: under the final rule, employers are not required to record as days away or restricted work cases those injuries and illnesses that result in time away or time on restriction or job transfer lasting only for the day of injury of illness onset.

Several commenters recommended that cases involving medical removal under the lead or cadmium standards or cases involving ''voluntary'' preventive actions, such as cases involving job transfer or restricted work activity, not be considered recordable under the final rule; these participants argued that requiring employers to record voluntary transfers or removals would create a disincentive for employers to take these protective actions (see, *e.g.*, Exs. 25, 15: 69, 156, 358, 406). Under the final rule (see section 1904.9), mandated removals made in accordance with an OSHA health standard must be recorded either as days away from work or as days of restricted work activity, depending on the specific action an employer takes. Since these actions are mandated, no disincentive to record is created by this recordkeeping rule.

Some commenters, however, urged OSHA to make an exception from the recording requirements for cases where the employer voluntarily, or for preventive purposes, temporarily transfers an employee to another job or restricts an employee's work activities. OSHA does not believe that this concept is relevant to the recordkeeping rule, for the following reasons. Transfers or restrictions taken *before* the employee has experienced an injury or illness do not meet the first recording requirement of the recordkeeping rule, i.e., that a work-related injury or illness must have occurred for recording to be considered at all. A truly preventive medical treatment, for example, would be a tetanus vaccination administered routinely to an outdoor worker. However, transfers or restrictions whose purpose is to allow an employee to recover from an injury or illness as well as to keep the injury or illness from becoming worse are recordable because they involve restriction or work transfer caused by the injury or illness. All restricted work cases and job transfer cases that result from an injury or illness that is work-related are recordable on the employer's Log.

As the regulatory text for paragraph (b)(4) makes clear, the final rule's requirements for the recording of restricted work cases are similar in many ways to those pertaining to restricted work under the former rule. First, like the former rule, the final rule only requires employers to record as restricted work cases those cases in which restrictions are imposed or recommended as a result of a work-related injury or illness. A work restriction that is made for another reason, such as to meet reduced production demands, is not a recordable restricted work case. For example, an employer might ''restrict'' employees from entering the area in which a toxic chemical spill has occurred or make an accommodation for an employee who is disabled as a result of a non-work-related injury or illness. These cases would not be recordable as restricted work cases because they are not associated with a work-related injury or illness. However, if an employee has a work-related injury or illness, and that employee's work is restricted by the employer to prevent exacerbation of, or to allow recuperation from, that injury or illness, the case is recordable as a restricted work case because the restriction was necessitated by the work-related injury or illness. In some cases, there may be more than one reason for imposing or recommending a work restriction, *e.g.*, to prevent an injury or illness from becoming worse or to prevent entry into a contaminated area. In such cases, if the employee's work-related illness or injury played *any* role in the restriction, OSHA considers the case to be a restricted work case.

Second, for the definition of restricted work to apply, the work restriction must be decided on by the employer, based on his or her best judgment or on the recommendation of a physician or other licensed health care professional. If a work restriction is not followed or implemented by the employee, the injury or illness must nevertheless be recorded on the Log as a restricted case. This was also the case under the former rule.

Third, like the former rule, the final rule's definition of restricted work relies on two components: whether the employee is able to perform the duties of his or her pre-injury job, and whether the employee is able to perform those duties for the same period of time as before.

The principal differences between the final and former rules' concept of restricted work cases are these: (1) the final rule permits employers to cap the total number of restricted work days for a particular case at 180 days, while the former rule required all restricted days for a given case to be recorded; (2) the final rule does not require employers to count the restriction of an employee's duties on the day the injury occurred or the illness began as restricted work, providing that the day the incident occurred is the only day on which work is restricted; and (3) the final rule defines work as restricted if the injured or ill employee is restricted from performing any job activity the employee would have regularly performed at least once per week before the injury or illness, while the former rule counted work as restricted if the employee was restricted in performing any activity he or she would have performed at least once per year.

In all other respects, the final rule continues to treat restricted work and job transfer cases in the same manner as they were treated under the former rule, including the counting of restricted days. Paragraph 1904.7(b)(4)(xi) requires the employer to count restricted days using the same rules as those for counting days away from work, using § 1904.7(b)(3)(i) to (viii), with one exception. Like the former rule, the final rule allows the employer to stop counting restricted days if the employee's job has been permanently modified in a manner that eliminates the routine functions the employee has been restricted from performing. Examples of permanent modifications would include reassigning an employee with a respiratory allergy to a job where such allergens are not present, or adding a mechanical assist to a job that formerly required manual lifting. To make it clear that employers may stop

counting restricted days when a job has been permanently changed, but not to eliminate the count of restricted work altogether, the rule makes it clear that at least one restricted workday must be counted, even if the restriction is imposed immediately. A discussion of the desirability of counting days of restricted work and job transfer at all is included in the explanation for the OSHA 300 form and the § 1904.29 requirements. The revisions to this category of cases that have been made in the final rule reflect the views of commenters, suggestions made by the Keystone report (Ex. 5), and OSHA's experience in enforcing the former recordkeeping rule.

Paragraph 1904.7(b)(5) Medical Treatment Beyond First Aid

The definitions of first aid and medical treatment have been central to the OSHA recordkeeping scheme since 1971, when the Agency's first recordkeeping rule was issued. Sections 8(c)(2) and 24(a) of the OSH Act specifically require employers to record all injuries and illnesses other than those ''requiring only first aid treatment and which do not involve medical treatment, loss of consciousness, restriction of work or motion, or transfer to another job.'' Many injuries and illnesses sustained at work do not result in death, loss of consciousness, days away from work or restricted work or job transfer. Accordingly, the first aid and medical treatment criteria may be the criteria most frequently evaluated by employers when deciding whether a given work-related injury must be recorded.

In the past, OSHA has not interpreted the distinction made by the Act between minor (i.e., first aid only) injuries and non-minor injuries as applying to occupational illnesses, and employers have therefore been required to record all occupational illnesses, regardless of severity. As a result of this final rule, OSHA will now apply the same recordability criteria to both injuries and illnesses (see the discussion of this issue in the Legal Authority section of this preamble). The Agency believes that doing so will simplify the decision-making process that employers carry out when determining which work-related injuries and illnesses to record and will also result in more complete data on occupational illness, because employers will know that they must record these cases when they result in medical treatment beyond first aid, regardless of whether or not a physician or other licensed health care professional has made a diagnosis.

The former recordkeeping rule defined first aid as ''any one-time treatment and any follow-up visit for the purpose of observation, of minor scratches, cuts, burns, splinters, and so forth, which do not ordinarily require medical care.'' Medical treatment was formerly defined as ''treatment administered by a physician or by registered professional personnel under the standing orders of a physician.''

To help employers determine the recordability of a given injury, the *Recordkeeping Guidelines,* issued by the Bureau of Labor Statistics (BLS) in 1986, provided numerous examples of medical treatments and of first aid treatments (Ex. 2). These examples were published as mutually exclusive lists, i.e., a treatment listed as a medical treatment did not also appear on the first-aid list. Thus, for example, a positive x-ray diagnosis (fractures, broken bones, etc.) was included among the treatments generally considered medical treatment, while a negative x-ray diagnosis (showing no fractures) was generally considered first aid. Despite the guidance provided by the *Guidelines,* OSHA continued to receive requests from employers for interpretations of the recordability of specific cases, and a large number of letters of interpretation addressing the distinction between first aid and medical treatment have been issued. The following sections discuss the definitions of medical treatment and first aid proposed by OSHA, the comments received in response to the proposal, and the definition of medical treatment that OSHA has decided to include in the final rule.

In the proposed rule, OSHA presented a simplified approach: to define as first aid anything on a list of first aid treatments, and to define as medical treatment any treatment not on that list. Specifically, medical treatment was defined as ''any medical cure or treatment beyond first aid'' (61 FR 4059).

The proposal contained a comprehensive list of all treatments that would be considered ''first aid'' regardless of the provider:

(1) Visit(s) to a health care provider limited to observation

(2) Diagnostic procedures, including the use of prescription medications solely for diagnostic purposes (*e.g.* eye drops to dilate pupils)

(3) Use of nonprescription medications, including antiseptics

(4) Simple administration of oxygen

(5) Administration of tetanus or diphtheria shot(s) or booster(s)

(6) Cleaning, flushing or soaking wounds on skin surface

(7) Use of wound coverings such as bandages, gauze pads, etc.

(8) Use of any hot/cold therapy (*e.g.* compresses, soaking, whirlpools, non-prescription skin creams/lotions for local relief, etc.) except for musculoskeletal disorders (see Mandatory Appendix B to Part 1904)

(9) Use of any totally non-rigid, non-immobilizing means of support (*e.g.* elastic bandages)

(10) Drilling of a nail to relieve pressure for subungual hematoma

(11) Use of eye patches

(12) Removal of foreign bodies not embedded in the eye if only irrigation or removal with a cotton swab is required

(13) Removal of splinters or foreign material from areas other than the eyes by irrigation, tweezers, cotton swabs or other simple means (61 FR 4059)

OSHA also solicited comment on three specific definitional questions:

(A) Should any treatments on the proposed first aid list be excluded and should any treatments be added?

(B) Should a list of medical treatments also be provided? Which treatments?

(C) Should simple administration of oxygen be defined to exclude more severe procedures such as Intermittent Positive Pressure Breathing (IPPB)? If so, how?

OSHA received many comments on the general approach taken in the proposal, i.e., that employers rely on a comprehensive list of first aid treatment and define any treatment not on that list as medical treatment. The Agency also received many comments on the individual items on the proposed first aid list. The following discussion addresses comments on the general approach adopted in the final rule and then deals with comments on specific items and OSHA's responses to each issue.

A large number of commenters agreed with OSHA's proposal to rely on a finite list of treatments considered first aid and to consider all other treatments medical treatment (see, *e.g.*, Exs. 15: 9, 13, 26, 27, 74, 76, 87, 95, 122, 127, 156, 163, 185, 188, 199, 204, 218, 242, 263, 269, 270, 283, 297, 324, 332, 338, 347, 357, 359, 377, 378, 385, 386, 387, 395, 397, 405, 407, 414, 434). Several commenters wanted no change to the proposal (see, *e.g.*, Exs. 15: 26, 76, 204, 385, 378), while others agreed with the general approach but stated that the first aid list should be more comprehensive (see, *e.g.*, Exs. 15: 199, 332, 338, 357, 386, 387).

Commenters supported the proposed approach for a variety of reasons. For example, some stated that a finite list

would improve the clarity of the definition, reduce confusion for employers, and reduce inaccuracy in the data (see, *e.g.*, Exs. 15: 87, 95, 122, 127, 163, 185, 188, 395, 338, 242, 270, 269, 263, 347, 377, 386). The statement of the American Iron and Steel Institute exemplified these comments:

> Consistent with its statutory mandate, OSHA's proposal would also require the recording of all work-related injuries and illnesses that result in medical treatment beyond first aid. The expanded and finite list of treatments that constitute first aid would clarify the task of deciding what to record, because any treatment that does not appear on this list will be considered a medical treatment. (Ex. 15: 395)

The Ford Motor Company agreed, stating:

> Ford supports that the definition of first aid be modified to consist of a comprehensive list of treatments. Treatments not found on the first aid list would be considered medical treatment for recordkeeping purposes. Assuming that the list will be comprehensive, it will reduce confusion, lead to consistent recordkeeping, and greatly simplify the decision making process (Ex. 15: 347).

Some commenters stated that the proposed approach would be simpler for employers, generate more consistent records, and facilitate better comparisons of injury and illness data over time (see, *e.g.*, Exs. 15: 13, 122, 127, 242, 270, 269, 263, 283, 297, 347, 359, 377, 405, 407). According to the Southern Nuclear Operating Company: ''Providing a comprehensive list of all first-aid treatments will remove the current ambiguity in deciding if a case involves first aid only or if it is medical treatment. This should provide more consistent recordkeeping and allow for more meaningful comparisons of accident histories'' (Ex. 15: 242, p. 2).

A number of commenters, however, disagreed that defining first aid by listing first aid treatments was appropriate (see, *e.g.*, Exs. 15: 18, 63, 83, 87, 96, 119, 123, 129, 145, 159, 171, 173, 176, 182, 201, 225, 229, 247, 260, 262, 265, 272, 281, 303, 307, 308, 335, 337, 338, 341, 348, 349, 357, 364, 375, 380, 382, 389, 396, 401, 413, 418, 430, 434). Several of these commenters argued that it would not be possible to list every first aid treatment (see, *e.g.*, Exs. 15: 225, 335, 337, 396, 430). Some commenters stated that the proposed approach would not provide sufficient clarity, would involve a definition of medical treatment that was overly vague, and would not be helpful to employers without additional definitions (see, *e.g.*, Exs. 15: 159, 171, 176, 229, 281, 348, 357, 396). Another group of commenters stated that the approach did not provide flexibility to adapt to changing medical practice, and would not be capable of responding to changes in technology (see, *e.g.*, Exs. 15: 18, 63, 96, 335, 348). The comments of the Dow Chemical Corporation are representative of these views:

> Dow believes that OSHA should provide non-exhaustive lists for both first aid and medical treatment, rather than defining one solely by the exclusion of the other. Dow believes this suggested approach is necessary to take into account that these lists cannot be comprehensive or all-inclusive as it is impossible to list every possible contingency. Moreover, technology is constantly changing and cannot be accounted for in a static list. For example, one can now obtain Steri-Strips over the counter where previously it would have been considered ''medical treatment.'' Since exhaustive lists do not allow the flexibility to take these technologies into account nor capture every possible situation, much would still be left to supposition. By providing an illustrative list for both first aid and medical treatment, OSHA would be giving adequate guidance for the regulated community. Dow recommends OSHA make this modification in the final rule. (Ex. 15: 335)

A number of commenters urged OSHA to use the definition of medical treatment as a way to focus primarily on the seriousness of the injury or illness (see, *e.g.*, Exs. 15: 147, 201, 308, 341, 375, 395, 418). For example, the American Petroleum Institute remarked ''* * * the fundamental issue is the seriousness of the injury or illness, not the treatment'' (Ex. 375–A, p. 7). The Caterpillar Corporation provided lengthy comments on the definition of medical treatment, including the following criticism of the proposed approach:

> Insignificant injuries for which medical treatment is provided do not provide valuable information for safety and health analysis. This proposal attempts to oversimplify the recordkeeping process which will result in many insignificant injuries and illnesses being recorded because of the unnecessarily restrictive definitions for first aid and medical treatment. The definition and listing of first aid cannot be a comprehensive or exclusive listing and definition. Medical treatment may be provided for insignificant injuries and significant injuries may receive little or no medical treatment. The medical treatment process and options are too complicated to be adequately described by one list which makes the treatments mutually exclusive. OSHA should continue the current practice with lists for both first aid and medical treatment. Further, the treatments cannot be mutually exclusive since treatment does not necessarily recognize the severity of the injury or illness (Ex. 15: 201, p. 4).

Some commenters who disagreed with the proposed approach provided suggestions and alternative definitions. A number of commenters suggested that OSHA keep its former definitions of first aid and medical treatment (see, *e.g.*, Exs. 15: 83, 119, 123, 129, 145, 225, 337, 380, 389, 418, 430). Several commenters urged OSHA to update the former rule's definitions using the proposed rule's listing of first aid treatments (see, *e.g.*, Exs. 15: 83, 380, 418). Other commenters urged OSHA not to change the definition in any way because it would produce a break in the historical series of occupational injury and illness data (see, *e.g.*, Exs. 15: 123, 145, 389).

Several commenters made suggestions that they believed would introduce flexibility into the proposed rule's first aid definition. The National Restaurant Association suggested that OSHA add a ''catchall'' category to the list to include ''any similar type of treatment'' (Ex. 15: 96, p. 5). The General Electric Company urged that the following language be added: ''Other treatments may be considered first aid so long as they are recognized as first aid actions and [are] not listed in the definition of medical treatment'' (Ex. 15: 349, p. 8). Some commenters suggested allowing the health care professional to determine whether the activity was properly classified as first aid or medical treatment (see, *e.g.*, Exs. 27; 15: 131, 173, 176, 201, 334, 382, 392, 434). A typical comment along these lines was one from the American Forest and Paper Association, which stated that ''* * * we believe a qualified health care professional should have the authority to determine what is properly characterized as first aid and what should be properly characterized as medical treatment'' (Ex. 15:334, p. 7). Two commenters suggested that the health care professional be allowed to decide whether an action constituted first aid or medical treatment only if the treatment was not on either the first aid or medical treatment lists (see, *e.g.*, Exs. 27; 15: 382, 392, 434).

One commenter, the American Network of Community Options and Resources, supported the development of a finite first aid list, but suggested that OSHA define medical treatment as ''any treatment that requires professional medical intervention'' (Ex. 15: 393, p. 8).

A number of commenters agreed with OSHA that the first aid definition should focus on the type of treatment given, and not on the provider (see, *e.g.*, Exs. 15: 185, 308, 338, 349, 364, 443). Other comments argued that a distinction between first aid and medical treatment could be made on the basis of the number of times a particular treatment had been given. The AFL–CIO expressed a concern that, absent some

consideration of the number of times a treatment was administered, many serious injuries and illnesses would no longer be recordable and valuable data would be lost. The AFL–CIO stated that longer term treatments are more likely than shorter ones to be indicative of medical treatment:

> The proposed change in definition would seem to exclude cases where there are continued instances of the listed first aid treatments from the recordkeeping requirements. Those conditions which require continued treatments, including continued use of non-prescription drugs and repeated cleaning, flushing or soaking of wounds would no longer be recordable. The AFL–CIO believes that first aid should be limited to one time treatments as is the current practice, so that serious conditions which require multiple treatments are recorded on the log. We strongly urge OSHA to maintain the definition of first aid in the current recordkeeping guidelines and to use the listed conditions as examples of first aid. (Ex. 15: 418).

Similarly, the TIMEC group of companies believed that any one-time treatment should be considered first aid, saying:

> It is also TIMEC's perspective that the exclusion of a ''one time medical treatment'' provision from the list of first aids is unduly restrictive. Any condition that can be resolved or treated in one visit to the doctor should be considered minimal or negligible in the context of record keeping for industrial injuries. Under the proposed regulation, a condition that results in a one time medical treatment theoretically could be given the same weight, in terms of OSHA recordability, as a broken or severed limb. This seems unduly restrictive. Further, it may inhibit some employers from taking injured employees to the doctor in the first instance, in order to avoid a ''OSHA recordable injury.'' An employer may otherwise hope that the matter will heal itself without infection. This seems contrary to the goal of the Occupational Safety and Health Act, to ensure appropriate and prompt medical treatment and safety services to employees (Ex. 15: 18, p. 2).

In response to these comments and the evidence in the record of this rulemaking, the final rule essentially continues the proposed approach, i.e., it includes a list of first-aid treatments that is inclusive, and defines as medical treatment any treatment not on that list. OSHA recognizes, as several commenters pointed out, that no one can predict how medical care will change in the future. However, using a finite list of first aid treatments—knowing that it may have to be amended later based on new information—helps to limit the need for individual judgment about what constitutes first aid treatment. If OSHA adopted a more open-ended definition or one that relied on the judgment of a health care professional, employers and health care professionals would inevitably interpret different cases differently, which would compromise the consistency of the data. Under the system adopted in the final rule, once the employer has decided that a particular response to a work-related illness or injury is in fact treatment, he or she can simply turn to the first aid list to determine, without elaborate analysis, whether the treatment is first aid and thus not recordable. OSHA finds that this simple approach, by providing clear, unambiguous guidance, will reduce confusion for employers and improve the accuracy and consistency of the data.

The need for clear and unambiguous guidance is also OSHA's reason for not considering treatments from the first aid list to be medical treatment if carried out for a lengthier time, as suggested by the AFL–CIO. If an injured or ill employee is given first-aid treatment, such as non-prescription medications (at non-prescription strength), hot or cold therapy, massage therapy, or some other treatment on the first aid list, the treatment should not be considered medical treatment for OSHA recordkeeping purposes, regardless of the length of time or number of applications used. This approach will ensure that the recordkeeping system excludes truly minor injuries and illnesses, and capture the more serious cases that require treatment beyond first aid.

In the final rule, OSHA has adopted the approach taken in the proposal, in a slightly modified form. Under the final rule, employers will be able to rely on a single list of 14 first aid treatments. These treatments will be considered first aid whether they are provided by a lay person or a licensed health care professional. However, the final rule includes the following definition of medical treatment; ''management and care of a patient for the purpose of combating disease or disorder;'' this definition excludes observation and counseling, diagnostic procedures, and the listed first aid items. OSHA believes that providing a definition of medical treatment for recordkeeping purposes will help employers who are uncertain about what constitutes medical treatment. OSHA will also provide examples of medical treatments covered by this definition in compliance assistance documents designed to help smaller businesses comply with the rule. The following discussion describes the definitions of first aid and medical treatment in the final rule and explains the Agency's reasons for including each item on the first aid list.

Final Rule

The final rule, at § 1904.7(b)(5)(i), defines medical treatment as the management and care of a patient for the purpose of combating disease or disorder. For the purposes of Part 1904, medical treatment does not include:

> (A) Visits to a physician or other licensed health care professional solely for observation or counseling;
> (B) The conduct of diagnostic procedures, such as x-rays and blood tests, including the administration of prescription medications used solely for diagnostic purposes (*e.g.*, eye drops to dilate pupils); or
> (C) ''first aid'' as defined in paragraph (b)(5)(ii) of this section.

The final rule, at paragraph (b)(5)(ii), defines first aid as follows:

> (A) Using a nonprescription medication at nonprescription strength (for medications available in both prescription and non-prescription form, a recommendation by a physician or other licensed health care professional to use a non-prescription medication at prescription strength is considered medical treatment for recordkeeping purposes).
> (B) administering tetanus immunizations (other immunizations, such as hepatitis B vaccine or rabies vaccine, are considered medical treatment).
> (C) Cleaning, flushing or soaking wounds on the surface of the skin;
> (D) Using wound coverings, such as bandages, Band-Aids®, gauze pads, etc.; or using butterfly bandages or Steri-Strips® (other wound closing devices, such as sutures, staples, etc. are considered medical treatment);
> (E) Using hot or cold therapy;
> (F) Using any non-rigid means of support, such as elastic bandages, wraps, non-rigid back belts, etc. (devices with rigid stays or other systems designed to immobilize parts of the body are considered medical treatment for recordkeeping purposes);
> (G) Using temporary immobilization devices while transporting an accident victim (*e.g.* splints, slings, neck collars, back boards, etc.)
> (H) Drilling of a fingernail or toenail to relieve pressure, or draining fluid from a blister;
> (I) Using eye patches;
> (J) Removing foreign bodies from the eye using only irrigation or a cotton swab;
> (K) Removing splinters or foreign material from areas other than the eye by irrigation, tweezers, cotton swabs, or other simple means;
> (L) Using finger guards;
> (M) Using massages (physical therapy or chiropractic treatment are considered medical treatment for recordkeeping purposes);
> (N) Drinking fluids for relief of heat stress.

This list of first aid treatments is comprehensive, i.e., any treatment not included on this list is not considered

first aid for OSHA recordkeeping purposes. OSHA considers the listed treatments to be first aid regardless of the professional qualifications of the person providing the treatment; even when these treatments are provided by a physician, nurse, or other health care professional, they are considered first aid for recordkeeping purposes.

The definition of medical treatment in the final rule differs both from the definition used in the former rule (''treatment administered by a physician or by registered professional personnel under the standing orders of a physician'') and the proposed definition (''medical treatment includes any medical care or treatment beyond first aid''). The medical treatment definition in the final rule is taken from *Dorland's Illustrated Medical Dictionary,* and is thus consistent with usage in the medical community.

The three listed exclusions from the definition—visits to a health care professional solely for observation or counseling; diagnostic procedures, including prescribing or administering of prescription medications used solely for diagnostic purposes; and procedures defined in the final rule as first aid—clarify the applicability of the definition and are designed to help employers in their determinations of recordability.

OSHA received several comments on the proposed definition of medical treatment. These dealt primarily with the general approach OSHA was proposing, i.e., the use of an all-inclusive list of first aid applications, and defining any treatment not on the list as medical treatment. The remaining comments (see, *e.g.*, Exs. 15: 87, 171, 173, 176, 182, 229, 247, 260, 262, 265, 272, 303, 307, 357, 338, 375, 382, 396, 401, 413) urged OSHA to develop an all-inclusive list of medical treatments, to provide examples of some medical treatments, or to provide a non-mandatory appendix with such examples.

OSHA has not adopted the suggestions made by these commenters because the Agency finds that simplicity and clarity are best served by adopting a single, all-inclusive first aid list and explicitly stating that any treatment not on the list is considered, for recordkeeping purposes, to be medical treatment. Employers will thus be clear that any condition that is treated, or that should have been treated, with a treatment not on the first aid list is a recordable injury or illness for recordkeeping purposes.

This simplified approach addresses the concerns expressed by several commenters, who emphasized that the distinction between first aid and medical treatment made in the Act was meant to ensure that all occupational injuries and illnesses that were other than minor be captured by OSHA's recordkeeping system but that minor conditions not be recorded (see, *e.g.*, Exs. 15–308, 375A, p. 7). As the American Petroleum Institute commented (Ex. 375A), ''* * * the fundamental issue is the seriousness of the injury or illness, not the treatment.'' OSHA concludes, based on its review of the record, that the final rule's definitions of medical treatment and first aid will work together to achieve Congress's intent, as specified in sections 8 and 24 of the Act.

In making its decisions about the items to be included on the list of first aid treatments, OSHA relied on its experience with the former rule, the advice of the Agency's occupational medicine and occupational nursing staff, and a thorough review of the record comments. In general, first aid treatment can be distinguished from medical treatment as follows:

- First aid is usually administered after the injury or illness occurs and at the location (*e.g.*, workplace) where the injury or illness occurred.
- First aid generally consists of one-time or short-term treatment.
- First aid treatments are usually simple and require little or no technology.
- First aid can be administered by people with little training (beyond first aid training) and even by the injured or ill person.
- First aid is usually administered to keep the condition from worsening, while the injured or ill person is awaiting medical treatment.

The final rule's list of treatments considered first aid is based on the record of the rulemaking, OSHA's experience in implementing the recordkeeping rule since 1986, a review of the BLS *Recordkeeping Guidelines,* letters of interpretation, and the professional judgment of the Agency's occupational physicians and nurses.

Specific Items on the Proposed First Aid List in the NPRM

Item 1 listed in the NPRM definition of first aid was ''Visit(s) to a health care provider limited to observation.'' Two commenters raised the issue of counseling with regard to the recording of mental disorders (Exs. 15: 226, 395). The American Ambulance Association (AAA) stated that: ''This is and should be considered preventive treatment aimed at preventing stress-related illnesses. OSHA's adoption of such a policy will allow and encourage employers to provide CISD (critical incident stress debriefing) counseling'' (Ex. 15: 226, p. 3). The AAA recommended that OSHA add preventive counseling, such as critical incident stress debriefing, to the first aid listing.

OSHA agrees that counseling should not be considered medical treatment and has expressly excluded it from the definition of medical treatment. Counseling is often provided to large groups of workers who have been exposed to potentially traumatic events. Counseling may be provided on a short-term basis by either a licensed health care professional or an unlicensed person with limited training. OSHA believes that capturing cases where counseling was the only treatment provided do not rise to the level of recording; other counseling cases, where prescription medications, days away from work, or restricted work activity is involved, would be captured under those criteria.

The Brookhaven National Laboratory recommended that the first aid list include any return visit to evaluate diagnostic decisions (Ex. 15: 163). Caterpillar, Inc. suggested that visits for observation, testing or diagnosis of injuries should also be considered first aid (Ex. 15: 201). The Chemical Manufacturers Association and Marathon Oil Company encouraged OSHA to add visits to the hospital for observation to the first-aid list (Exs. 15: 308, 310)

OSHA generally agrees with these commenters. OSHA believes that visits to a health care professional for observation, testing, diagnosis, or to evaluate diagnostic decisions should be excluded from the definition of medical treatment in the final rule. Visits to a hospital, clinic, emergency room, physician's office or other facility for the purpose of seeking the advice of a health care professional do not themselves constitute treatment. OSHA believes that visits to a hospital for observation or counseling are not, of and by themselves, medical treatment. Accordingly, the final rule excludes these activities from the definition of medical treatment.

Item 2 listed in the NPRM definition of first aid was ''Diagnostic procedures, including the use of prescription medications solely for diagnostic purposes (*e.g.* eye drops to dilate pupils).'' Several commenters believed that diagnostic procedures such as x-rays and blood tests should not be considered medical treatment (see, *e.g.*, Exs. 15: 176, 301, 347, 349, 375, 443). For example, General Electric (GE) stated ''Diagnostic tests should not be considered medical treatment.

Considering a diagnostic test to be a recordable injury without consideration of the test results is illogical and will establish a disincentive to test. GE's position is that a definition of medical treatment should also be included in the proposed regulation. Proposed wording is as follows: ''Medical treatment'' includes any medical care or treatment beyond ''first aid'' and does not include diagnostic procedures.''

Two commenters opposed the exclusion of diagnostic procedures. The National Institute for Occupational Safety and Health (NIOSH) said ''the term diagnostic procedures'' in item #2 is too broad, and the example given is vague. These procedures should not be considered first aid'' (Ex. 15: 407, p. 17). The United Steelworkers of America stated '' * * * delete the use of prescription drugs for diagnostic purposes. This will be abused by the company'' (Ex. 15: 429).

OSHA disagrees with NIOSH that the exclusion for diagnostic procedures is overly vague. It is the experience of the Agency that employers generally understand the difference between procedures used to combat an injury or illness and those used to diagnose or assess an injury or illness. In the event that the employer does not have this knowledge, he or she may contact the health care professional to obtain help with this decision. If the employer does not have this knowledge, and elects not to contact the health care professional, OSHA would expect the employer to refer to the first aid list and, if the procedure is not on the list, to presume that the procedure is medical treatment and record the case. OSHA also does not believe that this provision will be subject to abuse, because the procedures used for diagnosis are generally quite different from those involving treatment.

OSHA agrees with those commenters who recommended the exclusion of diagnostic procedures from the definition of medical treatment. Diagnostic procedures are used to determine whether or not an injury or illness exists, and do not encompass therapeutic treatment of the patient. OSHA has included such procedures on the first aid list in the final rule with two examples of diagnostic procedures to help reduce confusion about the types of procedures that are excluded.

Item 3 listed in the NPRM definition of first aid was ''Use of nonprescription medications, including antiseptics.'' This issue received a large number of comments, more than any other issue related to the proposed definition of medical treatment and first aid. Most of the comments requested that OSHA consider some uses of prescription drugs to be first aid treatment (see, *e.g.*, Exs. 15: 13, 60, 147, 159, 201, 218, 225, 246, 247, 297, 308, 332, 335, 336, 348, 349, 359, 374, 375, 386, 387, 395, 405, 414, 430, 434). The most common reason given by commenters for treating some prescription drugs as first aid was their use when they were given for preventive rather than therapeutic intervention. Several commenters asked for a broad exception from medical treatment for prescription drugs taken for preventive or prophylactic purposes (see, *e.g.*, Exs. 55X 15: 247, 336, 375, 395). For example, the American Iron and Steel Institute stated ''AISI encourages OSHA to make one change: add the use of prescription medications for prophylactic reasons to the first aid list. In many instances, a health care professional will prescribe antibiotics as a precaution against a possible infection. An employer should not be required to record a minor injury solely because a health care professional opted to respond aggressively'' (Exs. 15: 395; 55X).

Several commenters asked for an exception from the medical treatment for antibiotics and antiseptics (see, *e.g.*, Exs. 15: 218, 246, 332, 349, 375, 395, 414, 430). Raytheon Constructors, Inc. commented: ''We believe the following treatments should be added [to the first aid list]: Application of antiseptics, as often as needed. This is for prevention of infection after an injury. Infection is not caused by the work environment. Treatment for an infection, such as prescription drugs. Again, infection is not the result of the work environment'' (Ex. 15: 414).

A number of employers asked OSHA to define the use of prescription drugs for comfort, or to relieve pain or inflammation, as first aid (see, *e.g.*, Exs. 15: 60, 147, 201, 225, 247, 308, 348, 349). The American Gas Association stated that: we propose that 'prescription medications for comfort' be added to the list. Medical practitioners frequently ''prescribe drugs to comfort people after an injury'' (Ex. 15: 225), and the Proctor and Gamble Company stated ''[p]rescription medication to prevent complications or reduce pain should not be a sole basis for recording injuries and illnesses. It is our view that preventive measures or action taken to reduce pain should not in themselves be the basis for recording'' (Ex. 15: 147). Entergy Services Inc. suggested that OSHA include Benadryl shots as first aid since they are often given to prevent allergic reactions to insect bites and poison oak/ivy/sumac (Ex. 15: 13). The Arizona Public Service Company remarked: ''Treatment for bee stings should be addressed (perhaps listed on the First Aid list). For instance, if a doctor administers the same treatment that an employee could have administered themselves it should not be considered medical treatment'' (Ex. 15: 247).

Another set of comments suggested that prescription medications should be considered first aid if they were used only once or for a limited period of time. A number of comments requested that OSHA continue to treat a single dose of prescription medication as first aid. (see, *e.g.*, Exs. 15: 201, 332, 348, 349, 359, 374, 386, 387, 405, 430, 434). Typical of these comments was one from the National Safety Council:

> [t]hat administration of a single dose of prescription medication on first visit for minor injury or discomfort remain first aid. For example, minor muscle aches and pains may occasionally be eased with a single dose of 800 mg ibuprofen. This is currently considered first aid and should remain so. Another example would be the treatment of first degree burns. This is currently considered first aid treatment, even though treatment frequently involves the application of a single dose of prescription-strength ointment. (Ex.15: 359, p. 12)

Other commenters suggested that prescription medications used for 24 hours, 48 hours, or five days be considered first aid (see, *e.g.*, Exs. 15: 159, 246, 297, 308, 335, 375).

In the final rule, OSHA has not included prescription medications, whether given once or over a longer period of time, in the list of first aid treatments. The Agency believes that the use of prescription medications is not first aid because prescription medications are powerful substances that can only be prescribed by a licensed health care professional, and for the majority of medications in the majority of states, by a licensed physician. The availability of these substances is carefully controlled and limited because they must be prescribed and administered by a highly trained and knowledgeable professional, can have detrimental side effects, and should not be self-administered.

Some commenters asked whether a case where a prescription was written by a physician and given to the injured or ill employee but was not actually filled or taken would be recordable. In some instances the employee, for religious or other reasons, refuses to fill the prescription and take the medicine. In other cases, the prescriptions are issued on a ''take-as-needed'' basis. In these cases, the health care professional gives the patient a prescription, often for pain medication, and tells the patient to fill and take the prescription if he or she

needs pain relief. OSHA's long-standing policy has been that if a prescription of this type has been issued, medical treatment has been provided and the case must therefore be recorded. Numerous commenters asked OSHA to reverse or clarify its policy and consider these prescriptions to be first aid in the final rule (see, *e.g.*, Exs. 15: 13, 105, 247, 260, 262, 279, 281, 295, 300, 308, 359, 362, 386, 414). For example, the National Safety Council requested that ''OSHA should specify whether the treatment must actually be given or merely be appropriate or normal for the injury or illness. For example, is medical treatment given when a prescription is written or when it is filled or when it is taken by the employee'' (Ex. 15: 359).

OSHA has decided to retain its long-standing policy of requiring the recording of cases in which a health care professional issues a prescription, whether that prescription is filled or taken or not. The patient's acceptance or refusal of the treatment does not alter the fact that, in the health care professional's judgment, the case warrants medical treatment. In addition, a rule that relied on whether a prescription is filled or taken, rather than on whether the medicine was prescribed, would create administrative difficulties for employers, because such a rule would mean that the employer would have to investigate whether a given prescription had been filled or the medicine had actually been taken. Finally, many employers and employees might well consider an employer's inquiry about the filling of a prescription an invasion of the employee's privacy. For these reasons, the final rule continues OSHA's longstanding policy of considering the giving of a prescription medical treatment. It departs from former practice with regard to the administration of a single dose of a prescription medicine, however, because there is no medical reason for differentiating medical treatment from first aid on the basis of the number of doses involved. This is particularly well illustrated by the recent trend toward giving a single large dose of antibiotics instead of the more traditional pattern involving several smaller doses given over several days.

Yet another issue raised by commenters about medications involved the use of non-prescription medications at prescription strength. In recent years, many drugs have been made available both as prescription and ''over-the-counter'' medications, depending on the strength or dosage of the product. Some examples include various non-steroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen, and cortisone creams. OSHA's policy has been that if these drugs are used in the over-the-counter form they are first aid, but if they are used in prescription form, they are medical treatment. Some commenters stated that these drugs should always be considered first aid (see, *e.g.*, Exs. 15: 300, 308, 414). For example, Heritage Environmental Services, Inc. stated:

> While the proposed rule includes the use of non-prescription medications in the definition of first aid, it fails to address the use of prescription quantities of over-the-counter medications (i.e., Tylenol, Motrin). It has been Heritage's experience that the requirement of the current rule to record cases where physicians have prescribed over the counter medications has resulted in the inclusion of a broad range of minor cases, that in all other respects would not have been recordable. In working with occupational health care providers for many years, Heritage has found that frequently, physicians prescribe prescription quantities of over the counter medications for reasons other than the severity of the injury. Many physicians are unaware that the distribution of OTC medications in such a manner results in an OSHA recordable injury/illness.* * * Heritage strongly favors the inclusion of a statement within the definition of first aid that eliminates the need to record cases where the sole reason for the recording of the case is the administration of prescription quantities of over-the-counter medications. (Ex. 15: 300)

Other commenters stated that the use of nonprescription medications should be considered medical treatment if they are used at prescription strength (Ex. 15: 279) or that the continued use of non-prescription drugs, especially anti-inflammatory drugs, should be considered medical treatment (see, *e.g.*, Exs. 15: 362, 371, 380, 418). The Union of Needletrades, Industrial and Textile Employees (UNITE) stated that ''the self-administration of medication, when used on a recurring basis, should trigger the recording of cases'' (Ex. 15: 380), and the United Food and Commercial Workers Union, pointed out that ''When the employee reports pain that has lasted for over a week, they are given over-the-counter medication for as long as they ask. These cases, which can go on for a month or longer, are never recorded'' (Ex. 15: 371).

One commenter suggested that health care professionals might prescribe over-the-counter medications rather than prescription medications for economic reasons (Ex. 15: 279).

The final rule does not consider the prescribing of non-prescription medications, such as aspirin or over-the-counter skin creams, as medical treatment. However, if the drug is one that is available both in prescription and nonprescription strengths, such as ibuprofen, and is used or recommended for use by a physician or other licensed health care professional at prescription strength, the medical treatment criterion is met and the case must be recorded. There is no reason for one case to be recorded and another not to be recorded simply because one physician issued a prescription and another told the employee to use the same medication at prescription strength but to obtain it over the counter. Both cases received equal treatment and should be recorded equally. This relatively small change in the recordkeeping rule will improve the consistency and accuracy of the data on occupational injuries and illnesses and simplify the system as well.

Two commenters asked OSHA to add non-prescription ointments to item 3 on the first aid list (Exs. 15: 308, 443). The final rule simply lists non-prescription medications, and expects non-prescription medications to be included regardless of form. Therefore, non-prescription medicines at non-prescription strength, whether in ointment, cream, pill, liquid, spray, or any other form are considered first aid. OSHA has also removed antiseptics from the description of non-prescription medications. Following the same logic used for ointments, there is no need to list the variety of possible uses of non-prescription medications. Non-prescription medicines are first aid regardless of the way in which they are used.

Item 4 listed in the NPRM definition of first aid was ''Simple administration of oxygen.'' Some commenters agreed with OSHA's proposal to define the giving of oxygen as first aid (see, *e.g.*, Exs. 15: 34, 74, 78, 201, 281, 378, 414).

Several commenters, however, asked OSHA to provide more guidance as to what qualified as the ''simple'' administration of oxygen (see, *e.g.*, Exs. 15: 13, 170, 188, 229, 260, 262, 265, 272, 303, 374, 401, 405), while others suggested alternatives that would make some uses of oxygen first aid and other uses medical treatment. The American Petroleum Institute recommended: ''Simple oxygen administration is standard operating procedure for EMTs and should remain first aid. Oxygen therapy, if prescribed, should be considered medical treatment'' (15: 375). A group of utilities said ''Simple administration of oxygen should be defined to include the preventive aspects following an injury. This would include, for example, administration at the pre-hospital site or while in the emergency room or hospital for observation. Identifying oxygen administration in this manner would

eliminate the need to identify which of the more advanced uses of oxygen should be considered as medical treatment'' (see, *e.g.*, Exs. 15: 260, 262, 265, 401).

A number of commenters opposed the inclusion of oxygen as a first aid treatment (see, *e.g.*, Exs. 15: 9, 87, 156, 290, 350, 395, 415, 429). The American Red Cross stated:

> The simple administration of oxygen * * * is inappropriately considered first aid. Simple administration of oxygen is not so simple. If oxygen is administered to someone with chronic pulmonary disease (a medical condition not generally recognized by untrained individuals), the victim could die. Carbon dioxide build-up in the blood forces an individual with this condition to breathe; therefore, administration of oxygen would obstruct the involuntary breathing action, resulting in pulmonary arrest. Red Cross would argue that no administration of oxygen is ''simple'' (Ex. 15: 290).

The United Brotherhood of Carpenters Health & Safety Fund of North America (USC H&SF) remarked, ''[w]e urge that OSHA remove the simple administration of oxygen from first aid treatment. This procedure requires considerable training above what is recognized as First Aid by either the Red Cross's or National Safety Council's First Aid training courses'' (Ex. 15: 350). The Muscatine Iowa Chamber of Commerce Safety Committee added:

> We feel that oxygen administration, as a first aid treatment would extend beyond the intent of the standards. The training and equipment requirements for the delivery of oxygen are extensive and beyond the simple first aid kits. We believe that the delivery of even the most minimal amount of oxygen constitutes an advanced level of care to an employee. All oxygen administration should be considered as medical treatment, no matter how delivered or how much is used, for whatever the reason'' (Ex. 15: 87, p. 4).

OSHA is persuaded by the views of the Red Cross and others, which point to the potential complexities and consequences of the administration of oxygen. Accordingly, the Agency has decided to remove the use of oxygen from the first aid list and to consider any use of oxygen medical treatment. Oxygen administration is a treatment that can only be provided by trained medical personnel, uses relatively complex technology, and is used to treat serious injuries and illnesses. The use of any artificial respiration technology, such as Intermittent Positive Pressure Breathing (IPPB), would also clearly be considered medical treatment under the final rule.

Item 5 listed in the NPRM definition of first aid was ''administration of tetanus or diphtheria shot(s) or booster(s).'' These treatments have been considered first aid by OSHA for some time when they are administered routinely, *i.e.*, in the absence of an injury or illness (see the Recordkeeping Guidelines (Ex. 2, p. 43)). Several commenters expressed their support for continuing to include tetanus and diphtheria shots and boosters as first aid (see, *e.g.*, Exs. 15: 197, 201, 218, 247, 302, 308, 348, 385, 386, 393). Bell Atlantic commented that ''Bell Atlantic supports the proposed inclusion of tetanus/diphtheria shots on the first aid list. Such preventative actions should not be considered medical treatment'' (Ex. 15: 218). One commenter, Countrymark Cooperative, Inc., agreed that tetanus shots or boosters should be considered first aid, but did not believe diphtheria shots or boosters should be (Ex. 15: 9).

Two commenters recommended that tetanus and diphtheria shots be considered medical treatment, whether or not they are administered in connection with a work-related injury or illness. The American Red Cross stated, ''inappropriately considered * * * administration of diphtheria and tetanus shots or boosters cannot be performed without a prescription from a physician. The person administering the shots must also be cognizant of potential side effects, *i.e.*, anaphylactic shock, which can result from such an action, and be prepared to address them'' (Ex. 15: 290). The International Brotherhood of Teamsters added ''International Brotherhood of Teamsters encourages OSHA to discontinue tetanus and diphtheria booster shots as first aid. They should be considered medical treatment. They are usually administered both after exposure and before diagnosis. The International Brotherhood of Teamsters considers it similar to the prophylaxis medical treatment given after exposure to Hepatitis B Virus'' (Ex. 15: 369).

A number of commenters recommended the addition to the first aid list of other immunizations, including gamma globulin; vaccines for hepatitis B, hepatitis C, and rabies; or other prophylactic immunizations (see, *e.g.*, Exs. 15: 197, 201, 218, 302, 308, 347, 348, 386). Caterpillar, Inc. recommended, ''[c]learly exclude any immunizations and inoculations which are preventative in nature. Immunizations and inoculations are not usually provided in response to a specific injury or illness and should be excluded from OSHA records'' (Ex. 15: 201).

In the final rule, tetanus immunizations are included as item B on the first aid list. These immunizations are often administered to a worker routinely to maintain the required level of immunity to the tetanus bacillus. These immunizations are thus based not on the severity of the injury but on the length of time since the worker has last been immunized.

The issue of whether or not immunizations and inoculations are first aid or medical treatment is irrelevant for recordkeeping purposes unless a work-related injury or illness has occurred. Immunizations and inoculations that are provided for public health or other purposes, where there is no work-related injury or illness, are not first aid or medical treatment, and do not in themselves make the case recordable. However, when inoculations such as gamma globulin, rabies, etc. are given to treat a specific injury or illness, or in response to workplace exposure, medical treatment has been rendered and the case must be recorded. The following example illustrates the distinction OSHA is making about inoculations and immunizations: if a health care worker is given a hepatitis B shot when he or she is first hired, the action is considered first aid and the case would not be recordable; on the other hand, if the same health care worker has been occupationally exposed to a splash of potentially contaminated blood and a hepatitis B shot is administered as prophylaxis, the shot constitutes medical treatment and the case is recordable.

Item 6 listed in the NPRM definition of first aid was ''cleaning, flushing or soaking wounds on skin surface.'' OSHA received only one specific comment on this item. The American Federation of State, County, and Municipal Employees (AFSCME) commented: ''Cleaning, flushing or soaking wounds on skin surfaces. This is the initial treatment for needle stick injuries. AFSCME requests that OSHA clarify its position that cleaning, flushing or soaking of sharps injuries is considered a medical treatment'' (Ex. 15: 362).

The AFL–CIO disagreed with OSHA's proposed approach to skin surface wounds, based on the belief that valuable information about serious work-related injuries would be lost if the approach were adopted:

> The proposed change in definition would seem to exclude cases where there are continued instances of the listed first aid treatments from the recordkeeping requirements. Those conditions which require continued treatments, including continued use of non-prescription drugs and repeated cleaning, flushing or soaking of wounds would no longer be recordable. The AFL–CIO believes that first aid should be limited to one time treatments as is the

current practice, so that serious conditions which require multiple treatments are recorded on the log. We strongly urge OSHA to maintain the definition of first aid in the current recordkeeping guidelines and to use the listed conditions as examples of first aid (Ex. 15: 418).

OSHA believes that cleaning, flushing or soaking of wounds on the skin surface is the initial emergency treatment for almost all surface wounds and that these procedures do not rise to the level of medical treatment. This relatively simple type of treatment does not require technology, training, or even a visit to a health care professional. More serious wounds will be captured as recordable cases because they will meet other recording criteria, such as prescription medications, sutures, restricted work, or days away from work. Therefore, OSHA has included cleaning, flushing or soaking of wounds on the skin surface as an item on the first aid list. As stated previously, OSHA does not believe that multiple applications of first aid should constitute medical treatment; it is the nature of the treatment, not how many times it is applied, that determines whether it is first aid or medical treatment.

Item 7 listed in the NPRM definition of first aid was ''Use of wound coverings, such as bandages, gauze pads, etc.'' These treatments were considered first aid treatments by the *Recordkeeping Guidelines* (Ex. 2, p. 43). OSHA received no comments opposing the proposed definition of wound coverings as first aid. However, the issue of whether or not butterfly bandages and Steri-strips™ are first aid was raised. Steri-strips™ are a product of the 3M Company, which advertises them as a comfortable adhesive strip used to secure, close and support small cuts, wounds and surgical incisions. ''Butterfly bandages'' is a generic term used for similar adhesive strips designed for small wounds.

All of the commenters who raised the issue suggested that OSHA add Steri-strips and butterfly bandages to this first aid item (see, *e.g.*, Exs. 15: 45, 108, 163, 201, 247, 308, 332, 349, 387, 405). Some commenters believed that the use of Steri-strips™ and butterfly bandages should always be considered first aid (see, *e.g.*, Exs. 15: 45, 247, 332, 349, 387), while others believed they should be considered medical treatment only when used as a replacement for, or in lieu of, sutures (see, *e.g.*, Exs. 15: 108, 163, 201, 308, 405). The Westinghouse Electric Corporation stated, ''Steri-strips should be added to the list of first-aid treatments, when determined by the attending medical provider that the Steri-strip™ was not applied in lieu of sutures. Often medical care providers use a Steri-strip™ rather than a bandage, even though the injury does not require closure of any type'' (Ex. 15: 405).

These treatments were listed in the 1986 *Recordkeeping Guidelines* as medical treatment when applied ''in lieu of sutures'' (Ex. 2, p. 43). In the past, this provision in the *Guidelines* has been the subject of several letters of interpretation. For example, in a 1993 letter from Ms. Monica Verros, R.N., C.O.H.N, of the IBP company, Ms. Verros asked, ''[a]re all applications of butterfly adhesive dressing(s) and Steri-strip(s) considered medical treatment?'' OSHA's answer was simply ''yes'' (Ex. 70: 136).

OSHA agrees with the commenters who suggested that these devices be considered first aid treatment. They are included in item D of the first aid list. Steri strips and butterfly bandages are relatively simple and require little or no training to apply, and thus are appropriately considered first aid.

Two commenters also raised the issue of whether or not sutures or stitches should be considered first aid (Exs. 15: 229, 348). The National Pest Control Association (NPCA) stated:

NPCA believes cuts requiring five or less external stitches should also be categorized as first aid as well unless the employee has to go back to the medical provider because of the cut or there are more than five external stitches. Some of the examples the agency has included in its list of first aid, such as drilling of a nail to relieve pressure for subungual hematoma and removal of splinters or foreign material from areas other than eyes by irrigation, tweezers, cotton, swabs or other simple means, seems to be comparable to cuts requiring a minimal amount of stitches. Therefore, we believe it should be added to the list (Ex. 15: 229, p. 4).

The Dupont Company suggested: ''Expand the 'suture' category to say that any device used for closure for therapeutic reasons is an automatic MTC (medical treatment case). Leeway should be given for when a care provider gives 'unnecessary' treatment, for example, sutures for cosmetic reasons instead of for therapeutic closure, where the doctor provides the documentation'' (Ex. 15: 348).

OSHA believes that including sutures or stitches in the first aid list would not be appropriate. Performing these procedures requires substantial medical training, and they are used only for more serious wounds and are generally considered to go beyond first aid. OSHA has also decided not to provide exclusions for first aid items based on their purpose or intent. If the medical professional decides stitches or sutures are necessary and proper for the given injury, they are medical treatment.

Because OSHA has decided not to include a list of medical treatments in the final rule, there is no need to articulate that the use of other wound closing devices, such as surgical staples, tapes, glues or other means are medical treatment. Because they are not included on the first aid list, they are by definition medical treatment.

Item 8 listed in the proposed definition of first aid was ''[u]se of any hot/cold therapy (*e.g.* compresses, soaking, whirlpools, non prescription skin creams/lotions for local relief, etc.) except for musculoskeletal disorders'' (61 FR 4059). *The Recordkeeping Guidelines* defined heat therapy, hot or cold therapy compresses or soaking therapy, or whirlpool bath therapy on a second or subsequent visit to be medical treatment (Ex. 2, p. 43). OSHA has restated this guidance in numerous letters of interpretation, most of them related to the issue of the recording of musculoskeletal disorders (MSDs).

A number of commenters recommended that hot or cold therapy be defined as first aid regardless of the number of times it is administered or the type of condition for which it is used (see, *e.g.*, Exs. 15: 39, 45, 95, 109, 156, 163, 199, 201, 218, 246, 308, 347, 348, 359, 386, 414, 430, 443). Several of the comments cited consistency as an issue (see, *e.g.*, Exs. 15: 39, 109, 347, 348, 430). For example, the Dupont Company stated that ''Item 8 on the 'First Aid Treatment' list considers the same treatment as either first aid or medical treatment depending on the condition for which it is applied. The treatment is used for reduction of swelling and discomfort. The condition for which it is used should not matter. * * * Exclude the 'except for musculoskeletal disorders * * *' clause from item 8 (Ex. 15: 348, p. 9).

Another issue raised was that hot and cold treatments do not require special training (Ex. 15: 414). For example, Raytheon Constructors stated ''[w]e believe the following treatments should be added: Soaking, whirlpool and hot/cold therapy with no limit on the number of times. Many physicians choose this conservative treatment, plus, any first aid trained person and/or the injured person can do this'' (Ex. 15: 414). Other commenters stated that serious musculoskeletal disorders would be captured more consistently by other recording criteria (see, *e.g.*, Exs. 15: 199, 347). The Ford Motor Company stated:

> We have a major disagreement with the proposed rule that the use of any hot or cold therapy is first aid, except for musculoskeletal disorders. The use of hot or cold therapy should always be considered first aid. If an individual has a significant or serious musculoskeletal disorder, it would require prescription medicine, restriction of work or motion, transfer to another job, a day away from work, or medical treatment. Considering hot or cold therapy to always be first aid simplifies the system, reduces confusion, and does not discourage practitioners from using hot or cold therapy for minor or insignificant musculoskeletal disorders. If all musculoskeletal disorders which include two or more applications of hot or cold therapy as directed by a health care provider are recordable, the data on musculoskeletal disorders will be absolutely useless (Ex. 15: 347).

Several commenters believed that multiple hot or cold treatments should be considered medical treatment (see, *e.g.*, Exs. 15: 371, 418). The AFL–CIO disagreed with OSHA's proposal; it recommended that multiple treatments of all types be considered medical treatment, based on the belief that valuable information about serious work-related injuries would otherwise be lost. The AFL–CIO said:

> The proposed change in definition would seem to exclude cases where there are continued instances of the listed first aid treatments from the recordkeeping requirements. * * * The AFL–CIO believes that first aid should be limited to one time treatments as is the current practice, so that serious conditions which require multiple treatments are recorded on the log. We strongly urge OSHA to maintain the definition of first aid in the current recordkeeping guidelines and to use the listed conditions as examples of first aid (15: 418).

The Tosco Corporation proposed an alternative, recommending that hot/cold treatments for musculoskeletal disorders be considered first aid for the first four treatments (Ex. 15: 246).

In the final rule, OSHA has included hot and cold treatment as first aid treatment, regardless of the number of times it is applied, where it is applied, or the injury or illness to which it is applied. The Agency has decided that hot or cold therapy must be defined as either first aid or medical treatment regardless of the condition being treated, a decision that departs from the proposal. It is OSHA's judgment that hot and cold treatment is simple to apply, does not require special training, and is rarely used as the only treatment for any significant injury or illness. If the worker has sustained a significant injury or illness, the case almost always involves some other form of medical treatment (such as prescription drugs, physical therapy, or chiropractic treatment); restricted work; or days away from work. Therefore, there is no need to consider hot and cold therapy to be medical treatment, in and of itself. Considering hot and cold therapy to be first aid also clarifies and simplifies the rule, because it means that employers will not need to consider whether to record when an employee uses hot or cold therapy without the direction or guidance of a physician or other licensed health care professional.

Item 9 listed in the NPRM definition of first aid was ''[u]se of any totally non-rigid, non-immobilizing means of support (*e.g.* elastic bandages).'' The proposal reflected OSHA's guidance to employers under past interpretations. The *Recordkeeping Guidelines* defined first aid treatment as ''use of elastic bandage(s) during first visit to medical personnel'' (Ex. 2, p. 43). The *Guidelines* do not provide specific guidance on the use of other types of orthopedic devices such as splints, casts, or braces. In response to requests from the public to clarify the issue of which devices are medical treatment and which are first aid treatment, OSHA issued several letters of interpretation stating that the use of wraps or non-constraining devices such as wristlets, tennis elbow bands or elastic bandages are first aid treatment, regardless of how long or how often they are used. The use of casts, splints, or orthopedic devices designed to immobilize a body part to permit it to rest and recover is considered medical treatment. Generally, orthopedic devices used for immobilization are made rigid, in whole or in part, through the use of stays or non-bending supports (see, *e.g.*, Exs. 70: 40, 158).

OSHA received several comments recommending that it provide additional clarification of this issue (see, *e.g.*, Exs. 15: 176, 290). Several commenters suggested that OSHA include wrist splints as first aid, on the grounds that wrist splints are used as a prophylactic treatment (see, *e.g.*, Exs. 15: 332, 349, 386, 387). Other commenters recommended that finger splints be considered first aid (see, *e.g.*, Exs. 15: 201, 349, 386). The Caterpillar Company suggested that OSHA ''[e]xpand item 9 to include rigid finger splints, which are used only to prevent further injury or to maintain the cleanliness of finger lacerations and other minor wounds, rather than as part of the required medical treatment. Only splints that are used to provide rigidity as part of the required medical treatment should trigger recordability'' (Ex. 15: 201).

Several comments centered on the issue of immobilization for injuries while the worker is being transported to a medical care facility (see, *e.g.*, Exs. 15: 290, 347, 434). The Ford Motor Company remarked, ''[t]he first aid list should be expanded to include the use of any partially or totally rigid immobilizing means of support when used solely for the purpose of immobilization during initial transport for medical evaluation. For example, the use of a back board, stiff neck collar, or air splint'' (Ex. 15: 347). The American Red Cross added:

> While Red Cross would agree that this is ''first aid,'' it is unclear whether OSHA intends for use of rigid support to be considered ''medical treatment.'' In most traditional first aid classes, including those taught by Red Cross, students are taught that if, for example, a victim has broken a bone, any rigid means of support that would immobilize the limb until further medical care can be obtained should be utilized. Examples of rigid support include newspapers, magazines, sticks, boards, splints, etc., anything that is available to prevent further injury. This action may be performed by anyone who has been trained in first aid, and Red Cross does not believe that ''rigidity'' is the appropriate qualification to consider this action ''medical treatment'' (15: 290).

The General Electric Corporation (GE) recommended that OSHA rely, not on the design of the device but on whether or not the device resulted in restricted activity. GE recommended ''the following additions to the list: Use of rigid or non-rigid immobilization devices, if they don't result in restricted activity, *e.g.* wrist braces, finger splints, immobilization for transport'' (Ex. 15: 349).

OSHA has included two items related to orthopedic devices in the final definition of first aid. Item F includes ''[u]sing any non-rigid means of support, such as elastic bandages, wraps, non-rigid back belts, etc. (devices with rigid stays or other systems designed to immobilize parts of the body are considered medical treatment for recordkeeping purposes).'' OSHA has included more examples of the devices (wraps and non-rigid back belts) to help make the definition clearer. However, OSHA believes that the use of orthopedic devices such as splints or casts should be considered medical treatment and not first aid. They are typically prescribed by licensed health care professionals for long term use, are typically used for serious injuries and illnesses, and are beyond the everyday definition of first aid. OSHA believes that it would be inappropriate to rely on ''restricted activity,'' as recommended by GE, because there may be situations where orthopedic devices are prescribed, the worker is not placed on

restrictions, but an injury or illness warranting recording has occurred.

However, OSHA agrees with those commenters who stated that the use of these devices during an emergency to stabilize an accident victim during transport to a medical facility is not medical treatment. In this specific situation, a splint or other device is used as temporary first aid treatment, may be applied by non-licensed personnel using common materials at hand, and often does not reflect the severity of the injury. OSHA has included this item as G on the first aid list: ''[u]sing temporary immobilization devices while transporting an accident victim (*e.g.* splints, slings, neck collars, etc.)''

Item 10 listed in the proposed definition of first aid was ''drilling of a nail to relieve pressure for subungual hematoma.'' A subungual hematoma is an accumulation of blood underneath a finger or toenail that is normally caused by a sharp blow to the nail. When pressure builds beneath the nail, pain results. The normal course of treatment for this injury is to drill a small hole through the nail to relieve the pressure. In the past, OSHA considered such treatment to be medical treatment and not first aid. For example, a 1993 letter from IBP, Inc. asked whether ''[d]rilling a hole through a fingernail to relieve pressure (subungual hematoma) is considered medical treatment?'' OSHA's answer was ''Yes, the draining of any fluids or blood is to be considered medical treatment'' (Ex. 70: 136).

OSHA received very few comments on this first aid item. Linda Ballas & Associates stated ''The drilling of a nail to relieve pressure for subungual hematoma should be included as medical treatment and not first aid'' (Ex. 15: 31, p. 5). The American Textile Manufacturers Institute recommended that OSHA change the item to: ''Simple relieving of the pressure of a subungual hematoma. The use of the word drilling is too restrictive. There are a number of simple procedures to relieve pressure that are considered first aid'' (Ex. 15:156). OSHA also received a similar comment from Oxychem Corporation stating that lancing a blister should be considered first aid (Ex. 15: 386).

OSHA has decided to retain this item on the first aid list and to add the lancing of blisters as well. These are both one time treatments provided to relieve minor soreness caused by the pressure beneath the nail or in the blister. These are relatively minor procedures that are often performed by licensed personnel but may also be performed by the injured worker. More serious injuries of this type will continue to be captured if they meet one or more of the other recording criteria. OSHA has specifically mentioned finger nails and toenails to provide clarity. These treatments are now included as item H on the first aid list.

Item 11 listed in the proposed definition of first aid was ''Use of eye patches.'' The *Recordkeeping Guidelines* did not provide specific guidance about eye patches. However, in a 1992 letter, OSHA provided an interpretation that the use of eye patches was first aid treatment; in that letter, ELB Inc. asked OSHA to ''[e]xplain if pressure patches on eyes are recordable or if a patch over an eye to prevent light from entering is recordable? Is the use of an eye patch recordable?'' OSHA answered '' The use of a normal eye patch is considered to be first aid. However, if the employee is unable to perform all of his/her normal job duties because of the patch, the case should be recorded based on restricted work activity. The use of a pressure eye patch is medical treatment'' (Ex. 70: 161) .

OSHA received only one comment specific to this item. The National Institute for Occupational Safety and Health (NIOSH) stated that the initial use of an eye patch would generally require medical evaluation and should not be considered first aid (Ex. 15: 407). In the final rule, OSHA has included the use of eye patches as first aid in item I of the first aid list. Eye patches can be purchased without a prescription, and are used for both serious and non-serious injuries and illnesses. OSHA believes that the more serious injuries to the eyes will that NIOSH refers to require medical treatment, such as prescription drugs or removal of foreign material by means other than irrigation or a cotton swab, and will thus be recordable.

Item 12 listed in the proposed definition of first aid was ''removal of foreign bodies not embedded in the eye if only irrigation or removal with a cotton swab is required.'' The effect of including this item in the list of first aid treatments would be to make any case involving a foreign body embedded in the eye a recordable injury.

The *Recordkeeping Guidelines* listed ''removal of foreign bodies embedded in the eye'' as medical treatment and ''removal of foreign bodies not embedded in eye if only irrigation is required'' as first aid (Ex. 2, p. 43). In subsequent letters of interpretation, the use of a cotton swab to remove a foreign body from the eye was interpreted to be first aid; injuries requiring any removal method other than irrigation or a cotton swab made the case recordable (Ex. 70: 92).

OSHA received few comments on this first aid item. NIOSH stated that any case involving a foreign body in the eye should be recorded, because ''even though removal of a foreign body from the eye may be a first aid procedure, the presence of a work-related foreign body in the eye should be recordable. These procedures should not be considered first aid'' (Ex. 15: 407). The Ford Motor Company asked OSHA to clarify that a foreign body ''embedded in or adhered to'' the eye and removed by the methods proposed would be considered first aid. Ford added that ''[t]he use of a prescription medication to anesthetize the eye for a diagnostic procedure, an assessment procedure, or flushing to remove a loose foreign body should not be considered medical treatment'' (Ex. 15: 347). Countrymark Cooperative, Inc. asked that the definition of this item be expanded to include other means of removal, stating: ''We suggest wording such as * * * Removal of foreign bodies not embedded in the eye if only irrigation or simple removal techniques are required, or comparable'' (Ex. 15: 9).

In the final rule, OSHA has included as item J ''Removing foreign bodies from the eye using only irrigation or a cotton swab.'' OSHA believes that it is often difficult for the health care professional to determine if the object is embedded or adhered to the eye, and has not included this suggested language in the final rule. In all probability, if the object is embedded or adhered, it will not be removed simply with irrigation or a cotton swab, and the case will be recorded because it will require additional treatment.

OSHA believes that it is appropriate to exclude those cases from the Log that involve a foreign body in the eye of a worker that can be removed from the eye merely by rinsing it with water (irrigation) or touching it with a cotton swab. These cases represent minor injuries that do not rise to the level requiring recording. More significant eye injuries will be captured by the records because they involve medical treatment, result in work restrictions, or cause days away from work.

Item 13, the last item listed in the proposed definition of first aid, was ''Removal of splinters or foreign material from areas other than the eyes by irrigation, tweezers, cotton swabs or other simple means.'' The *Recordkeeping Guidelines* distinguished between foreign body removal cases on the basis of the complexity of the removal technique used. According to the *Guidelines*, the ''removal of foreign bodies from a wound if the procedure is

complicated because of depth of embedment, size or location'' was medical treatment, while ''removal of foreign bodies from wound, if procedure is uncomplicated, and is, for example, by tweezers or other simple technique'' was first aid (Ex. 2, p. 43).

OSHA received one comment specific to this proposed first aid item. The Muscatine Iowa Chamber of Commerce Safety Committee stated ''The list appears to be very inclusive of what items are currently understood as first aid treatments. Our only concern is the ambiguous ending of Number 13. ''* * * or other simple means.'' This should be further defined. Change number 13 to read: ''Removal of splinters or foreign material from areas other than the eyes by irrigation, tweezers, cotton swabs or by excision not to exceed the depth of the outer layer of skin'' (Ex. 15: 87).

In the final rule, OSHA has decided to retain item 13 essentially as proposed, and this first aid treatment appears as item K on the first aid list. The inclusion of the phrase ''other simple means'' will provide some flexibility and permit simple means other than those listed to be considered first aid. Cases involving more complicated removal procedures will be captured on the Log because they will require medical treatment such as prescription drugs or stitches or will involve restricted work or days away from work. OSHA believes that cases involving the excision of the outer layer of skin are not appropriately considered first aid, as suggested by the Muscatine Iowa Chamber of Commerce; excision of tissue requires training and the use of surgical instruments.

Additions to the First Aid List Suggested by Commenters

In addition to comments about the first aid items OSHA proposed to consider first aid, a number of commenters asked for additional clarifications or recommended additions to the first aid list. The items suggested included exercise, chiropractic treatment, massage, debridement, poison ivy, bee stings, heat disorders, and burns.

Exercise: Several commenters requested adding exercise, performed either at home or at work, to the list (see, *e.g.*, Exs. 15: 201, 308, 349, 396). For example, Caterpillar suggested that OSHA ''[a]dd a listing for range of motion exercises and minor physical therapy performed at home'' (Ex. 15: 201). These comments described exercises that amount to self-administered physical therapy, and are normally recommended by a health care professional who trains the worker in the proper frequency, duration and intensity of the exercise. Physical therapy treatments are normally provided over an extended time as therapy for a serious injury or illness, and OSHA believes that such treatments are beyond first aid and that cases requiring them involve medical treatment.

Chiropractic treatment: A few commenters believe that chiropractic treatment should be treated as first aid (see, *e.g.*, Exs. 15: 154, 299, 396). For example, the Sandoz Corporation stated ''[i]t would simplify our record keeping if there were better definition of the use of chiropractors. Is one visit counted or do you have to have multiple visits'' (Ex. 15: 299). OSHA does not distinguish, for recordkeeping purposes, between first aid and medical treatment cases on the basis of number of treatments administered. OSHA also does not distinguish between various kinds of health care professionals, assuming they are operating within their scope of practice. If a chiropractor provides observation, counseling, diagnostic procedures, or first aid procedures for a work-related injury or illness, the case would not be recordable. On the other hand, if a chiropractor provides medical treatment or prescribes work restrictions, the case would be recordable.

Massage therapy: The Union Carbide company recommended the addition of massages and prescribed physical therapy to the first aid list (Ex. 15: 396). OSHA believes that massages are appropriately considered first aid and has included them as item M in the final rule's first aid list. However, physical therapy or chiropractic manipulation are treatments used for more serious injuries, and are provided by licensed personnel with advanced training and therefore rise to the level of medical treatment beyond first aid.

Debridement: Several commenters recommended that OSHA include debridement as a first aid treatment (see, *e.g.*, Exs. 15: 201, 332, 349, 387). Debridement is the surgical excision, or cutting away, of dead or contaminated tissue from a wound. The *Recordkeeping Guidelines* listed ''cutting away dead skin (surgical debridement)'' as an example of medical treatment (Ex. 2, p. 43). The Caterpillar Company recommended that OSHA ''[a]dd to the [first aid] listing provisions for the minor removal of nonviable tissue as first aid treatment'' (Ex. 15: 201).

OSHA has decided not to include debridement as a first aid treatment. This procedure must be performed by a highly trained professional using surgical instruments. Debridement is also usually performed in conjunction with other forms of medical treatment, such as sutures, prescription drugs, etc.

Intravenous (IV) administration of glucose and saline: Two commenters (Exs. 15: 154, 395) argued that the intravenous administration of saline (salt) and glucose (sugar) should be considered first aid. In former letters of interpretation, OSHA considered these treatments first aid in injury cases (see, *e.g.*, Exs. 15: 154, 395). In the final rule, however, OSHA has decided not to include the IV administration of fluids on the first aid list because these treatments are used for serious medical events, such as post-shock, dehydration or heat stroke. The administration of IVs is an advanced procedure that can only be administered by a person with advanced medical training, and is usually performed under the supervision of a physician.

The Union Carbide Corporation (Ex. 15: 396) also recommended three additions to the first aid list: UV treatment of blisters, rashes and dermatitis; acupuncture, when administered by a licensed health care professional; and electronic stimulation. After careful consideration, OSHA has decided not to include these treatments as first aid. Each of these treatments must be provided by a person with specialized training, and is usually administered only after recommendation by a physician or other licensed health care professional.

Several commenters asked that treatments for two specific types of disorders be added to the list: heat disorders and burns. OSHA has not added these types of conditions to the first aid list because the list includes treatments rather than conditions. However, OSHA has added fluids given by mouth for the relief of heat disorders to the list, in response to comments received.

Two commenters asked about the recording of heat disorders and how they relate to the definition of first aid and medical treatment. Union Carbide recommended an addition to the first aid list to state ''fluids taken internally for heat stress'' (Ex. 15: 396). The Arizona Public Service Company remarked: ''Recordability of heat stress and heat rash should be addressed based on classification of treatment (first aid vs. medical)'' (Ex. 15: 247). Under OSHA's former recordkeeping system, heat stress was recordable as an occupational illness because it results from non-instantaneous exposures that occur over time and all occupational

illnesses, including minor ones, were considered recordable.

In the final rule, OSHA agrees with Union Carbide that drinking fluids for the relief of heat disorders is a first aid rather than medical treatment and item N on the final first aid list is ''drinking fluids for relief of heat stress.'' However, as discussed above, OSHA believes that more extensive treatment, including the administration of fluids by intravenous injections (IV), are medical treatment, and more serious cases of heat disorders involving them must be entered into the records. In addition, any diagnosis by a physician or other licensed health care professional of heat syncope (fainting due to heat) is recordable under paragraph 1904.7(b)(6), Loss of Consciousness.

Burns: Many commenters recommended that OSHA include the treatment of burns on the first aid list (see, *e.g.*, Exs. 45, 170, 260, 262, 265, 288, 301, 401, 414, 443). Teepak Inc. stated ''[s]econd degree burns treated by first aid measures only, with no infection or complication or prescription medication, should be considered first aid'' (Ex. 15: 45). The Georgia Power Company argued that ''[t]reatment of all first degree burns should be added to the list of first aid treatments because they are minor injuries that are exempt from the requirements of the Act. Omission of first degree and second degree burns receiving only first aid treatment from this list is inconsistent with the recording criteria listed for burns of the skin in [proposed] Appendix B'' (Ex. 15: 260). The Chemical Manufacturers Association recommended that OSHA add ''[b]urns that require only one-time treatment. Subsequent observations and changing of bandages does not constitute medical treatment'' (Ex. 15: 301).

The former *Recordkeeping Guidelines* listed the treatment of first degree burns as an example of first aid treatment and did not consider such treatment to be recordable (Ex. 2, p. 43). In the final rule, OSHA has decided not to include burn treatments on the first aid list. If first, second, or third degree burns result in days away from work, restricted work activity, or medical treatment beyond first aid, such as prescription drugs or complex removal of foreign material from the wound, they will rise to the level that requires recording.

Taking this approach means that burns will be treated just as other types of injury are, *i.e.,* minor burn injuries will not be recordable, while more serious burns will be recorded because they will involve medical treatment. For example, a small second degree burn to the forearm that is treated with nothing more than a bandage is not recordable. A larger or more severe second degree burn that is treated with prescription creams or antibiotics, or results in restricted work, job transfer, or days away from work is recordable. The vast majority of first degree burns and minor second degree burns will not be recorded because they will not meet the recording criteria, including medical treatment. However, more serious first and second degree burns that receive medical treatment will be recorded, and third degree burns should always be recorded because they require medical treatment.

Miscellaneous First Aid and Medical Treatment Issues

The American Association of Occupational Health Nurses (AAOHN) was concerned that the public might interpret the fact that treatments were listed as first aid to mean that they did not have to be administered, in some cases, by a health care professional:

> OSHA must clarify that categorizing certain actions as first aid does not necessarily imply that these actions can be delegated to a non-health care professional. While a list of actions considered first aid treatment will offer guidance for employers in determining recordability of incidents, situations exist that will require the professional judgment of a health care professional. One example is the administration of tetanus/diphtheria shots. While it is appropriate to consider these treatments first aid for recordability, injections pose issues that require the judgment and expertise of a health care professional. One potential hazard of this treatment is the risk of side effects. The ability to identify the reaction and take appropriate measures should be handled by a qualified health care professional (Ex. 15: 181).

OSHA agrees with the AAOHN that certain treatments and interventions require the professional judgment of a health care professional. The Agency believes that these matters are best left to state agencies and licensing boards, and the final rule's definition of health care professional (see Subpart G) makes this clear.

The State of New York expressed a concern about the possible confusion some employers might experience between OSHA's requirements and those of the state workers' compensation systems. The New York Workers' Compensation Board stated:

> The proposed rule contains a broad list of treatments which will qualify as first aid, with less emphasis on the number of treatments or the resulting amount of lost time from work. It is possible that many of the items listed in the OSHA rule as first-aid treatments which do not require reporting under the proposed OSHA standard (*i.e.* use of splints, drilling a nail in a hematoma, use of compresses and non-prescription medications), may still require reporting under the WCL because in a particular case the treatment qualifies as medical treatment or because it has caused lost time from work beyond the working day. The only problem would be if employers, in complying with proposed OSHA requirements, failed to continue to comply with New York's recording and reporting requirements (Ex. 15: 68).

OSHA's reporting requirements do not in any way interfere with or have any impact on state workers compensation reporting requirements. Employers are required to record certain injuries and illnesses under the OSHA recordkeeping regulation and to observe certain other requirements under workers' compensation law. The two laws have separate functions: workers' compensation is designed to compensate injured or ill workers, while the OSH Act is designed to prevent injuries and illnesses and to create a body of information to improve understanding of their causes. Thus, certain injuries and illnesses may be reportable under state workers' compensation law but not under the OSHA recordkeeping rule, and certain injuries and illnesses may be reportable under the OSHA rule but not under one or more workers' compensation statutes. OSHA notes that employers have been following the requirements of both systems for years, and have generally not experienced difficulty in doing so.

Several commenters remarked on the need for OSHA to update the first aid list in the future (see, *e.g.*, Exs. 234, 247, 384, 407). One commenter remarked: ''The suggested first aid list adds and clarifies some treatments as first aid. There should be a mechanism for adding or removing treatments to first aid and medical treatment lists as new information becomes available'' (Ex. 15: 234). The Akzo Nobel Company suggested that ''[w]ith the assistance of occupational physicians, updates could be made quarterly and distributed via the Internet'' (Ex. 15: 384). The National Institute for Occupational Safety and Health (NIOSH) recommended ''[t]he first aid list, however, should be included as an appendix, rather than in the rule itself, in order to allow revisions to be made more easily as medical practice evolves'' (Ex. 15: 407).

In response, OSHA notes that the list is part of a definition that sets mandatory recording and reporting requirements and is a part of the regulation itself. Including the first aid list as a non-mandatory appendix would

provide additional flexibility for future updates, but doing so would not meet the purposes for which the list is intended. The list is mandatory, and making it non-mandatory would only introduce additional confusion about what is or is not to be entered into the records. As a result, the mechanism OSHA will use to update or modify the first aid list will be to pursue a future rulemaking, if and when such a rulemaking is needed. OSHA will continue to issue letters of interpretation to help employers understand the requirements as they apply to specific situations.

Paragraph 1904.7(b)(6) Loss of Consciousness

The final rule, like the former rule, requires the employer to record any work-related injury or illness resulting in a loss of consciousness. The recording of occupational injuries and illnesses resulting in loss of consciousness is clearly required by Sections 8(c) and 24 of the OSH Act. The new rule differs from the former rule only in clearly applying the loss of consciousness criterion to illnesses as well as injuries. Since the former rule required the recording of all illnesses, illnesses involving loss of consciousness were recordable, and thus OSHA expects that this clarification will not change recording practices. Thus, any time a worker becomes unconscious as a result of a workplace exposure to chemicals, heat, an oxygen deficient environment, a blow to the head, or some other workplace hazard that causes loss of consciousness, the employer must record the case.

Very few commenters addressed the issue of loss of consciousness. Three commenters asked OSHA to make sure that these cases are not recordable unless they are the result of a work-related injury or illness (see, *e.g.*, Exs. 15: 102, 159, 176). The American Frozen Food Institute (AFFI) stated that ''[l]oss of consciousness should not be reported unless it is the clear result of a work related injury or illness'' (Ex. 15: 102). The Chemical Manufacturers Association added ''OSHA must clearly indicate in the final recordkeeping rule that loss of consciousness must be induced by an occupational exposure. For example, if someone faints at work due to pregnancy or has an epileptic seizure, such loss of consciousness should not be recordable'' (Ex. 15: 176).

OSHA agrees with these commenters that, in order to be a recordable event, a loss of consciousness must be the result of a workplace event or exposure. Loss of consciousness is no different, in this respect, from any other injury or illness. The exceptions to the presumption of work-relationship at § 1904.5(b)(2)(ii) allow the employer to exclude cases that ''involve signs or symptoms that surface at work but result solely from a non-work-related event or exposure that occurs outside the work environment.'' This exception allows the employer to exclude cases where a loss of consciousness is due solely to a personal health condition, such as epilepsy, diabetes, or narcolepsy.

The American Crystal Sugar Company (Ex. 15: 363) raised the issue of phobias resulting in loss of consciousness:

> I would also like to suggest exempting an employee's loss of consciousness based on a fear-based phobia, i.e., fainting at the sight of blood. Occasionally an OSHA regulation may require blood tests, such as checking lead levels in blood. There are a few employees that will lose consciousness at the sight of a needle. These phobias are not limited to medical procedures, but may include spiders, snakes, etc. In several of our factories, the occupational health nurse will administer tetanus boosters as a service to our employees. Employees that have a phobia about injections can (and do) lose consciousness, which now makes what was intended as a service an OSHA recordable accident.

The final rule does not contain an exception for loss of consciousness associated with phobias or first aid treatment. OSHA notes, however, that the exception at paragraph 1904.5(b)(2)(iii) allows the employer to rebut the presumption of work relationship if ''the injury or illness results solely from voluntary participation in a wellness program or in a medical, fitness, or recreational activity such as blood donation, physical, flu shot, exercise class, racquetball, or baseball.'' This exception would eliminate the recording of fainting episodes involving voluntary vaccination programs, blood donations and the like. However, episodes of fainting from mandatory medical procedures such as blood tests mandated by OSHA standards, mandatory physicals, and so on would be considered work-related events, and would be recordable on the Log if they meet one or more of the recording criteria. Similarly, a fainting episode involving a phobia stemming from an event or exposure in the work environment would be recordable.

The Union Carbide Corporation (Ex. 15: 396) asked OSHA to be more precise about the definition of loss of consciousness, stating that ''[m]ost people generally understand this term without a definition, but it can be open to interpretation. For example, is 'feeling woozy' for a few seconds considered to be a loss of consciousness? Perhaps OSHA should define the term to avoid any confusion.'' In this final rule, OSHA has not included a separate definition for the term ''loss of consciousness.'' However, the language of paragraph 1904.7(b)(6) has been carefully crafted to address two issues. First, the paragraph refers to a worker becoming ''unconscious,'' which means a complete loss of consciousness and not a sense of disorientation, ''feeling woozy,'' or a other diminished level of awareness. Second, the final rule makes it clear that loss of consciousness does not depend on the amount of time the employee is unconscious. If the employee is rendered unconscious for any length of time, no matter how brief, the case must be recorded on the OSHA 300 Log.

Paragraph 1904.7(b)(7) Recording Significant Work-Related Injuries and Illnesses Diagnosed by a Physician or Other Licensed Health Care Professional

Paragraph 1904.7(b)(7) of this final rule requires the recording of any significant work-related injury or illness diagnosed by a physician or other licensed health care professional. Paragraph 1904.7(b)(7) clarifies which significant, diagnosed work-related injuries and illnesses OSHA requires the employer to record in those rare cases where a significant work-related injury or illness has not triggered recording under one or more of the general recording criteria, i.e, has not resulted in death, loss of consciousness, medical treatment beyond first aid, restricted work or job transfer, or days away from work. Based on the Agency's prior recordkeeping experience, OSHA believes that the great majority of significant occupational injuries and illnesses will be captured by one or more of the other general recording criteria in Section 1904.7. However, OSHA has found that there is a limited class of significant work-related injuries and illnesses that may not be captured under the other § 1904.7 criteria. Therefore, the final rule stipulates at paragraph 1904.7(b)(7) that any significant work-related occupational injury or illness that is not captured by any of the general recording criteria but is diagnosed by a physician or other licensed health care professional be recorded in the employer's records.

Under the final rule, an injury or illness case is considered significant if it is a work-related case involving occupational cancer (*e.g.*, mesothelioma), chronic irreversible disease (*e.g.*, chronic beryllium disease), a fractured or cracked bone (*e.g.*, broken arm, cracked rib), or a punctured

eardrum. The employer must record such cases within 7 days of receiving a diagnosis from a physician or other licensed health care professional that an injury or illness of this kind has occurred. As explained in the note to paragraph 1904.7(b)(7), OSHA believes that the great majority of significant work-related injuries and illnesses will be recorded because they meet one or more of the other recording criteria listed in § 1904.7(a): death, days away from work, restricted work or job transfer, medical treatment beyond first aid, or loss of consciousness. However, there are some significant injuries, such as a punctured eardrum or a fractured toe or rib, for which neither medical treatment nor work restrictions may be administered or recommended.

There are also a number of significant occupational diseases that progress once the disease process begins or reaches a certain point, such as byssinosis, silicosis, and some types of cancer, for which medical treatment or work restrictions may not be recommended at the time of diagnosis, although medical treatment and loss of work certainly will occur at later stages. This provision of the final rule is designed to capture this small group of significant work-related cases. Although the employer is required to record these illnesses even if they manifest themselves after the employee leaves employment (assuming the illness meets the standards for work-relatedness that apply to all recordable incidents), these cases are less likely to be recorded once the employee has left employment. OSHA believes that work-related cancer, chronic irreversible diseases, fractures of bones or teeth and punctured eardrums are generally recognized as constituting significant diagnoses and, if the condition is work-related, are appropriately recorded at the time of initial diagnosis even if, at that time, medical treatment or work restrictions are not recommended.

As discussed in the Legal Authority section, above, OSHA has modified the Agency's prior position so that, under the final rule, minor occupational illnesses no longer are required to be recorded on the Log. The requirement pertaining to the recording of all significant diagnosed injuries and illnesses in this paragraph of the final rule, on the other hand, will ensure that all significant (non-minor) injuries and illnesses are in fact captured on the Log, as required by the OSH Act. Requiring significant cases involving diagnosis to be recorded will help to achieve several of the goals of this rulemaking. First, adherence to this requirement will produce better data on occupational injury and illness by providing for more complete recording of significant occupational conditions. Second, this requirement will produce more timely records because it provides for the immediate recording of significant disorders on first diagnosis. Many occupational illnesses manifest themselves through gradual onset and worsening of the condition. In some cases, a worker could be diagnosed with a significant illness, such as an irreversible respiratory disorder, not be given medical treatment because no effective treatment was available, not lose time from work because the illness was not debilitating at the time, and not have his or her case recorded on the Log because none of the recording criteria had been met. If such a worker left employment or changed employers before one of the other recording criteria had been met, this serious occupational illness case would never be recorded. The requirements in paragraph 1904.7(b)(7) remedy this deficiency and will thus ensure the capture of more complete and timely data on these injuries and illnesses.

The provisions of paragraph 1904.7(b)(7) are an outgrowth of Appendix B of the proposed rule, which included provisions for the recording of individual conditions, such as blood lead levels, musculoskeletal disorders, and various respiratory ailments. As OSHA explained in the preamble to the proposed rule (61 FR 4039–4042), the proposed requirements were intended to ensure the recording of significant non-fatal cases that did not meet the general criteria (days away, restricted work, medical treatment, etc.).

Proposed Appendix B has not been included in the final rule, which instead includes additional separate criteria for several of the conditions proposed to be included in Appendix B; these criteria, which cover tuberculosis cases, hearing loss cases, and so on, appear in the final rule at § 1904.8 through § 1904.12. The requirements at paragraph 1904.7(b)(7) of the final rule, which require the recording of significant injuries and illnesses not meeting one or more of the general recording criteria, will ensure the recording of the small number of significant conditions that would have been covered by proposed Appendix B and are not elsewhere addressed in the final rule. Thus, OSHA believes that cases involving the conditions listed in proposed Appendix B will be captured either by the requirements in this significant diagnosed case section or by the other general recording criteria.

In developing the text of paragraph 1904.7(b)(7) of the final rule, OSHA reviewed the following questions as they related to proposed Appendix B. Each of these questions, and the comments received, are discussed in greater detail below: (1) Are additional recording criteria beyond loss of consciousness, medical treatment, restricted work, job transfer, days away, or death needed in the final rule?; (2) if so, should these additional criteria address a finite list of specific conditions or address a broader range of disorders?; (3) how should the agency define ''significant'' injuries and illnesses?; and (4) how should the final rule ensure the work-relatedness of these cases?

Are Additional Recording Criteria Needed?

Many commenters viewed proposed Appendix B as an unnecessary addition to the other general recording criteria and argued that OSHA should use the general criteria listed in the OSH Act itself for most if not all of the listed conditions (see, *e.g.,* Exs. 15: 52, 146, 200, 203, 219, 260, 262, 265, 271, 272, 303, 313, 329, 348, 352, 353, 368, 401, 427). For example, the Atlantic Richfield Company (ARCO) stated that:

> [t]his broadening of the recordability criteria particularly as detailed in [proposed] mandatory Appendix B dilutes the significant data with marginal data and does not, in our view, fit with OSHA's stated goals for improved Log accuracy and utility. ARCO believes that for almost all of these specific exposures, the appropriate data can be captured through the normal performance criteria of whether the condition or exposure has caused a day away from work, restriction on activity, or resulted in medical treatment. It is, therefore, our opinion that Appendix B is unnecessary and appropriate for deletion (Ex. 15: 329).

However, other commenters saw a need for and supported the inclusion of additional recording criteria in the final rule (see, *e.g.,* Exs. 15: 201, 301, 304, 318). For example, the National Federation of Independent Business (NFIB) agreed that ''[t]here are some conditions which are serious enough to be recorded, but could escape the proposed recordkeeping criteria of medical treatment, restricted or loss workdays or job transfer'' (Ex. 15: 304). Caterpillar agreed ''[w]ith the basic concept proposed in Appendix B that additional guidelines are needed to capture some injuries and illnesses serious enough to be recorded, which may not be captured by the basic recordkeeping criteria'' (Ex. 15: 201).

OSHA agrees with those commenters who supported the inclusion in the final rule of an additional mechanism to ensure the capture of significant work-related injuries and illnesses that are diagnosed by a physician or other licensed health care professional but do

not, at least at the time of diagnosis, meet the criteria of death, days away from work, restricted work or job transfer, medical treatment beyond first aid, or loss of consciousness. The recording of *all* non-minor injuries and illnesses is consistent with the OSH Act (see the Legal Authority section) and has been the intent of the recordkeeping system for many years. The primary goal of the requirement at paragraph 1904.7(b)(7) is to produce more accurate and complete data on non-minor work-related injuries and illnesses. Because the number of significant work-related injuries and illnesses may not be captured by one or more of the other general recording criteria, OSHA finds that this additional criterion is needed. However, OSHA believes that most cases will be captured by the general recording criteria.

Should Additional Criteria Address a Finite List of Specific Conditions or Address a Broader Range of Disorders?

Proposed Appendix B was composed of a finite list of disorders and their associated recording criteria. A number of commenters were concerned that an inclusive list would overlook other conditions that did not meet the general recording criteria and were not included in proposed Appendix B. For example, OxyChem wrote:

> [f]or example, aniline is a substance having specific effects from occupational exposure, but it is not listed in Appendix B. How will occupational illness cases related to aniline be treated? Under OSHA's proposal, employers will apply the general recordability criteria to make a decision, and the case will very likely not be recorded unless it involves medical treatment, loss of consciousness, etc. (Ex. 15: 386)

This issue was also raised by the International Chemical Workers, who wrote that ''[a]ppendix B limits the types of illnesses which are recordable. It needs to be textually and visually clear that this list is not an all inclusive list of recordable illnesses '' (Ex. 15: 415). Additionally, the American Industrial Hygiene Association had the following thoughts on this subject:

> [a]n addition should be made to the end of Appendix B to clarify and expand on the recording of new or emerging occupational illnesses as introduced by OSHA in Appendix B, second paragraph at the end of page 4063: ''Conditions not included in this Appendix that otherwise meet the criteria in the § 1904.4.(c) must be recorded.'' Medical diagnoses, including laboratory and diagnostic tests should be the principal criteria for recording occupational illnesses.
>
> The above quotation ''Conditions not included in this Appendix * * * must be recorded'' should be reworded to include the statement ''including symptomology with a clear workplace link'' (Ex. 15: 153).

OSHA generally agrees with these points. Limiting the recording of non-minor occupational injuries and illnesses to a finite list runs counter to the goal of this rule, which is to capture comprehensive data on all non-minor work-related injuries and illnesses, and thus including such a list would not meet the Agency's statutory mandate to collect such data. OSHA believes there will be very few injuries and illnesses that are not captured by the general recording criteria. For example, non-minor acute illnesses, such as the skin disorders potentially associated with aniline exposure, will be captured by the other criteria, particularly medical treatment beyond first aid, restricted work or job transfer, or days away from work. However, to address the gap in case capture presented by significant injury and illness cases that escape the general recording criteria, OSHA is requiring employers to record cases of chronic, irreversible disease under the § 1904.7(b)(7) criterion. This means that if long-term workplace exposure to aniline results in a chronic, irreversible liver or kidney disease, the case would be recordable at the time of diagnosis, even if no medical treatment is administered at that time and no time is lost from work. The regulatory text of paragraph 1904.7(b)(7) limits the types of conditions that are recordable, however, to significant diagnosed injury and illness cases, which are defined as cancer, chronic irreversible diseases, fractured or cracked bones, and punctured eardrums.

How Should the Agency Define ''Significant'' Injury or Illness?

Although there was considerable support in the record for the final rule to include a list of conditions that might not be captured under the general recordkeeping criteria, there was far less agreement among commenters on the specific conditions that should be listed. Many commenters agreed with Amoco, which testified that ''[t]he criteria currently listed in the proposed rule would require recording of signs, symptoms and laboratory abnormalities; situations which are not disabling, serious, or significant'' (Ex. 22). Waste Management, Inc., commented that ''[t]he definition of an illness [in the proposal] or injury refers to an adverse change in the individual. This is interpreted to mean a change which is permanent or a change which is clinically demonstrable to be adverse to the individual as a result of occupational exposure in the workplace. Some of the guidance provided in Appendix B does not meet these criteria'' (Ex. 15: 389). The Chemical Manufacturers Association suggested that only those conditions ''[w]hose seriousness is approximately equal to that of conditions captured by traditional criteria'' be included in Appendix B (Ex. 15: 301), and the Dupont Company proposed that the conditions listed in Appendix B ''[i]nclude only situations that cause a permanent change to the body structure where medical treatment may not be given'' (Ex. 15: 348). Dupont also stated that ''[O]SHA should provide scientific evidence that a change in a lab reading [laboratory tests results were also included in proposed Appendix B] is the equivalent of a serious or significant change to the body structure'' (Ex. 15: 348). Other commenters such as the Marathon Oil Company questioned whether OSHA had the legal authority ''[t]o require employers to record these non-serious exposures. The OSHA proposed criteria do not represent serious, significant or disabling injuries/illnesses as required by Section 24(a) of the Act'' (Ex. 15: 308).

OSHA believes that the conditions that are required to be recorded under § 1904.7(b)(7) of the final rule represent significant occupational injuries and illnesses as described in the OSH Act. Some clearly significant injuries or illnesses are not amenable to medical treatment, at least at the time of initial diagnosis. For example, a fractured rib, a broken toe, or a punctured eardrum are often, after being diagnosed, left to heal on their own without medical treatment and may not result in days away from work, but they are clearly significant injuries. Similarly, an untreatable occupational cancer is clearly a significant injury or illness. The second set of conditions identified in paragraph 1904.7(b)(7), chronic irreversible diseases, are cases that would clearly become recordable at some point in the future (unless the employee leaves employment before medical treatment is provided), when the employee's condition worsens to a point where medical treatment, time away from work, or restricted work are needed. By providing for recording at the time of diagnosis, paragraph 1904.7(b)(7) of the final rule makes the significant, work-related condition recordable on discovery, a method that ensures the collection of timely data. This approach will result in better injury and illness data and also is likely to be more straightforward for employers to comply with, since there is no further need to track the case to

determine whether, and at what point, it becomes recordable.

The core of the recording requirement codified at § 1904.7(b)(7) is the employer's determination that a ''significant'' injury or illness has been diagnosed. The Agency's former *Recordkeeping Guidelines* addressed this issue in interpretations about ''non minor'' injuries that did not meet the general recording criteria of death, days away, restricted work, transfer to another job, medical treatment or loss of consciousness. The *Guidelines* stated (Ex. 2, p. 42) that:

> The distinction between medical treatment and first aid depends not only on the treatment provided, but also on the severity of the injury being treated. First aid is: (1) Limited to one-time treatment and subsequent observation; and (2) involves treatment of only minor injuries, not emergency treatment of serious injuries. Injuries are not minor if:
> (a) They must be treated only by a physician or licensed medical personnel;
> (b) They impair bodily function (*i.e.,* normal use of senses, limbs, etc.);
> (c) They result in damage to the physical structure of a nonsuperficial nature (*e.g.*, fractures); or
> (d) They involve complications requiring followup medical treatment.

Many commenters on the proposal simply stated that the system must include all serious, significant or disabling injuries, and exclude cases that did not rise to that level (see, *e.g.*, Exs. 25; 15: 55, 135, 144, 154, 158, 162, 165, 193, 201, 206, 207, 211, 212, 220, 228, 238, 240, 243, 252, 253, 257, 258, 261, 264, 267, 272, 274, 276, 286, 293, 303, 305, 306, 309, 318, 320, 346, 354, 358, 365, 368, 375, 382, 383, 395, 397, 408, 412, 420, 421, 427, 434). The comments of the American Petroleum Institute (API) reflect this view: ''[A]PI is strongly opposed to any provision which would require a case to be recorded which is not serious or which is not likely to become serious. API strongly disagrees that non-serious subjective signs, symptoms, abnormal health test results, or evidence of exposure in and of themselves should be recorded on the OSHA log—unless the case otherwise meets one of the traditional criteria (*e.g.*, medical treatment, *et al.*) or results in, or is expected to result in a serious impairment'' (Ex. 15: 375).

Many comments believed that the recordability of occupational illnesses should rely on the diagnosis of a health care professional. For example, the U.S. Small Business Administration recommended that ''[a] recordable incident under the [proposed] 'Specific Conditions' should be subject to a health care provider's clinical diagnosis'' (Ed. 15: 67); Fort Howard recommended that ''[t]he Company disagrees with the [proposed] Mandatory Appendix B concept particularly in light of the statement in the Proposal that an employer can not rely solely on the clinical diagnosis of an injury or illness by a physician. Fort Howard recommends that an employer be allowed to specifically rely on the conclusions of those trained in this field, namely physicians'' (Ex. 15: 194); and Country Mark Cooperative recommended that '' [i]f an illness is diagnosed by a medical provider as linked to the cause agent, then it would be recorded as 'otherwise recordable' until such time as other recordable criteria are met such as days unable to work'' (Ex. 15: 9). BASF commented that ''[proposed] Appendix B should not require the recording of merely signs, symptoms, or laboratory abnormalities. Instead, it should also include objective findings or observations on the part of health care providers regarding the diagnosis of a serious illness or effect not otherwise subject to recording requirements'' (Ex. 15: 403).

Only a few commenters suggested methods for differentiating between serious and non-serious cases, in the context of conditions that should be listed in the final rule (see, *e.g.*, Exs. 15: 135, 176, 193, 199, 258, 375, 396). The API suggested that, if OSHA identifies a need to define ''disabling, serious or significant'' explicitly, the Agency should consider the following criteria:

> [a]ny other case which results in a serious impairment or significant injury for which no effective treatment exists, or
> involves a diagnosis of a condition which in time is expected to result in a serious impairment (or death), *e.g.*, certain asbestos-related diseases; or
> involves evidence of a chemical exposure at biological levels where criteria in an OSHA standard requires medical removal (Ex. 15: 375).

Elsewhere in their comments, the API recommended criteria for selecting which conditions would be listed in proposed Appendix B as follows:

> [t]he purpose of this appendix [proposed Appendix B] is to provide for the mandatory recording of occupational injuries and illnesses which are also serious or significant—but which do not immediately result in medical treatment, restricted work * * *
> Such cases fall into three broad categories. They occur when the injury or illness either
> Results in a serious impairment (unable to perform any normal life activity such as walking, eating, thinking, talking, breathing, seeing, smelling, hearing, driving a car. Incontinence and impotence would also be included)
> Involves a diagnosis of a condition which in time is expected to result in serious impairment (or death), *e.g.* certain asbestos related diseases,
> or
> Involved evidence of a chemical exposure at biological levels where criteria in an OSHA standard requires medical removal (Ex. 15: 375).

Adapto, Inc. (Ex. 15: 258) focused on the major life activity concept, stating that:

> [a]s mentioned previously, Congress intended that the statistical data compiled under this rule be limited to cases involving disabling, serious, or significant injuries or illness. Adapto, Inc. believes this phrase generally refers to a work-related condition that results in a physical or mental impairment that substantially limits a major life activity.

Union Carbide (Ex. 15: 396) urged that the following factors be used for determining the conditions that should be included in the final rule:

> Serious illnesses caused by exposures which are chronic and cumulative in nature
> Serious illnesses with a long latency period between exposure and recognition of the significant illness condition
> Serious illnesses which are likely to result in significant impairment
> Serious illnesses without a known or widely recognized medical treatment until advanced stages.

The Chemical Manufacturing Association (Ex. 15: 176) restated the same factors articulated by Union Carbide and added another factor: ''[s]erious illnesses that are not treatable.'' The NYNEX Corporation (Ex. 15: 199), the National Broiler Council (NBC), and the National Turkey Federation (Ex. 15: 193), in identical comments, focused on the idea of cases with an expectation of serious impairment or death, stating:

> [w]e do recognize, however, that there are some cases that do not meet this criteria that do have the expectation of resulting in serious impairment or even death. We are in agreement that cases of this potential seriousness should be recorded when they are diagnosed by a competent physician or medical professional as work-related.

The Macon Corporation (Ex. 15: 135) suggested using a material impairment test, suggesting that ''[w]e need to establish an effective system for the collection of data on serious work related injuries and illnesses which, at the time of recording, represent a material impairment to the health or functional capacity [of the injured or ill worker].'' OSHA has not adopted the material impairment alternative in the final rule because the term has specific meaning in the context of OSHA rulemaking. Section 6(b)(5) of the Act,

which sets forth the criteria for promulgating standards dealing with toxic substances or harmful physical agents, states that OSHA shall ''set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer *material impairment of health or functional capacity even* if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life (emphasis added).'' OSHA believes that use of this term in the recordkeeping rule could cause confusion among employers.

In the final rule, OSHA has adopted an approach similar to that suggested by the American Petroleum Institute, *i.e.,* focusing on two types of injury and illness: those that may be essentially untreatable, at least in the early stages and perhaps never (fractured and cracked bones, certain types of occupational cancer, and punctured eardrums) and those expected to progressively worsen and become serious over time (chronic irreversible diseases). The final rule is also responsive to the many commenters who urged OSHA to adopt a definition of severity for this requirement that would include all serious and significant injuries and illnesses, while excluding less serious cases. The language of paragraph 1904.(b)(7) of the final rule also responds to comments presented by commenters on the proposal who argued that relying on test results or other measures as indicators of serious occupational injury or illness was inappropriate. Instead, the final rule relies exclusively on the diagnosis of a limited class of injuries and illnesses by a physician or other licensed health care professional.

Clarifying That Cases Captured by Paragraph 1904.7(b)(7) Must Be Work Related

A number of commenters on the proposal expressed concern that proposed Appendix B was not clear enough about the fact that conditions must be work-related to be recordable on the OSHA forms. For example, several commenters asked OSHA to make sure that recordable cases of asthma are work-related (see, *e.g.*, Exs. 15: 38, 78, 80, 83, 89, 105, 157, 163, 188, 197, 203, 239, 279, 281, 297, 299, 302, 337, 345, 378, 395, 414). The Jewel Coal and Coke Company (Ex. 15: 281) stated that ''[asthma, in nearly all cases, is genetic and, to be recordable, we feel must be a direct result of something in the working OSHA environment. To require anything else would cause the unnecessary recording of cases of genetic asthma with no relationship to the working environment and would serve no purpose other than to balloon the statistics.''

OSHA wishes to reiterate that *any* condition that is recordable on the OSHA injury and illness recordkeeping forms must be work-related, and § 1904.7(b)(7) includes the term ''work-related'' to make this fact clear. In addition, because the employer will be dealing with a physician or other licensed health care professional, he or she may also be able to consult with the health care professional about the work-relatedness of the particular case. If the employer determines, based either on his or her own findings or those of the professional, that the symptoms are merely arising at work, but are caused by some non-work illness, then the case would not be recorded, under exception (b)(2)(ii) to the work-relatedness presumption at § 1904.5(b)(2) of the final rule. Similarly, if workplace events or exposures contributed only insignificantly to the aggravation of a worker's preexisting condition, the case need not be recorded under § 1904.5(a) and § 1904.5(b)(3) of the final rule.

The provisions of § 1904.7(b)(7) of the final rule thus meet the objectives of (1) capturing significant injuries and illnesses that do not meet the other general recording criteria of death, days away from work, restricted work or job transfer, medical treatment beyond first aid, or loss of consciousness; (2) excluding minor injuries and illnesses; (3) addressing a limited range of disorders; and (4) making it clear that these injuries and illnesses must be work-related before they must be recorded.

Section 1904.8 Additional Recording Criteria for Needlestick and Sharps Injuries

Section 1904.8 of the final rule being published today deals with the recording of a specific class of occupational injuries involving punctures, cuts and lacerations caused by needles or other sharp objects contaminated or reasonably anticipated to be contaminated with blood or other potentially infectious materials that may lead to bloodborne diseases, such as Acquired Immunodeficiency Syndrome (AIDs), hepatitis B or hepatitis C. The final rule uses the terms ''contaminated,'' ''other potentially infectious material,'' and ''occupational exposure'' as these terms are defined in OSHA's Bloodborne Pathogens standard (29 CFR 1910.1030). These injuries are of special concern to healthcare workers because they use needles and other sharp devices in the performance of their work duties and are therefore at risk of bloodborne infections caused by exposures involving contaminated needles and other sharps. Although healthcare workers are at particular risk of bloodborne infection from these injuries, other workers may also be at risk of contracting potentially fatal bloodborne disease. For example, a worker in a hospital laundry could be stuck by a contaminated needle left in a patient's bedding, or a worker in a hazardous waste treatment facility could be occupationally exposed to bloodborne pathogens if contaminated waste from a medical facility was not treated before being sent to waste treatment.

Section 1904.8(a) requires employers to record on the OSHA Log all work-related needlestick and sharps injuries involving objects contaminated (or reasonably anticipated to be contaminated) with another person's blood or other potentially infectious material (OPIM). The rule prohibits the employer from entering the name of the affected employee on the Log to protect the individual's privacy; employees are understandably sensitive about others knowing that they may have contracted a bloodborne disease. For these cases, and other types of privacy concern cases, the employer simply enters ''privacy concern case'' in the space reserved for the employee's name. The employer then keeps a separate, confidential list of privacy concern cases with the case number from the Log and the employee's name; this list is used by the employer to keep track of the injury or illness so that the Log can later be updated, if necessary, and to ensure that the information will be available if a government representative needs information about injured or ill employees during a workplace inspection (see § 1904.40). The regulatory text of § 1904.8 refers recordkeepers and others to § 1904.29(b)(6) through § 1904.29(b)(10) of the rule for more information about how to record privacy concern cases of all types, including those involving needlesticks and sharps injuries. The implementation section of § 1904.8(b)(1) defines ''other potentially infectious material'' as it is defined in OSHA's Bloodborne Pathogens Standard (29 CFR § 1910.1030, paragraph (b)). Other potentially infectious materials include (i) human bodily fluids, human tissues and organs, and (ii) other materials infected with the HIV or hepatitis B (HBV) virus such as laboratory cultures or tissues from experimental animals. (For a complete list of OPIM, see paragraph (b) of 29 CFR 1910.1030.)

Although the final rule requires the recording of all workplace cut and puncture injuries resulting from an event involving contaminated sharps, it does not require the recording of all cuts and punctures. For example, a cut made by a knife or other sharp instrument that was not contaminated by blood or OPIM would not generally be recordable, and a laceration made by a dirty tin can or greasy tool would also generally not be recordable, providing that the injury did not result from a contaminated sharp and did not meet one of the general recording criteria of medical treatment, restricted work, etc. Paragraph (b)(2) of § 1904.8 contains provisions indicating which cuts and punctures must be recorded because they involve contaminated sharps and which must be recorded only if they meet the general recording criteria.

Paragraph (b)(3) of § 1904.8 contains requirements for updating the OSHA 300 Log when a worker experiences a wound caused by a contaminated needle or sharp and is later diagnosed as having a bloodborne illness, such as AIDS, hepatitis B or hepatitis C. The final rule requires the employer to update the classification of such a privacy concern case on the OSHA 300 Log if the outcome of the case changes, i.e., if it subsequently results in death, days away from work, restricted work, or job transfer. The employer must also update the case description on the Log to indicate the name of the bloodborne illness and to change the classification of the case from an injury (i.e., the needlestick) to an illness (i.e., the illness that resulted from the needlestick). In no case may the employer enter the employee's name on the Log itself, whether when initially recording the needlestick or sharp injury or when subsequently updating the record.

The privacy concern provisions of the final rule make it possible, for the first time, for the identity of the bloodborne illness caused by the needlestick or sharps injury to be included on the Log. By excluding the name of the injured or ill employee throughout the recordkeeping process, employee privacy is assured. This approach will allow OSHA to gather valuable data about the kinds of bloodborne illnesses healthcare and other workers are contracting as a result of these occupational injuries, and will provide the most accurate and informative data possible, including the seroconversion status of the affected worker, the name of the illness he or she contracted, and, on the OSHA 301 Form for the original case, more detailed information about how the injury occurred, the equipment and materials involved, and so forth. Use of the privacy case concept thus meets the primary objective of this rulemaking, providing the best data possible, while simultaneously ensuring that an important public policy goal—the protection of privacy about medical matters—is met. OSHA recognizes that requiring employers to treat privacy cases differently from other cases adds some complexity to the recordkeeping system and imposes a burden on those employers whose employees experience such injuries and illnesses, but believes that the gain in data quality and employee privacy outweigh these disadvantages considerably.

The last paragraph (paragraph (c)) of § 1904.8 deals with the recording of cases involving workplace contact with blood or other potentially infectious materials that do not involve needlesticks or sharps, such as splashes to the eye, mucous membranes, or non-intact skin. The final recordkeeping rule does not require employers to record these incidents unless they meet the final rule's general recording criteria (i.e., death, medical treatment, loss of consciousness, restricted work or motion, days away from work, diagnosis by an HCP) or the employee subsequently develops an illness caused by bloodborne pathogens. The final rule thus provides employers, for the first time, with regulatory language delineating how they are to record injuries caused by contaminated needles and other sharps, and how they are to treat other exposure incidents (as defined in the Bloodborne Pathogens standard) involving blood or OPIM. ''Contaminated'' is defined just as it is in the Bloodborne Pathogens standard: ''Contaminated means the presence or the reasonably anticipated presence of blood or other potentially infectious materials on an item or surface.''

Before issuance of this final recordkeeping rule, the OSHA compliance directive CPL 2–2.44C for the Bloodborne Pathogens standard, ''Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens Standard, 29 CFR 1910.1030'' provided recording guidance to employers of occupationally exposed employees. The CPL 2–2.44C guidance treated cuts, lacerations and exposure incidents identically, classifying all of the events as injuries because they usually result from instantaneous events or exposures. The employer was required to record an incident when it met one of the following requirements:

1. The incident is a work-related injury that involves loss of consciousness, transfer to another job, or restriction of work or motion.

2. The incident results in the recommendation of medical treatment beyond first aid (*e.g.*, gamma globulin, hepatitis B immune globulin, hepatitis B vaccine, or zidovudine) regardless of dosage.

3. The incident results in a diagnosis of seroconversion. The serological status of the employee shall not be recorded on the OSHA 200. If a case of seroconversion is known, it shall be recorded on the OSHA 200 as an injury (*e.g.*, ''needlestick'' rather than ''seroconversion'') in the following manner:

a. If the date of the event or exposure is known, the original injury shall be recorded with the date of the event or exposure in column B.

b. If there are multiple events or exposures, the most recent injury shall be recorded with the date that seroconversion is determined in column B.

In 1999, OSHA updated CPL 2–2.44 and changed this language to simply refer to the Part 1904 regulation, in anticipation of the publication of this final recordkeeping rule.

The proposal

In the 1996 **Federal Register** notice, OSHA proposed recording criteria for needlestick and sharps injuries that were the same as the criteria being set forth in this final rule. The requirements in the final rule have been stated in slightly different language from those in the proposal to be consistent with the format of the remainder of the rule. The only substantive difference between the approach taken in the proposal and that in the final rule is the way that cases are handled to protect the privacy of the injured or ill worker. Appendix B of the proposed rule (61 FR 4065) included requirements to record the following:

''any workplace bloodborne pathogen exposure incident (as defined in 1910.1030(b)) that results in a positive blood test or diagnosis by a health care provider indicating AIDS, HIV seroconversion, hepatitis B or hepatitis C.

OR

any laceration or puncture wound that involves contact with another person's blood or other potentially infectious materials.

Note: to protect employee confidentiality, employers shall record occupationally acquired bloodborne pathogen diseases, such as hepatitis B, simply as the initial bloodborne exposure incident and note the exposure type (*e.g.* needlestick). Seroconversion and specific type of bloodborne disease shall not be recorded.''

OSHA explained in its proposal that recording these incidents was appropriate because these injuries are clearly non-minor, and recording them would be consistent with the Agency's mandate to collect information related to the death, illness, and injury of workers (61 FR 4041). OSHA then requested comment on whether it would be appropriate to record small puncture

wounds and lacerations that do not lead to disease, and whether OSHA should require employers to record all ''exposure incidents'' involving exposure to blood or OPIM, not just *injuries* involving contaminated needles and sharps. The proposal also asked for comment about the special privacy concerns potentially associated with bloodborne pathogen injuries and illnesses, and asked the following questions: ''What data is useful to collect? Are there other criteria for the recording of bloodborne infectious diseases which should be considered? What experience do employers have in data collection systems for this hazard?''

These proposed recording criteria for needlesticks and sharps injury cases prompted many comments to the rulemaking record. Very few of the comments supported OSHA's proposed position on this issue. Commenters either recommended recording all bloodborne pathogen exposure incidents or sharply limiting the recording of these events. A large number of commenters either objected specifically to the recording of all bloodborne pathogen exposure incidents or objected to the entire contents of proposed Appendix B (see, *e.g.*, Exs. 15: 1, 37, 38, 39, 44, 48, 52, 61, 66, 69, 74, 78, 82, 89, 100, 119, 121, 122, 126, 133, 146, 151, 152, 154, 156, 179, 193, 197, 200, 201, 203, 204, 213, 218, 219, 239, 254, 260, 262, 265, 271, 272, 277, 287, 297, 299, 301, 303, 305, 308, 310, 313, 317, 322, 329, 335, 345, 346, 347, 348, 349, 351, 352, 353, 361, 364, 373, 374, 375, 378, 392, 393, 395, 396, 398, 401, 403, 405, 407, 408, 409, 425, 434, 435). The most frequent suggestion made by commenters was that the only criterion for recording bloodborne pathogen diseases should be a positive blood test or diagnosis by a health care professional (see, *e.g.*, Exs. 15: 1, 38, 61, 65, 78, 82, 119, 122, 133, 151, 152, 179, 201, 213, 260, 262, 265, 290, 299, 301, 317, 345, 347, 373, 374, 393, 401, 407, 408, 435, 442). Many of the commenters who objected to recording all bloodborne incidents on the Log argued that these cases reflect exposure only and do not usually reflect cases that rise to the level of an injury or illness (see, *e.g.*, Exs. 15: 44, 69, 78, 151, 152, 179, 197, 201, 239, 272, 277, 287, 303, 308, 313, 345, 347, 348, 349, 351, 352, 353, 364, 373, 374, 375, 386, 392, 395, 396, 403, 405, 423, 425, 442). Other commenters urged OSHA to consider these cases minor injuries if they do not result in disease (see, *e.g.*, Exs. 15: 52, 290, 317, 403, 409, 434). Many agreed with the comments submitted by Bellin Hospital, which stated ''[r]ecording of all Significant Exposures is unnecessary. Seroconversions after exposure, regardless of mode of exposure is appropriate recordkeeping only'' (Ex. 15: 38). Several commenters made similar points. For example, Atlantic Dry Dock (Ex. 15: 179) wrote that ''[n]ot all contact [with blood or other potentially infectious materials] will result in an infection. There is no injury/illness unless an infection has actually resulted from the contact.''

Some commenters suggested that only those cases that resulted in either medical treatment or seroconversion should be recorded on the Log (see, *e.g.*, Exs. 15: 48, 100, 213, 310, 395, 416, 423), while others advocated recording lacerations and puncture wounds only if they met the rule's general recording criteria (see, *e.g.*, Exs. 15: 52, 200, 203, 219, 260, 262, 265, 271, 313, 329, 348, 352, 353, 401). As Bell Atlantic (Ex. 15: 128) commented, ''[s]erious lacerations and puncture wounds involving contact with bloodborne pathogens should be reported. But the mechanism driving such reporting is the severity of the wound and NOT the presence of bloodborne pathogens. Even with the absence of bloodborne pathogens, such serious injuries would be recorded.''

The American Hospital Association and the Georgia Hospital Association expressed concern that bloodborne pathogen disease criteria require ''the recording of all instances of certain conditions that meet specific criteria, whether or not they meet OSHA's established criteria for recordability (work-relationship; involves medical treatment or death, loss of consciousness, or in-patient hospitalization, or days away from work restricted work activity, or job transfer)'' (Exs. 15: 100, 219).

Several commenters stated that the recording of all bloodborne pathogen incidents would be redundant and unnecessary (see, *e.g.*, Exs. 15: 66, 121, 299, 322, 408, 435). Some commenters said that OSHA's bloodborne pathogen standard already requires recordkeeping and tracking of bloodborne pathogen exposure incidents (see, *e.g.*, Exs. 15:39, 89, 121, 310, 351, 378, 393, 405, 416), and others remarked that general medical records already contained adequate data (see, *e.g.*, Exs. 15: 151, 152, 179).

A number of commenters discussed the effect on injury and illness statistics that would be caused by recording all bloodborne pathogen incidents (see, *e.g.*, Exs. 15: 39, 44, 48, 61, 66, 69, 126, 146, 151, 152, 179, 201, 239, 287, 290, 308, 313, 329, 345, 352, 353, 364, 405). The Society of the Plastics Industry, Inc. (Ex. 15: 364) said that ''Requiring recording of exposure incidents rather than actual illnesses will improperly inflate the statistics regarding these diseases.'' Patrick Tyson, a partner at Constangy, Brooks & Smith, LLC, (Ex. 15: 345) stated:

> In effect, the Proposed Recordkeeping Rule would include on the Log those exposure incidents where a medical follow-up examination actually rules out the resulting illness. I believe that the Logs should not be used in this fashion any more than they should be used to record incidents of high levels of workplace noise in the absence of actual hearing loss, or incidents of employee exposure to highly repetitive jobs in the absence of resulting musculo-skeletal disorders. Simply stated, the OSH Act does not contemplate or intend the recording of mere exposure incidents on the OSHA Log. To do so would artificially overstate the relative safety and health risk in the American workplace.

On the other hand, a number of commenters recommended that OSHA require the recording of all bloodborne pathogen incidents as defined in the bloodborne pathogens standard (see, *e.g.*, Exs. 24, 15: 72, 153, 181, 196, 198, 289, 379, 380, 418). Several of these commenters urged the recording of all exposure incidents to improve the information on these injuries and promote better protection for workers (see, *e.g.*, Exs. 24, 15: 72, 153, 181, 196, 289, 379, 380). The American Association of Occupational Health Nurses (AAOHN) remarked ''The benefit in keeping these detailed records of bloodborne pathogen exposures will be the ability to track the root cause of resultant injuries and illnesses, regardless of latency'' (Ex. 15: 181). The National Association of Operating Room Nurses (Ex. 15: 72) added ''Reporting exposures may raise consciousness resulting in work practice changes and decreased hazard.''

Two commenters cited the severity of these incidents as a reason for requiring the recording of all exposure incidents (Exs. 24; 15: 379). The American Nurses Association based its arguments on the severity of the risk, stating ''While the Center for Disease Control and Prevention (CDC) Cooperative Needlestick Surveillance Group reported no seroconversions to HIV positive from mucous membrane or skin exposure, Hepatitis infections have been reported following exposures via these routes. The nature of the risk to HIV however small is very severe, deadly in fact; and the risk of Hepatitis is even greater. Because of the severity of the risk, we believe that all exposures must be recorded'' (Ex. 24). The Service Employees International Union (SEIU) added ''The lives of thousands of health

care workers each year are unnecessarily devastated by occupational exposure to hepatitis B, hepatitis C and HIV. A workplace exposure to blood or other potentially infectious materials represents a significant event in the life of a health care worker, regardless of whether or not the exposure results in infection with hepatitis B, hepatitis C or HIV'' (Ex. 15: 379).

A few commenters remarked on the need for consistency between the bloodborne pathogens standard and the recordkeeping requirements (see, *e.g.*, Exs. 15: 153, 198, 379). The National Association for Home Care (NAHC) stated ''NAHC believes that OSHA should maintain consistency between individual OSHA bloodborne pathogen requirements and general OSHA reporting requirements. Reporting of all exposure incidents is consistent with OSHA's bloodborne pathogen regulations for health care settings which require medical follow-up of employees for all exposure incidents'' (Ex. 15: 198).

Several commenters suggested recording all incidents as a method for masking the identity of workers who actually contract disease as a result of their injury (see, *e.g.*, Exs. 15: 379, 380, 418). The AFL–CIO (Ex. 15: 418) stated:

> The AFL–CIO believes that exposures to bloodborne pathogens pose a unique case with respect to confidentiality and privacy concerns. As the Agency has recognized in the Bloodborne Pathogen Standard, 29 CFR 1910.1030, there are real and legitimate concerns about discrimination against individuals who have tested positive for HIV and other bloodborne infectious diseases. To address these legitimate confidentiality concerns, the AFL–CIO believes that a different approach to recording cases related to bloodborne pathogens is required. For these cases, we recommend that the Agency require the recording of needlestick injuries and all exposures to blood or blood contaminated body fluids on the Log 300 and on the 301. Cases involving actual seroconversions should be recorded in the confidential medical record. This approach would be consistent with the approach and language in the bloodborne pathogen standard. It would permit the log to be used to track individual cases of exposure for prevention purposes, while at the same time maintaining the confidentiality of individuals whose health status had changed as a result of exposure. The AFL–CIO recognizes that this approach will require the recording of exposure incidents which do not result in the change of health status and sets different criteria for recording cases related to bloodborne pathogens. Given the unique confidentiality concerns associated with this set of conditions, we believe that this special treatment for these conditions is warranted.

After a review of the many comments in the record on this issue, OSHA has decided to require the recording of all workplace injuries from needlesticks and sharp objects that are contaminated with another person's blood or other potentially infectious material (OPIM) on the OSHA Log. These cases must be recorded, as described above, as privacy concern cases, and the employer must keep a separate list of the injured employees' names to enable government personnel to track these cases. OSHA does not agree with those commenters who were of the opinion that contaminated needlestick and sharps injuries are minor injuries comparable in importance to a puncture by a sewing needle or leather punch. OSHA also disagrees with those commenters who believed these incidents are merely exposure incidents roughly comparable with exposure to loud noises. These incidents are clearly injuries, where the worker has experienced a cut or laceration wound.

OSHA recognizes that these injuries are different from most workplace cuts and lacerations, whose seriousness depends largely on the size, location, jaggedness, or degree of contamination of the cut, which determines the need for medical treatment, restricted work, or time away for recuperation and thus the recordability of the incident. In contrast, all injuries from contaminated needles and sharps are serious because of the risk of contracting a potentially fatal bloodborne disease that is associated with them.

Many commenters argued that needlestick and sharps injuries are not the kinds of injuries that Congress intended employers to record, as articulated in the OSH Act (see, *e.g.*, Exs. 15: 239, 308, 313, 345, 352, 353, 375, 395). As discussed earlier in the Legal Authority section, OSHA disagrees, believing that Congress mandated the recording of all non-minor injuries and illnesses as well as all injuries resulting in medical treatment or one of the other general recording criteria. OSHA finds that needlestick and sharps injuries involving blood or other potentially infectious materials are non-minor injuries, and therefore must be recorded. This conclusion is consistent with the Senate Committee on Appropriations report accompanying the fiscal year 1999 *Departments of Labor, Health and Human Services, and Education and Related Agencies Appropriation Bill, 1999* (S. 2440) which included the following language:

> Accidental injuries from contaminated needles and other sharps jeopardize the well-being of our Nation's health care workers and result in preventable transmission of devastating bloodborne illnesses, including HIV, hepatitis B, and hepatitis C. The committee is concerned that the OSHA 200 Log does not accurately reflect the occurrence of these injuries. The committee understands that the reporting and recordkeeping standard (29 CFR 1904) requires the recording on the OSHA 200 Log of injuries from potentially contaminated needles and other sharps that result in: the recommendation or administration of medical treatment beyond first aid; death, restriction of work or motion; loss of consciousness, transfer to another job, or seroconversion in the worker. Accidental injuries with potentially contaminated needles or other sharps require treatment beyond first aid. Therefore, the Committee urges OSHA to require the recording on the OSHA 200 log of injuries from needles and other sharps potentially contaminated with bloodborne pathogens (Senate Report 105–300).

OSHA finds that these injuries are significant injuries because of the risk of seroconversion, disease, and death, they pose (see the preamble to the OSHA Bloodborne Pathogens Standard at 56 FR 64004).

OSHA recognizes that requiring the recording of all injuries from contaminated needles and sharps will result in more cases being recorded on employers' Logs and will increase the number of such injuries reflected in the Nation's statistics. However, the Agency does not agree that the statistics will be inappropriately inflated. Instead, OSHA believes that the statistics will henceforth include, for the first time, cases that reflect the incidence of these significant injuries accurately. Adding these cases to the Nation's statistics will create a more accurate accounting of work-related injury and illness cases, information that will be useful to employers, employees, the government and the public. In addition, the collection of this information at the establishment level will generate data employers and employees can use to analyze injury and illness patterns and make improvements in work practices and equipment. Recording these injuries will thus help to realize one of this rulemaking's primary goals, to improve the utility and quality of the information in the records.

If OSHA were to adopt a final rule that only required the recording of seroconversion cases and cases that met the general recording criteria, as many commenters suggested (see, *e.g.*, Exs. 15: 52, 200. 203, 219, 260, 262, 265, 271, 313, 329, 348, 352, 353, 401), the Nation's statistics would not be as complete and accurate, and workplace records would not have the same preventive value for employees and employers. In addition, that approach would be more complex because it

would require employers to evaluate each case against several criteria before recording it. The approach taken in the final rule is considerably simpler. Recording all such injuries also helps to protect the privacy of workers who have been injured in this way. Needlestick and sharps injuries raise special privacy concerns. The comments on this subject show a universal concern for the privacy of a worker's medical information and disease status, and OSHA has taken several special precautions, discussed elsewhere in the preamble, to protect this privacy. Several commenters suggested recording all needlesticks and sharps incidents as a method for masking the identify of workers who actually contract disease (see, *e.g.*, Exs. 15: 379, 380, 418). OSHA has adopted this practice in the final rule because recording all of these injuries will help to protect the privacy of individual workers as well as produce higher quality data.

OSHA disagrees with those commenters who argued that the § 1904.8 recording requirement would be duplicative or redundant with the requirements in the Bloodborne Pathogens standard (29 CFR 1910.1030). That standard requires the employer to document the route(s) of exposure and the circumstances under which the exposure incident occurred, but does not require that it be recorded on the Log (instead, the standard requires only that such documentation be maintained with an employee's medical records). The standard also has no provisions requiring an employer to aggregate such information so that it can be analyzed and used to correct hazardous conditions before they result in additional exposures and/or infections. The same is true for other medical records kept by employers: they do not substitute for the OSHA Log or meet the purposes of the Log, even though they may contain information about a case that is also recorded on the Log.

OSHA is requiring only that lacerations and puncture wounds that involve contact with another person's blood or other potentially infectious materials be recorded on the Log. Exposure incidents involving exposure of the eyes, mouth, other mucous membranes or non-intact skin to another person's blood or OPIM need not be recorded unless they meet one or more of the general recording criteria, result in a positive blood test (seroconversion), or result in the diagnosis of a significant illness by a health care professional. Otherwise, these exposure incidents are considered only to involve exposure and not to constitute an injury or illness. In contrast, a needlestick laceration or puncture wound is clearly an injury and, if it involves exposure to human blood or other potentially infectious materials, it rises to the level of seriousness that requires recording. For splashes and other exposure incidents, the case does not rise to this level any more than a chemical exposure does. If an employee who has been exposed via a splash in the eye from the blood or OPIM of a person with a bloodborne disease actually contracts an illness, or seroconverts, the case would be recorded (provided that it meets one or more of the general recording criteria).

Privacy Issues

There was support in the record for OSHA's proposal to record occupationally acquired bloodborne pathogen diseases simply as the initial bloodborne exposure incident to protect employee confidentiality. Eli Lilly and Company (Ex. 15: 434) commented:

> Lilly agrees with the Agency's proposed method of recording exposure incidents that result in disease. All of these recordable incidents should be recorded simply as the type of bloodborne exposure incident (*e.g.* needlestick) with no reference to the type of disease. While Lilly is concerned about protecting the privacy of every individual employee's medical information, Lilly concedes that the current social stigma resulting from bloodborne pathogen diseases demands a more simple recordkeeping requirement.

Privacy issues, however, concerned many of the commenters to the rulemaking record. Metropolitan Edison/Pennsylvania Electric Company (M/P), for example, was so concerned with employee privacy that ''[d]ue to the sensitivity of Bloodborne Pathogenic diseases and related confidentiality concerns, M/P disagrees with recording these types of incidents'' (Ex. 15: 254). The American Automobile Manufacturers Association (AAMA), among others, expressed concern that the recording requirement for bloodborne pathogen diseases would discourage employees from reporting exposures and might also discourage individuals from seeking treatment. AAMA wrote:

> [m]any individuals who contract an infectious disease from a workplace event or exposure will be against having their names on the OSHA log for scrutiny by any employee or former employee of the establishment. To openly list (on the OSHA log) an individual with an infectious disease will discourage some employees from reporting exposures. It may also discourage individuals from seeking treatment, which may be lifesaving or which may limit the spread of the disease. We oppose the development of any system which directly or indirectly discourages individuals from seeking medical evaluation or treatment, for the sake of data collection (Ex. 15: 409).

The AAMA proposed as an alternative ''to remove all personal identifiers for infectious disease cases from the OSHA log. Some type of employer created coding system could be instituted, as long as the code was consistently applied. Authorized medical personnel and government representatives would be the only individuals permitted access to the personal identifiers and/or key to the coding system'' (Ex. 15: 409). The Quaker Oats Company and the Ford Motor Company supported similar alternatives (Exs. 15: 289, 347). A number of commenters specifically supported the use of a coding system (see, *e.g.*, Exs. 15: 146, 213, 260, 262, 265, 345, 347, 409).

OSHA shares these commenters' concern about the privacy of employees who seroconvert as the result of a bloodborne pathogens-related needlestick or sharps incident and finds that these incidents are clearly the type of non-minor occupational injury and illness Congress intended to be included in the OSHA recordkeeping system. If the Agency were to exclude these cases categorically from the records, it would not be meeting the requirements of the OSH Act to produce accurate statistics on occupational death, injury and illness.

The final recordkeeping rule addresses this issue by prohibiting the entry of the employee's name on the OSHA 300 Log for injury and illness cases involving blood and other potentially infectious material. Further, by requiring employers to record all needlestick and sharps incidents, regardless of the seroconversion status of the employee, coworkers and representatives who have access to the Log will be unable to ascertain the disease status of the injured worker. OSHA believes that the privacy concern case approach of the final rule obviates the need for a coding system because the case number assigned to the recorded injury will serve the purpose of a code, without adding additional complexity or burden. A discussion of access to the records is contained in the portion of the preamble associated with section 1904.35, Employee Involvement.

The College of American Pathologists objected to the inclusion of hepatitis C in the list of bloodborne pathogen diseases. They commented that ''the great majority of cases of hepatitis C lack any identifiable source of exposure. More cases of HCV infection occur among non-health care workers than among health care workers. To presume that an individual who is infected with

HCV acquired it on the job just because they work in a health care setting is unjustified'' (Ex. 15: 37). On the other hand, a commenter from Waukesha Memorial Hospital suggested that OSHA ''should include all blood borne pathogen disease that develops as a result of an exposure incident, not just HIV, Hep B, Hep C, even though those are the major players in a hospital setting. Since we must teach that there are many bloodborne pathogens, it doesn't make sense to me to only record some and not all'' (Ex. 15: 436). OSHA believes that hepatitis C cases should, like other illness cases, be tested for recordability using the geographic presumption that provides the principal rationale for determining work-relatedness throughout this rule. OSHA also agrees with the commenter from Waukesha Memorial Hospital that *all* bloodborne pathogen diseases resulting from events or exposures in the workplace should be recorded. Therefore, OSHA has modified the final regulatory text of paragraph 1904.8(b)(4)(i) to reflect this decision.

Section 1904.9 Additional Recording Criteria for Cases Involving Medical Removal Under OSHA Standards

The final rule, in paragraph 1904.9(a), requires an employer to record an injury or illness case on the OSHA 300 Log when the employee is medically removed under the medical surveillance requirements of any OSHA standard. Paragraph 1904.9(b)(1) requires each such case to be recorded as a case involving days away from work (if the employee does not work during the medical removal) or as a case involving restricted work activity (if the employee continues to work but in an area where exposures are not present.) This paragraph also requires any medical removal related to chemical exposure to be recorded as a poisoning illness.

Paragraph 1904.9(b)(2) informs employers that some OSHA standards have medical removal provisions and others do not. For example, the Bloodborne Pathogen Standard (29 CFR 1910.1030) and the Occupational Noise Standard (29 CFR 1910.95) do not require medical removal. Many of the OSHA standards that contain medical removal provisions are related to specific chemical substances, such as lead (29 CFR 1901.1025), cadmium (29 CFR 1910.1027), methylene chloride (29 CFR 1910.1052), formaldehyde (29 CFR 1910.1048), and benzene (29 CFR 1910.1028).

Paragraph 1904.9(b)(3) addresses the issue of medical removals that are not required by an OSHA standard. In some cases employers voluntarily rotate employees from one job to another to reduce exposure to hazardous substances; job rotation is an administrative method of reducing exposure that is permitted in some OSHA standards. Removal (job transfer) of an asymptomatic employee for administrative exposure control reasons does not require the case to be recorded on the OSHA 300 Log because no injury or illness—the first step in the recordkeeping process—exists. Paragraph 1904.9(b)(3) only applies to those substances with OSHA mandated medical removal criteria. For injuries or illnesses caused by exposure to other substances or hazards, the employer must look to the general requirements of paragraphs 1910.7(b)(3) and (4) to determine how to record the days away or days of restricted work.

The provisions of § 1904.9 are not the only recording criteria for recording injuries and illnesses from these occupational exposures. These provisions merely clarify the need to record specific cases, which are often established with medical test results, that result in days away from work, restricted work, or job transfer. The § 1904.9 provisions are included to produce more consistent data and provide needed interpretation of the requirements for employers. However, if an injury or illness results in the other criteria of § 1904.7 (death, medical treatment, loss of consciousness, days away from work, restricted work, transfer to another job, or diagnosis as a significant illness or injury by a physician or other licensed health care professional) the case must be recorded whether or not the medical removal provisions of an OSHA standard have been met.

The recording of OSHA mandated medical removals was not addressed in the 1996 recordkeeping proposal. OSHA has included the provisions of § 1904.9 in the final rule to address a deficiency noted by a number of commenters, and as a replacement for criteria that were contemplated for the recording of various ailments in proposed Appendix B (61 FR 4063–4065). For example, R. L. Powell, Personnel Safety Manager for Union Carbide Corporation, (Ex. 15: 396) asked about medical removal and restricted work:

> How does this criteria [restricted work] apply to ''medical removal?'' Medical removal is sometimes mandated by other OSHA standards under certain conditions. A similar technique may also be used by a physician to conduct controlled tests to assess the impact of workplace factors on a condition such as a chemical sensitivity.

A number of commenters recommended the use of medical removal criteria as the correct recording level for various substances listed in proposed Appendix B (see, *e.g.*, Exs. 22; 15: 113, 155, 192, 199, 213, 242, 262, 272, 303, 304, 307, 326, 338, 340, 349). Many of these commenters suggested the medical removal criteria as a substitute for the proposed recording levels for lead and cadmium (Ex. 22; 15: 113, 155, 192, 340, 349). For example, Newport News Shipbuilding (Ex. 15: 113) said:

> The proposed regulation requires recording lead and cadmium cases based on biological action levels rather than on the onset of illness. The purpose of the biological action level is to identify those employees who are at greater risk of reaching the limits for medical removal, so that onset of illness may be prevented. The use of biological action levels as the basis of defining and recording illness is inappropriate. Rather, lead and cadmium cases should be recorded when medical removal is required by the specific standard.

The Institute of Scrap Recycling Industries, Inc. (Ex. 15: 192) added:

> This [proposed] statement clearly subverts the clear intent of the OSHA lead standard that a blood lead level of 50 μg/100 g of whole blood and not 40 μg/100 g of whole blood is the criteria for medical removal and therefore also the criteria for documentation on the OSHA injury and illness log. Had the scientific evidence on which the OSHA lead standard was based pointed clearly to 40 μg/100 g of whole blood as the medical removal standard and therefore the standard for documentation on the OSHA injury and illness log the standard would have reflected this. Therefore it would clearly subvert the purpose and scope of the OSHA lead standard, that was based on scientific evidence and an exhaustive public comment period on the scientific data, to establish a clear benchmark for a recordable event on the injury and illness log without the benefit of supporting scientific study and data and a public comment period on such information.

The Institute of Scrap Recycling Industries, Inc is incorrect about the lead standard's determination of recording criteria on the OSHA injury and illness log. The lead standard (§ 1910.1025) does not specifically address the recording issue, but the lead standard does address the medical removal issue. The Institute points to the benefit of using medical removal criteria for recording purposes, and OSHA agrees that these criteria are useful for recordkeeping purposes. The medical removal provisions of each standard were set using scientific evidence established in the record devoted to that rulemaking. OSHA takes care when setting the medical removal provisions of standards to ensure that these provision reflect a material harm, *i.e.,* the existence of an abnormal condition that is non-minor and thus

worthy of entry in the OSHA injury and illness records.

Other commenters urged OSHA to use the medical removal criteria as a replacement for all of proposed Appendix B. (see, *e.g.*, Exs. 15: 199, 213, 242, 262, 303, 304, 307, 326, 338, 375). For example, Southern Nuclear Operating Company (Ex. 15: 242) stated that:

> Mercury, Lead, Cadmium, Benzene: In these cases, it is appropriate to distinguish between biological markers that merely point to exposure versus those that relate to illness or disease. All of the recordability criteria for these substances are based on various ''action'' levels stated in their respective OSHA regulations. Southern Nuclear Operating Company believes that the appropriate criteria for recording these cases as illnesses should be the ''medical removal'' criteria stated in their respective regulations coupled with a physician's diagnosis of disease rather that the ''action'' levels as stated in the proposal. These ''medical removal'' criteria are more indicative of disease or illness. If the ''action'' levels for these substances are used as the recording criteria, the number of illnesses recorded on the OSHA log would more accurately reflect the numbers of workers covered by a given exposure control program as opposed to the number of illnesses that result from an inadequate program.

The American Petroleum Institute (API) argued that:

> API incorporates in its recommended Appendix B the recording of cases when medical removal is required by a specific OSHA standard. API concedes this is inconsistent with the concept of ''serious or significant''—and inconsistent with API's fundamental belief that actions by employers to prevent cases from becoming serious should not be recorded—because such medical removals are by design preventive; that is, intended to occur before a case becomes serious. However, API acknowledges that it is extremely difficult to define and get substantial agreement on any straight-forward and verifiable criteria when such cases are indeed ''serious''. Therefore, API has decided to recommend the medical-removal criterion for Appendix B as the best on-balance solution for situations involving toxic substance adsorption. (Ex. 15: 375)

A number of commenters opposed the use of mandatory medical removal levels for injury and illness recording purposes (see, *e.g.*, Exs. 25; 15: 146, 193, 258, 261, 304, 305, 318, 346, 358). Many argued that the OSH Act did not support the use of medical removals (see, *e.g.*, Exs. 25; 15: 258, 261, 304, 358). For example, the National Association of Manufacturers (NAM) commented:

> There is no reference in Section 24(a) or Section 8(c)(2) of the OSH Act to recording exposure incidents that do not result in disabling, serious or significant injuries or illnesses; or is there any reference in those sections to medical removal provisions or other action levels that do not result in disabling, serious or significant injuries or illnesses. On the other hand, Section 8(c)(3) does discuss—as a separate component of OSHA's occupational safety and health statistics program—maintaining records of employee exposures to toxic materials and harmful physical agents pursuant to standards issued under Section 6 of the OSH Act.
>
> This is a rulemaking about the statistical program for tracking disabling, serious or significant injuries and illnesses—nothing more and nothing less. We believe Congress determined that those are the criteria that OSHA should utilize for this particular component of its statistical program. A statistical program that aggregates disabling, serious or significant injuries and illnesses with other conditions and exposure incidents, is contrary to both the congressional directive and the goal of this recordkeeping system.

While these commenters are correct in noting that the OSH Act does not specifically address medical removal levels and whether or not cases meeting these levels should be recorded, the Act also does not exclude them. The Act does require the recording of injuries and illnesses that result in ''restriction of work or motion'' or ''transfer to another job.'' OSHA finds that cases involving a mandatory medical removal are cases that involve serious, significant, disabling illnesses resulting in restriction of work and transfer to another job, or both. These medical restrictions result either in days away from work (form of restriction) or days when the worker can work but is restricted from performing his or her customary duties.

Other commenters objected to recording medical removals because they are precautionary in nature (Ex. 15: 146, 193, 258, 261, 305, 318, 346). The American Foundrymen's Society, Inc. (Ex. 15: 346) argued that:

> An abnormally high level of a toxic material in an individual's blood (*e.g.*, a lead level at or above the action level or the level requiring ''medical removal'' under OSHA's Lead Standard) is not and should not, in itself, be considered a recordable injury or illness. A preventive or prophylactic measure such as medical removal (as opposed to a restorative or curative measure) is not and should not be deemed medical treatment, a job transfer or restricted activity for purposes of recordability in the absence of a diagnosis of a substantial impairment of a bodily function.

As stated previously, a ''diagnosis of substantial impairment of a bodily function'' is not required for a case to meet OSHA recordkeeping criteria, nor is it a limitation to recordability under the OSH Act. Many injuries and illnesses meet the recording criteria of the Act but lack diagnosis of a substantial impairment of a bodily function. Although the medical removal provisions are included in OSHA's standards to encourage participation in the medical program by employees and to prevent progression to serious and perhaps irreversible illness, they also reflect illnesses caused by exposures in the workplace and are thus themselves recordable. The workers are being removed not only to prevent illness, but to prevent further damage beyond what has already been done. Thus OSHA does not agree that medical removal measures are purely preventive in nature; instead, they are also remedial measures taken when specific biological test results indicate that a worker has been made ill by workplace exposures.

OSHA has therefore included section 1904.9 in the final rule to provide a uniform, simple method for recording a variety of serious disorders that have been addressed by OSHA standards. The § 1904.9 provisions of the final rule cover all of the OSHA standards with medical removal provisions, regardless of whether or not those provisions are based on medical tests, physicians' opinions, or a combination of the two. Finally, by relying on the medical removal provisions in any OSHA standard, section 1904.9 of the final rule establishes recording criteria for future standards, and avoids the need to amend the recordkeeping rule whenever OSHA issues a standard containing a medical removal level.

Section 1904.10 Recording Criteria for Cases Involving Occupational Hearing Loss

The recording criteria employers should use to record occupational hearing loss on the OSHA recordkeeping forms have been an issue since OSHA first proposed to require hearing conservation programs for general industry employers (39 FR 37775, October 24, 1974). Job-related hearing loss is a significant occupational safety and health issue because millions of workers are employed in noisy workplaces and thousands of workers experience noise-induced hearing loss each year. Noise-induced hearing loss is a serious and irreversible condition that may affect the safety and well-being of workers for the rest of their lives.

For the nation as a whole in 1997, the BLS reported only 495 cases of occupational hearing loss resulting in days away from work (http://stats.bls.gov/case/ostb0684.txt; BLS Characteristics Data Table R15 of 04/22/1999). Hearing loss is not the type of occupational injury or illness that typically requires days away from work for recuperation, as is often the case for

a fracture, fall, or carpal tunnel syndrome case. OSHA believes that there are many cases of hearing loss—probably numbering in the thousands—that occur every year as a result of job-related noise exposure but do not result in days away from work and are thus not captured in the BLS statistics. Because these hearing losses are often permanent, a large number of Americans, both working and retired, are currently suffering the effects of hearing loss due to occupational exposure.

The changes being made to the OSHA 300 form in the final rule will improve the quality of the data collected nationally on this important occupational condition by providing consistent hearing loss recording criteria, thus improving the consistency of the hearing loss statistics generated by the BLS occupational injury and illness collection program. National hearing loss statistics will also be improved because OSHA has added a column to the OSHA 300 Log that will require employers, for the first time, to separately collect and summarize data specific to occupational hearing loss. These changes mean that the BLS will collect hearing loss data in future years, both for cases with and without days away from work, which will allow for more reliable published statistics concerning this widespread occupational disorder.

Paragraph 1904.10(a) of the final rule being published today requires an employer to record an employee's hearing test (audiogram) result if that result reveals that a Standard Threshold Shift (STS) for that employee has occurred. If the employee is one who is covered by the medical surveillance requirements of OSHA's Occupational Noise standard (29 CFR 1910.95), compliance with the standard will generate the information necessary to make recording decisions.

If the employee is not covered by the 29 CFR 1910.95 noise standard, OSHA rules do not require the employer to administer baseline or periodic audiograms, and the 1904 rule does not impose any new requirements for employers to obtain baseline information where it is not already required. However, some employers conduct such tests and acquire such information for other reasons. If the employer's workplace is a high noise environment (i.e., has noise levels that exceed 85 dBA) and the employer has the relevant audiogram information for an employee, the employer must record any identified work-related hearing loss equal to or greater than an OSHA-defined STS on the Log. This means that an employer in the construction industry, for example, who is aware that his or her work activities regularly generate high noise levels and who has audiometric data on the hearing level of the employees exposed to those noise levels must record on the Log any STS detected in those workers. OSHA believes that this approach to the recording of work-related hearing loss cases among these workers not covered by the noise standard is appropriate because it is reasonable, protective, and administratively straightforward.

Paragraph 1904.10(b)(1) of the final rule defines an STS as that term is defined in the Occupational Noise Standard: as a change in an employee's hearing threshold, relative to the baseline audiogram for that employee, of an average of 10 decibels (dB) or more at 2000, 3000, and 4000 hertz in one or both ears. The Noise standard, at paragraph 1910.95(c)(1), describes the employees in general industry who are covered by the required hearing conservation program as follows:

> The employer shall administer a continuing, effective hearing conservation program, as described in paragraphs (c) through (o) of this section, whenever employee noise exposures equal or exceed an 8-hour time-weighted average sound level (TWA) of 85 decibels measured on the A scale (slow response) or, equivalently, a dose of fifty percent. For purposes of the hearing conservation program, employee noise exposures shall be computed in accordance with appendix A and Table G–16a, and without regard to any attenuation provided by the use of personal protective equipment.

Paragraph 1904.10(b)(2) of the final recordkeeping rule directs employers how to determine whether a recordable STS has occurred. The paragraph deals with two situations: (1) where the employee has not previously experienced such a hearing loss, and (2) where the employee has experienced a past recordable hearing loss. If the employee has never previously experienced a recordable hearing loss, the employer must compare the results of the employee's current audiogram with the employee's baseline audiogram, if the employee has a baseline audiogram. The employee's baseline audiogram could either be that employee's original baseline audiogram or a revised baseline audiogram adopted in accordance with paragraph (g)(9) of 29 CFR 1910.95. For employees who have not previously had a recordable hearing loss with that employer, the loss in hearing is computed using the preemployment hearing test result so that any hearing loss the employee may have experienced before obtaining employment with the employer is not attributed to noise exposure in that employer's workplace.

If the employee has previously experienced a recordable hearing loss, the employer must compare the employee's current audiogram with the employee's revised baseline audiogram (i.e., the audiogram reflecting the prior recorded hearing loss). For employees who have had a previously recordable hearing loss with that employer, the final recordkeeping rule thus ensures that the employer does not record the same case of hearing loss twice, but that if a second STS occurs, the employer will record that additional hearing loss.

Paragraphs 1904.10(b)(3) and (4) of the final rule allow the employer to take into account the hearing loss that occurs as a result of the aging process and to retest an employee who has an STS on an audiogram to ensure that the STS is permanent before recording it. The employer may correct the employee's audiogram results for aging, using the same methods allowed by the OSHA Noise standard (29 CFR 1910.95). Appendix F of § 1910.95 provides age correction for presbycusis (age-induced hearing loss) in Tables F–1 (for males) and F–2 (for females). Further, as permitted by the Noise standard, the employer may obtain a second audiogram for employees whose first audiogram registers an STS if the second audiogram is taken within 30 days of the first audiogram. The employer may delay recording of the hearing loss case until the STS is confirmed by the second audiogram and is, or course, not required to record the case if the second audiogram reveals that the STS was not permanent.

Paragraph 1904.10(b)(5) of the final rule establishes how employers are to determine the work-relatedness of hearing loss cases. This paragraph specifies that, in accordance with the recordkeeping rule's definition of work-relationship, hearing loss is presumed to be work-related for recordkeeping purposes if the employee is exposed to noise in the workplace at an 8-hour time-weighted average of 85 dB(A) or greater, or to a total noise dose of 50 percent, as defined in 29 CFR 1910.95. (Noise dose is defined as the amount of actual employee exposure to noise relative to the permissible exposure limit for noise; a dose greater than 100% represents exposure above the limit.) For hearing loss cases where the employee is not exposed to this level of workplace noise, or where the employee is not covered by the Occupational Noise standard, the employer must use the rules set out in § 1904.5 to determine if the hearing loss is to be

considered work related for recordkeeping purposes.

Paragraph 1904.10(b)(6) allows the employer not to record a hearing loss case if physician or other licensed health care professional determines that the hearing loss is not work-related or has not been aggravated by occupational noise exposure. This provision is consistent with the Occupational Noise standard, and it allows the employer not to record a hearing loss case that is not related to workplace events or exposures; examples of such cases are hearing loss cases occurring before the employee is hired or those unrelated to workplace noise.

The recordkeeping provisions in section 1904.10 of the final recordkeeping rule thus match the provisions of the Occupational Noise standard by (1) covering the same employers and employees (with the exception of cases occurring among employees not covered by that standard whose employers have audiometric test results and high-noise workplaces); (2) using the same measurements of workplace noise; (3) using a common definition of hearing loss, i.e., the STS; (4) using the same hearing loss measurement methods; (5) using the same definitions of baseline audiogram and revised baseline audiogram; (6) using the same method to account for age correction in audiogram results; and (7) allowing certain temporary threshold shifts to be set aside if a subsequent audiogram demonstrates that they are not permanent or a physician or other licensed health care professional finds they are not related to workplace noise exposure.

The Former Rule

The regulatory text of OSHA's former recordkeeping rule did not specifically address the recording of hearing loss cases, and the § 1910.95 Occupational Noise Standard does not address the recording of hearing loss cases on the OSHA Log. However, the 1986 *Recordkeeping Guidelines* provided clear advice to employers to the effect that work-related hearing loss was a recordable disorder, that it could be either an injury or illness, depending on the events and exposures causing the hearing loss, and that all hearing loss illnesses were required to be recorded, regardless of the industry in which the employer worked (Ex. 2, p. 4). However, the *Guidelines* did not provide specific guidance on the kinds of hearing test or audiogram results that would constitute a recordable, work-related hearing loss.

In 1990, OSHA considered issuing a Compliance Directive addressing the recording of hearing loss cases on employers' OSHA 200 Logs, but decided that the issue of the recording of hearing loss cases should be addressed through notice-and-comment rulemaking at the time of the revision of the recordkeeping rule. To address this topic in the interim before the final recordkeeping rule was issued, OSHA sent a memorandum to its field staff (June 4, 1991) to clarify its enforcement policy on the recording of occupational hearing loss and cumulative trauma disorders on the OSHA 200 Log, on the grounds that these cases ''have received national attention and require immediate clarification.'' The memorandum specified that ''OSHA will issue citations to employers for failing to record work related shifts in hearing of an average of 25 dB or more at 2000, 3000, and 4000 hertz (Hz) in either ear on the OSHA 200 Log.'' The interim enforcement policy was intended to provide a conservative approach to the issue until the recordkeeping rulemaking was completed. The interim policy stated that ''The upcoming revision of the recordkeeping regulations, guidelines and related instructional materials will address the recordability criteria for all work related injuries and illnesses.'' The memo also mentioned the use of standard threshold shifts (STS) results, saying:

> Employers are presently required by 29 CFR 1910.95 to inform employees in writing within 21 days of the determination of a Standard Threshold Shift (an average of 10 dB or more at 2000, 3000 and 4000 Hz in either ear) and to conduct specific follow-up procedures as required in paragraph (g) of the standard. Employers should be encouraged to use this information as a tracking tool for focusing noise reduction and hearing protection efforts.

The Proposal

The proposed recordkeeping criterion for recording a case of hearing loss (61 FR 4064) was an average shift of 15 decibels (dB) or more at 2000, 3000, and 4000 hertz in one or both ears after the employee's hearing loss had been adjusted for presbycusis (age-related hearing loss). OSHA proposed to permit employers to delete the record of the hearing loss injury or illness if a retest performed within 30 days indicated that the original shift was not permanent. Once a 15 dB work-related shift had occurred, however, OSHA proposed that the employee's baseline audiogram (for recordkeeping purposes) be adjusted to reflect that loss. A subsequent audiogram would have to reveal an additional 15 dB shift from the new or revised baseline value to be considered a new hearing loss injury or illness. OSHA proposed to presume work-relationship if an employee was exposed on the job to an 8-hour time-weighted average noise level equaling 85 dB(A) (61 FR 4064).

OSHA also raised several issues related to hearing loss recording in the proposal (61 FR 4064):

> The lowest action level in the noise standard is an average shift of 10 decibels or more at 2000, 3000 and 4000 hertz. OSHA is proposing the 15 decibel criteria for recordkeeping purposes to account for variations in the reliability of individual audiometric testing results.
>
> OSHA asks for input on which level of a shift in hearing should be used as a recording criteria; 10 decibels? 20 decibels? 25 decibels? For each level, what baseline should be used? Preemployment (original) baseline? Audiometric zero? Is adjusting for presbycusis appropriate?

Comments on the Proposal

OSHA's proposed recording criterion for hearing loss received more comments than the proposed criterion for any other type of injury or illness other than musculoskeletal disorders. The hearing loss comments cover a wide variety of issues, including which hearing test results should or should not be considered an OSHA recordable illness, the choice of baseline audiograms, retesting and persistence of hearing loss, determining work relatedness, the appropriateness of correcting audiograms for aging (presbycusis), and the role of physicians and other licensed health care professionals in the determination of recordable hearing loss cases. The issues raised by commenters are organized by topic and discussed below.

The Definition of Recordable Hearing Loss

There was limited support among commenters for OSHA's proposed 15 dB shift recording criterion (see, *e.g.*, Exs. 15: 50, 61, 84, 111, 113, 156, 188, 233, 281, 289, 349, 407). However, many of these commenters supported the use of a 15 dB shift as the recording criterion only if the final recordkeeping rule also reflected other changes, such as eliminating the correction for aging (see, *e.g.*, Exs. 15: 50, 188, 407) or limiting the recording of hearing loss to one case per worker per lifetime (Ex. 15: 349). For example, General Electric (Ex. 15: 349) suggested limiting the recording of hearing loss to one case per employee:

> GE supports recording an average standard threshold shift of 15 decibels (dB) or more at 2000, 3000, and 4000 hertz in one or both ears, adjusted for presbycusis and with a deletion upon retest as described. The establishment of the recording criteria at a level slightly higher than STS requiring action in the noise standards allows the

employer the opportunity to take action before the STS progresses to a recordable injury. GE recommends, however, that, to reduce the administrative burden, the baseline not be revised after the shift, that the original baseline be maintained and the hearing loss only be recorded on the initial occasion of the 15 dB shift.

George R. Cook and Omar Jaurez, occupational audiologists (Ex. 15: 50), supported the 15dB level only if no adjustment for aging was allowed:

[t]he Noise Standard has two loopholes in the identification of STS. First it allows for revision of baseline when the loss is persistent. The Standard does not identify persistence and it is possible to revise a baseline early and subsequent STSs would be postponed. The second loophole is the allowance of presbycusis which hides changes in hearing. Therefore, a criteria which separates the recording criteria from STS and protects the required STS follow-up is necessary. A 20 or 25 dB criteria is felt to be too much change.

Most of the commenters, however, did not support the proposed 15 dB criterion (see, *e.g.*, Exs. 22; 26; 15: 25, 45, 108, 110, 119, 137, 146, 154, 171, 177, 201, 203, 213, 218, 246, 251, 262, 278, 295, 310, 329, 331, 334, 343, 347, 348, 350, 358, 369, 394, 396, 405, 424). Most of these commenters recommended a recording criterion of a 25 dB shift, i.e., the criterion used in OSHA's interim enforcement policy (see, *e.g.*, Exs. 22; 15: 45, 119, 137, 146, 154, 171, 177, 201, 203, 218, 246, 262, 278, 329, 331, 334, 343, 348, 358, 395, 424). Con Edison wrote ''[l]owering the dB shift criteria to 15 dB [from 25 dB] would result in recording cases which do not meet the clinical definition of hearing loss'' (Ex. 15: 213), and the Amoco Corporation testified that OSHA should ''[r]aise the hearing loss limit to a more appropriate indication of material impairment'' (Ex. 22). The American Iron and Steel Institute (Ex. 15: 395) commented:

The appropriate recording trigger should be the loss of hearing recognized by the American Medical Association (AMA) as the lowest indicator of any material impairment to the employee's hearing. According to the AMA, a person has suffered material impairment when testing reveals a 25 dB average hearing loss from audiometric zero at 500, 1000, 2000, and 3000 hertz. OSHA itself has recognized that this is the lowest level of hearing loss that constitutes any material hearing impairment. see 46 Fed. Reg. 4083 (Jan. 18, 1981). Below that level, an employee has suffered no noticeable injury or illness.

The American Iron and Steel Institute disagreed that a 10 or a 15 dB shift in hearing should be recorded, stating that ''While a 15 dB shift is arguably closer to a serious injury than a 10 dB shift, neither is a principled approximation of the onset of any disabling illness or injury, and each is inconsistent with OSHA's acknowledgment in Forging Indus. Ass'n v. Secretary of Labor, 773 F.2d 1436, 1447 n.18 (4th Cir. 1985), that no injury results until a person experiences a 25 dB loss.'' (OSHA does not agree with this characterization of its position.)

Similarly, the Monsanto Company commented ''OSHA acknowledges in the Hearing Conservation Amendment Standard that STS will occur and nothing is required to be done to prevent it from occurring. Therefore, it cannot be a measure of significantly impaired functional hearing capacity. In the preamble to this rule, OSHA cites several excerpts of testimony supporting this position'' (Ex. 15: 295).

Vulcan Chemicals commented that it ''believes the present requirement [of a hearing level shift of 25 dB for recordkeeping] is protective and recommends that the recordable criteria should remain at 25 decibels'' (Ex. 15: 171). New England Power justified its support for a 25 dB shift as the recording criteria with the comment that there ''is far too much variability with an individual subject and the equipment to ensure accuracy'' (Ex. 15: 170), and Tosco, arguing in a similar vein, commented that the ''existing 25 dB shift provides an easily identifiable measurement for determining injuries, and also provides for variation in background noise during testing, variability of the employee's health/hearing capability on the day being tested, as well as variation in the employee's home/social lifestyle which may contribute to hearing loss'' (Ex. 15: 246). The Can Manufacturers Institute commented that a 25 dB shift criterion ''would identify as consequential change in hearing acuity that is irreversible and minimize multiple recording of change over time'' (Ex. 15: 331).

There was also support in the rulemaking record for using a 20 dB shift as a criterion for recording hearing loss (see, *e.g.*, Exs. 15: 108, 295, 396, 405, 423). Most of the reasons given for supporting this level were the same as those provided as support for a 25 dB shift recording criterion. For example, the Westinghouse Electric Corporation commented that a ''20 decibel shift would not only allow for variances in individual audiometric tests, but would also allow for the fact that workplace noise levels are quite often more controlled and less severe than noise levels in the home environment (*e.g.*, trap shooting, stereo sound levels, lawn mowing, and other types of non job-related activities)'' (Ex. 15: 405). Commenting that a 20 dB shift is two times the action level of a 10 dB shift prescribed by OSHA's Occupational Noise standard (29 CFR 1910.95), Brown and Root, Inc. suggested that this level ''would allow for a program to be initiated [at the action level] and working before a case becomes recordable. If the program, however, is not as effective as desired, the recordable level would require that the case be logged'' (Ex. 15: 423). Finally, Union Carbide Corporation argued that using a 20 dB shift as a recording criterion.

[i]s in the direction of simplicity since this is an even multiple of 10 dB, which is the standard threshold shift and the action level for triggering certain hearing conservation requirements. Having an even multiple makes it much easier to track two different baselines one for the hearing conservation requirements and one for recordkeeping requirements. Our experience has shown that it is an administrative nightmare to track 10 dB baselines for hearing conservation and 25 dB baselines for recordkeeping (Ex. 15: 396).

Industrial Health, Inc. (Ex. 15: 84), a mobile audiometry vendor, supported either a 10 dB or 15 dB persistent shift as the recording criterion and provided an analysis, using their data base of over 4 million audiograms. Their comments on the merits of the 10 dB and 15 dB options, and whether each change is significant and noise related, are:

Noise relatedness: Using the OSHA shift formula across 2, 3 & 4 KHz (including OSHA's corrections for aging), a persistent shift of either 10dB or 15dB shows a strong correlation with audiogram patterns typical of exposure to noise (our samples showed more than 85 percent of such shifts appeared to be noise related, and most of the remainder had been flagged by the reviewing audiologist as either medical referrals or cases where the employee had given a medically related explanation for the shift in hearing). Hence, we conclude that a persistent shift based on the OSHA shift formula with age correction, whether 10 dB or 15 dB, is a reasonably accurate indication of a hearing change due to noise exposure provided that medically related shifts are excluded.

Significance of change: We calculated historic shifts based on both a 10 dB shift and a 15 dB shift on a sample industrial database. The following results are for persistent shifts only. The results showed that 15 dB shifts occurred less often than 10 dB shifts (as would be expected), with approximately 70% as many 15 dB shifts as 10 dB shifts. When both shifts occurred for an employee, most (over 80%) of the 15 dB shifts occurred at exactly the same test dates as did the 10 dB shifts, although in some cases (less than 20%) the 15 dB shifts occurred at later times. In general, the agreement was surprisingly good—much better than we had expected. In most (about 80%) of the instances where a 10 dB shift occurred but a 15 dB shift did not,

the significance of the 10 dB shift was questionable when the actual data were examined. Less than 5% of what we judged to be significant 10 dB shifts were missed by the 15 dB rule.

As a result, our analysis indicates the following (based again on all shifts having been demonstrated to be persistent):

a. A persistent 10 dB shift with age correction is a reasonably good yardstick for significant change due to noise, although it does flag some changes which are of questionable significance (perhaps as high as 20% of the shifts).

b. A persistent 15 dB shift with age correction is a better yardstick for significant change due to noise. In our tests it produced roughly 70 percent as many shifts as the 10 dB rule, but the difference was largely 10 dB shifts of questionable significance. It did report some changes later than the 10 dB rule and missed a few shifts (about 5%) which we judged to be of significance.

Finally, there was strong support in the rulemaking record for using a 10 dB shift (also identified as a standard threshold shift or STS in the OSHA Noise standard) as a recording criterion for hearing loss (see, *e.g.*, Exs. 26; 42; 15: 25, 110, 251, 310, 347, 350, 369, 394). For example, the American College of Occupational and Environmental Medicine noted that the ''STS is the earliest reliable indication of measurable hearing loss for practical purposes. This is the earliest practical level of early detection and prevention of further loss is quite possible if the correct measures are taken'' (Ex. 15: 251). The Ford Motor Company agreed. Commenting that it currently records any work-related hearing loss that results in an average loss of 10 dB or more, the company noted that ''[r]ecording hearing loss in its early stage provides Ford the information to correct hazardous conditions and prevent serious impairment to an employee'' (Ex. 15: 347). Ford further stated that its ''method of recording occupational hearing loss is consistent with the requirement of the Hearing Conservation Amendment which requires notification to the employee.'' The Laborer's Health and Safety Fund of North America also pointed out the inconsistency between OSHA's proposed recording criterion in the recordkeeping rule and the criterion in OSHA's occupational noise exposure standard. The Fund commented:

''The noise standard defines a 10 dB shift at 2, 3, and 4K as a standard threshold shift and allows a revision of the baseline should the shift persist. Along comes the recordkeeping rule which says that a 15 dB shift is recordable, and a baseline revision (for recordkeeping purposes) can be made when a 15 dB shift occurs. This situation is an administrative nightmare. It is possible that a hearing loss will never be recordable because the 'baseline' is revised at a 10 dB shift. To avoid this situation, an employer would have to establish 2 different baselines, one for the noise standard provisions, and one for the recordkeeping rule provisions. This situation is unacceptable. We recommend that standard threshold shifts of 10 dB be used as the recordability criteria, since it is consistent with the 1910.95 noise standard'' (Ex. 15: 310).

The Coalition to Preserve OSHA and NIOSH and Protect Workers' Hearing (Exs. 26, 42) recommended a recording policy that would capture instances of age-corrected STS, as defined in the OSHA noise standard, that are confirmed as persistent and that are determined to be work-related. The Coalition's comments are of particular interest because its members include professional and scientific organizations dedicated to the issue of studying and preventing hearing loss. Member associations include the American Speech-Language-Hearing Association, the American Industrial Hygiene Association, the National Hearing Conservation Association, the Acoustical Society of America, the Council for Accreditation in Occupational Hearing Conservation, Self Help for Hard of Hearing People, Inc. and the Institute for Noise Control Engineering. These groups represent well over 100,000 audiologists, acousticians, speech-language pathologists, industrial hygienists, safety and health professionals, and persons with hearing loss (Ex. 42, page 1).

The Coalition provided the following reasons for relying on a 10 dB shift in hearing as an OSHA recordable condition (Ex. 42, pp. 9–13).

1. An allowance in the recording criteria for test-retest variability is inappropriate (i.e. OSHA proposed the 15 dB criterion rather than the 10 dB criterion ''to account for variations in the reliability of individual audiometric results.''
2. An age-corrected STS is a large hearing change that can affect communicative competence.
3. Typical occupational noise exposures do not justify a larger shift criterion.
4. Recording OSHA STSs reduces the recordkeeping burden to industry.
5. Current OSHA STS rates are not high.
6. Recording OSHA STSs will promote effective hearing conservation programs.

Other commenters proposed still other criteria for recording hearing loss. For example, Detroit Edison stated that a shift in hearing level should not be used as a recording criterion for hearing loss because this ''is not indicative of an illness or injury, but only an indication that someone has had a slight change in their ability to hear'' and proposed instead that ''the level of hearing impairment should be used in recording hearing losses versus a threshold shift as compared to a baseline'' (Ex. 15: 377). OSHA does not agree with this commenter, however, because, as the record in the Noise standard rulemaking indicates, permanent threshold shifts do indicate a non-minor impairment, although not all STSs are disabling.

As is the case for many OSHA rules, the 1981 Noise standard was challenged in the courts, which stayed several provisions. In 1983, OSHA revised the hearing conservation amendment to revoke many of the provisions stayed by the court, lift an administrative stay implemented by OSHA, and make technical corrections (48 FR 9738). One of those provisions involved the definition of STS, which was renamed a ''standard'' rather than ''significant'' threshold shift to help differentiate the two separate methods used to calculate the STS in the 1981 and 1983 rules. Although OSHA changed the calculation method used to establish an STS in 1983, the role and importance of the STS concept in the context of a hearing conservation program was unchanged. The main reason for changing the definition of STS in the 1983 standard was to simplify the original calculation and address the concerns of employers and audiology professionals who wished to avoid using a computer to calculate an STS. The standard requires employers to take follow-up actions when an STS is identified, notify the affected employee, evaluate and refit hearing protectors, retrain the employee, and, if necessary, refer the employee for medical evaluation.

The arguments put forward by the Coalition to Preserve OSHA and NIOSH and Protect Workers' Hearing (Exs. 26, 42) are, in OSHA's view, compelling reasons for requiring employers to record on their Logs any case of work-related hearing loss that reaches the level of an STS. OSHA is particularly persuaded by the Coalition's argument that ''An age-corrected STS is a large hearing change that can affect communicative competence'' because an age-corrected STS represents a significant amount of cumulative hearing change from baseline hearing levels. In the words of the Coalition, ''For an individual with normal hearing on the baseline audiogram, STS usually involves age-corrected shifts of 15–20 dB at 3000 and 4000 Hz. For an individual with pre-existing high-frequency hearing loss on the baseline, STS usually involves substantial progression of the hearing loss into the critical speech frequencies. The absolute shift values before age corrections are

considerably larger.'' The Coalition also stressed that the method of averaging hearing loss at several frequencies, as is required to determine an STS under the OSHA Noise standard, tends to ''obscure the large hearing shifts at individual frequencies which usually occur before the average changes by a specified amount'' (Ex. 42, p. 10).

OSHA has rejected, for recordkeeping purposes, the use of the 25 dB shift from audiometric zero prescribed by the American Medical Association Guidelines for Material Impairment. The AMA's 25 dB criterion is intended to be used to determine the level at which the employee should be compensated for hearing loss-related medical bills or lost time. In the context of occupational noise exposure, hearing loss of this magnitude reflects a serious impairment of health or functional capacity. As discussed in the Legal Authority section, however, the Congress intended the OSHA recordkeeping system to capture all non-minor occupational injuries and illnesses, and OSHA believes that an STS loss of hearing represents such an injury. An STS is an abnormal condition that should be recorded because it represents a material loss in hearing ability, beyond the normal effects of aging.

OSHA has also rejected the 15 dB and 20 dB shift recording options, for several reasons. First, although OSHA suggested in the proposal that an additional 5 dB beyond the 10-dB STS shift was needed to account for variability in testing, this has not been supported by the record. As the Medical Educational Development Institute (Ex. 15: 25) stated: ''[t]est/re-test reliability of 5 dB is well established in hearing testing. For example, the Council on Accrediting Occupational Hearing Conservationists maintain this range of reliability in their training guidelines and this is recognized in American National Standard Method for Manual Pure-Tone Threshold Audiometry, S3.21—1978 (R1992).''

The Coalition to Preserve OSHA and NIOSH and Protect Workers' Hearing (Ex. 26) provided additional justification for dropping the proposed rule's 5 dB reliability margin: ''The allowance for a retest (or even multiple retests) should largely eliminate spurious shifts due to measurement error in audiometry. In fact, one of OSHA's original reasons for choosing a frequency-averaged shift (the OSHA STS) as a trigger level for employee follow-up was that the frequency averaging process reduces the influence of random audiometric variability.'' Because reliance on a frequency-averaged rather than single frequency shift increases the reliability of audiometric measurements, OSHA has not adopted NIOSH's recommendation that the hearing loss criterion should be a 15 dB shift at *any* frequency (Ex. 15: 407). Single frequency calculations are less reliable and may therefore lead to the under- or over-recording of hearing loss cases compared with the STS method of averaging loss over several frequencies.

In the final recordkeeping rule, OSHA has chosen to use the Occupational Noise standard's STS—an average shift in either ear of 10 dB or more at 2000, 3000, and 4000 hertz—as the shift in hearing that must be recorded by an employer on the OSHA log as a hearing loss case. An STS clearly represents a non-minor injury or illness of the type Congress identified as appropriate for recordkeeping purposes. The final rule allows the employer to adjust an employee's hearing test results for presbycusis (age), to retest within 30 days (the employer is not required to record if there is a retest within 30 days and the retest refutes the original test), and to have the test results evaluated by a physician or other licensed health care professional. Using the STS as the recording criterion also meets one of the primary purposes of this rulemaking, to improve the simplicity of the overall recordkeeping system. Relying on the Noise standard's STS shifts avoids the complexity referred to by many commenters (see, *e.g.*, Exs. 15: 310, 396) of maintaining multiple baselines for the Noise standard and the OSHA recordkeeping rule. As the Laborers' Health & Safety Fund of North America (Ex. 15: 310) commented:

> The noise standard defines a 10 dB shift at 2,3, and 4K as a standard threshold shift and allows a revision of the baseline should the shift persist. Along comes the recordkeeping rule which says that a 15 dB shift is recordable, and a baseline revision (for recordkeeping purposes) can be made when a 15 dB shift occurs. This situation is an administrative nightmare. It is possible that a hearing loss will never be recordable because the baseline is revised at a 10 dB shift. To avoid this situation, an employer would have to establish 2 different baselines, one for the noise standard provisions, and one for the recordkeeping rule provisions. This situation is unacceptable. We recommend that standard threshold shifts of 10 dB be used as the recordability criteria, since it is consistent with the 1910.95 noise standard.

Several commenters (see, *e.g.*, Exs. 15: 295, 395) argued that OSHA itself had discounted the significance of the 10 dB STS during the 29 CFR 1910.95 rulemaking. OSHA disagrees with this assessment of the Agency's position on the importance of an STS. In the 1981 preamble to the Hearing Conservation Amendment, OSHA found that a 10 dB shift in hearing threshold is significant because it is outside the range of audiometric error and ''it is serious enough to warrant prompt attention'' (46 FR 4144). The 1983 preamble reinforces these findings. It states that:

> Correctly identifying standard threshold shifts will enable employers and employees to take corrective action so that the progression of hearing loss may be stopped before it becomes handicapping. Moreover, a standardized definition of STS will ensure that the protection afforded to exposed employees is uniform in regard to follow-up procedures. * * *
>
> OSHA reaffirms its position on the ideal criterion for STS which was articulated in the January 16, 1981 promulgation (see 46 FR 4144). The criterion must be sensitive enough to identify meaningful changes in hearing level so that follow-up procedures can be implemented to prevent further deterioration of hearing but must not be so sensitive as to pick up spurious shifts (sometimes referred to as ''false positives''). In other words, the criterion selected must be outside the range of audiometric error (48 FR 9760).

The Fourth Circuit rejected an employer's argument that a 10 dB shift in hearing threshold is insignificant. In its decision upholding OSHA's use of a 10 dB STS as an action level in the Hearing Conservation Amendment, the court found that:

> [t]he amendment is concerned with protecting workers before they sustain an irreversible shift. Consequently, it was incumbent upon the Agency to select a trigger level that would protect workers by providing an early warning yet not to be so low as to be insignificant or within the range of audiometric error. We find that the Agency struck a reasonable balance between those concerns. * * *

Forging Indus. Ass'n v. *Secretary of Labor,* 773 F.2d 1436, 1450 (1985)(en banc).

OSHA believes that many of the reasons stated in the 1983 preamble make the STS an appropriate recording criterion for recordkeeping purposes. For example, employers are familiar with the STS definition, which is also sensitive enough to identify a non-minor change in hearing. Use of the STS also reduces the confusion that would arise were OSHA to require employers to maintain two baselines: one required by the Occupational Noise standard and one required for recordkeeping purposes.

Baseline Audiogram

In its proposal, OSHA also asked for comment on which baseline should be used as the starting point in determining recordable hearing loss. There was strong support in the record for using

the preemployment or original baseline for this purpose (see, *e.g.*, Exs. 26; 15: 25, 50, 78, 108, 110, 111, 113, 146, 154, 163, 181, 188, 218, 233, 262, 281, 295, 308, 348, 354, 402, 405), although a few commenters proposed using audiometric zero (see, *e.g.*, Ex. 15: 395). One commenter proposed that the reviewing professional should determine the appropriate baseline on a case-by-case basis (Ex. 15: 175), and another proposed that an audiologist should determine when a change in baseline audiograms is warranted (Ex. 15: 203). Some commenters supported adjusting the employee's baseline audiogram when a recordable hearing loss case has been identified (see, *e.g.*, Exs. 26; 15: 25, 108, 111, 146, 163, 290, 354, 405, 407).

OSHA agrees with those commenters who argued that the preemployment or original baseline should be used as the benchmark from which to determine recordable hearing loss. Using the preemployment or original baseline automatically corrects for any hearing loss that may have occurred before the worker was employed with his or her current employer and will prevent the recording of cases of nonoccupational hearing loss. This policy is also consistent with OSHA's Occupational Noise standard and therefore increases the simplicity of the recording system.

OSHA also agrees that an employee's baseline audiogram should be adjusted if that employee experiences a recordable hearing loss. Revising the baseline by substituting the revised audiogram for the original audiogram after an STS has occurred will avoid a second or third recording of the same STS. On the other hand, recording hearing loss in a given worker only once would overlook the additional hearing loss that may occur, either in the same or the other ear, and would not be consistent with the definition of a ''new'' case in Section 1904.6 of this rule, which requires employers to evaluate any ''new'' case that results from exposure in the workplace for recordability. Subsequent STS findings, i.e., further 10-dB shifts in hearing level, are more serious events than the first STS, because of the nonlinearity of the dB rating system and the progressive severity of increasing hearing loss. A second or third STS in a given worker is therefore also treated under the recordkeeping system as a recordable illness on the OSHA 300 Log. The final rule makes this clear by requiring the employee's audiogram to be compared to the preemployment baseline audiogram when the worker has not experienced a recordable hearing loss, and to the audiogram reflecting the most recent recorded hearing loss if the worker has experienced a prior recorded hearing loss case.

Correction for Aging

In its proposal, OSHA included provisions allowing the employer to adjust the results of audiograms for presbycusis (age-related hearing loss), and asked for comment on whether an age correction is appropriate. The vast majority of commenters agreed that it was (see, *e.g.*, Exs. 26; 42; 15: 39, 45, 84, 113, 137, 163, 175, 201, 203, 262, 278, 281, 283, 331, 347, 348, 396, 405). As the Westinghouse Hanford Company commented, ''[t]he adjusting for presbycusis is appropriate as the deterioration of the hearing related to age is an important factor in determining the amount of hearing loss related to workplace hazards'' (Ex. 15: 108). Julia Royster, Ph.D. CC-A/SLP, agreed with this view, stating that ''Age-related hearing loss is inevitable. There are individual differences in the rate of age-related hearing change and the amount of hearing loss eventually shown due to presbycusis. However, most people will eventually develop age-related hearing changes equivalent to one or more OSHA STSs. Therefore, presbycusis corrections are necessary to avoid attributing age-related hearing change to occupational causes'' (Ex. 26, Appendix C).

However, some commenters did not agree that the use of age corrections was appropriate (see, *e.g.*, Exs. 15: 50, 110, 188, 233, 407). For example, Occupational Audiologists (Ex. 15: 50) pointed out that ''[w]hen the tables [in 29 CFR 1910.95] are applied they ignore any hearing loss that may be present as a result of medical pathology or noise exposure prior to the baseline hearing test,'' and therefore the ''use of the presbycusis tables hides significant changes in hearing thus delaying the STS required procedures of follow-up, notification, fitting/re-fitting, educating and requiring the wearing of hearing protection for some individuals.'' Similarly, John P. Barry (Ex. 15: 110), commented:

> At the 4000 Hz test frequency where occupational hearing loss first occurs, application of the presbycusis correction may significantly reduce the noted threshold shift relative to the employee's baseline audiogram. However, the changes at 2000 and 3000 Hz often are equal to or less than the presbycusis corrections. When these corrections are applied to actual audiometric data, they mask the effects of occupational noise and hinder early detection of noise-induced hearing loss. While hearing loss due to aging (presbycusis) and hearing loss due to the non occupational environment (sociocusis) may account for some of hearing loss noted in serial audiograms, there is no scientifically valid way to correct the data for non occupational hearing loss. * * * It is inappropriate use of statistics to apply median values from one population on a different population when no foundation has been developed to justify such manipulation of data.

OSHA recognizes that using the correction for presbycusis when interpreting audiogram results is controversial among experts in the field of audiology and that NIOSH has developed a new criteria document on occupational noise exposure (''Criteria for a Recommended Standard; Occupational Noise Exposure, Revised Criteria, 1998; U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health; June 1998) which at present does not recommend applying presbycusis correction values to actual employee audiometric data. However, since the Occupational Noise standard itself permits employers to adjust the interpretation of audiograms for the effects of aging, it would be inconsistent and administratively complex to prohibit this practice in the recordkeeping rule. Accordingly, § 1904.10(b)(3) allows the employer to adjust for aging when determining the recordability of hearing loss. The adjustment is made using Tables F–1 or F–2, as appropriate (table F–1 applies to men and F–2 applies to women), in Appendix F of 29 CFR 1910.95. However, use of the correction for aging is not mandatory, just as it is not mandatory in the Noise standard itself.

Persistence of Hearing Loss

Yet another issue surrounding the recording of hearing loss involves the timing of the recording of a case on the OSHA forms when an audiogram has been performed on an employee. The issue is whether the results of an audiogram should be recorded within the interval for recording all cases, or whether the audiogram should be verified with a retest before recording is required. The proposed rule would have required the recording of hearing loss cases within 7 calendar days of the first audiogram, but then would have permitted employers to remove, or line out, a hearing loss case on the Log if a second audiogram taken on that employee within 30 days failed to show that the STS was persistent. Several commenters supported immediate recording with the 30 day retest provision (see, *e.g.*, Exs. 15: 295, 350, 394, 407). The Building and Construction Trades Department of the AFL–CIO (Ex. 15: 394) noted that if a

retest was not performed the case would never be recorded:

> We support OSHA, however, on requiring cases to be recorded and then lined out later if the loss does not persist. In construction, where a worker may never get a follow-up test because they have moved to a different worksite, the case needs to be recorded and presumed work-related. For construction workers that is a very good presumption to make. These changes should lead to more accurate reporting of hearing loss among construction workers.

Other commenters, however, did not agree with OSHA's proposal and believed the shifts should be confirmed before recording on the Log is required (see, *e.g.*, Exs. 26; 42; 15: 50, 84, 175, 181, 188, 201, 203, 331). Impact Health Services (Ex. 15: 175) expressed its opinion that

> The new hearing loss criterion should require recording of only confirmed work-related shifts in hearing. * * * There is no question that it is in the best interest of the hearing conservation program to identify shifts in hearing while they are still temporary so that follow-up action can be taken immediately to prevent permanent hearing loss. * * * However, requiring companies to record all shifts (both temporary and persistent) within six (proposed seven) days may have an unintended punitive effect. Companies are usually hesitant to record any incidents on Form 200 (proposed Form 300), even if lining-out the event at a later date is an option. Therefore, disallowing the OSHA 30-day retest for recording purposes may have a negative impact on programs which are designed to prevent hearing loss. By requiring recording of all shifts within seven days, companies may actually discontinue programs of conducting annual testing during the work shift, due to a reluctance to identify (and record) temporary threshold shift.

To address the problem identified by the Building and Construction Trades Department of the AFL–CIO, Impact Health Services recommended that ''[i]f a follow-up audiogram is not administered within 30 days of determination, or if the follow-up audiogram confirms the shift, then the shift is considered persistent and if determined to be work related, must be recorded on Form 300'' (Ex. 15: 175). The American Association of Occupational Health Nurses (Ex. 15: 181) noted that it ''would require less paperwork to record the hearing loss after confirmation by a re-test in thirty days, rather that recording the initial shift and then having to 'line out' the entry if the re-test was not indicative of any hearing loss.''

The Coalition to Preserve OSHA and NIOSH and Protect Workers' Hearing (Exs. 26; 42) stated:

> This urgency [as reflected in the proposal's provision requiring recording within 7 days] in recording unconfirmed shifts does not appear justified and creates additional burdens for the employer. The coalition recommends the following more efficient and suitably protective approach:
>
> —Only confirmed (i.e., persistent) work-related STSs are to be recorded on Form 300, unless a follow-up audiogram is not administered.
>
> —If a follow-up audiogram is not administered within 30 days of the initial determination of STS, or if the follow-up audiogram confirms the STS, then the shift is considered persistent, and if determined to be work-related, must be recorded on Form 300. * * *
>
> —If a follow-up audiogram given within 30 days of the initial determination of the STS does not confirm the STS, nothing is to be recorded on Form 300.

The Coalition also recommended that employers be allowed to remove, or line-out, recorded hearing losses that are not confirmed by subsequent retesting, or are found not to be work-related, within 15 months of the initial STS identification, at the discretion of the reviewing professional. Such a provision would allow employers to remove cases if the next annual audiogram showed an improvement in hearing (Exs. 26; 42).

Several commenters discussed the length of time OSHA should allow between the audiogram on which the STS was first detected and the confirmatory retest. The International Dairy Food Association suggested that allowing only a 30-day period ''may not be feasible in many situations where mobile van testing is utilized. * * * Thirty days are easily consumed during the compiling, mailing, interpreting, mailing, evaluation process'' (Ex. 15: 203). The Association recommended instead that ''OSHA increase the current requirement of 30 days to 45 days to allow employers and employees to obtain a re-test following an annual audiogram'' (Ex. 15: 403). For the same reasons, the Can Manufacturers Institute recommended that retests be permitted within 90 days of the original test, noting that ''[t]here is no magic regarding the current 30 day span'' (Ex. 15: 331). Industrial Health Inc. commented that ''there's no rush'' to retest and stated its preference for a time lapse longer than 30 days ''[i]n order to allow temporary [hearing loss] effects to subside'' (Ex. 15: 84). NIOSH (Ex. 15: 407) proposed that a confirmatory retest be permitted at any time provided that the retest was preceded by a 14-hour period of quiet.

After a review of the record on this point, OSHA has decided to require that any retest the employer chooses to perform be conducted within 30 days. Accordingly, in the final rule, at paragraph 1904.10(b)(4), employers are permitted, if they choose, to retest the employee to confirm or disprove that an STS reflected on the first audiogram was attributable to a cold or some other extraneous factor and was not persistent. If the employer elects to retest, the employer need not record the case until the retest is completed. If the retest confirms the hearing loss results, the case must be recorded within 7 calendar days. If the retest refutes the original test, the case is not recordable, and the employer does not have to take further action for OSHA recordkeeping purposes. The 30 day limit in the final recordkeeping rule is consistent with the 30 day retest provision of § 1910.95(g)(5)(ii), which allows the employer to obtain a retest within 30 days and consider the results of the retest as the annual audiogram if the STS recorded on the first test is determined not to persist.

OSHA believes that the 30 day retest option allows the employer to exclude false positive results and temporary threshold shifts from the data while ensuring the timely and appropriate recording of true positive results. Adding language to the final recordkeeping rule to specify different procedures, depending on whether the employer chooses to conduct a re-test within 30 days, adds some complexity to the final rule, but OSHA finds that this added complexity is appropriate because it will reduce burden for some employers and improve the accuracy of the hearing loss data.

Work-Relationship

One of the greatest sources of controversy in the record concerning OSHA's proposed criterion for recording hearing loss relates to the presumption of work-relationship in cases where an employee is exposed to an 8-hour time-weighted average sound level of noise equaling or exceeding 85 dB(A) (61 FR 4064). One commenter supported the recordkeeping proposal's approach on this matter. NIOSH (Ex. 15: 407) recommended that work-relationship be presumed ''if an employee is exposed to an 8-hour time-weighted sound level of noise equaling or exceeding 85 dB(A) or to peak sound levels equaling or exceeding 115 dB(A) regardless of brevity or infrequency.'' Several commenters advocated presuming work-relatedness if the employee experienced occupational exposures to 85 dB unless medical evidence showed that the hearing loss was not related to work (see, *e.g.*, Exs. 15: 39, 50, 146, 171, 188). For example, BF Goodrich (Ex. 15: 146) asked that ''[O]SHA give employers the opportunity to refute the work

relationship for employees found to have other than noise-induced hearing loss. If the employee is examined by an otolaryngologist or other qualified health professional and found to have a medical condition that causes hearing loss, the case should not be recordable.''

Several commenters objected to the proposed presumption of work-relationship (see, *e.g.*, Exs.15: 201, 263, 283, 289, 305, 318, 334, 390). The National Association of Manufacturers commented that ''There is no justification for presuming that hearing loss is work-related simply because an employee is exposed to an 8-hour time weighted average sound level of noise of 85 dB(A) or higher, even if it were a daily exposure and particularly where it could be as infrequent as once per year'' (Ex. 15: 305). Many commenters agreed with Mississippi Power, which wrote ''[t]he presumption of work relationship does not consider other potentially significant noise exposures such as noisy hobbies, or other noisy activities not associated with occupational noise exposures'' (Ex. 15: 263). Deere & Company argued that ''OSHA is not taking into account the noise-reducing effect of an effective hearing conservation program nor does it take into account the often significant noise exposure that many employees have away from the workplace '' (Ex. 15: 283).

There are numerous suggestions in the record on how best to deal with the presumption of work-relationship. Impact Health Services Inc., and others suggested that a case be considered work-related ''when in the judgement of the supervising audiologist or physician, the shift is due in full or in part to excessive noise exposure in the workplace'' (Ex. 15: 175). Akzo Nobel Chemicals proposed that work-relationship be presumed when ''there is no other reasonable non-work related explanation'' (Ex. 37), and the National Grain and Feed Association suggested ''that if an employer has an active and an enforceable hearing conservation program in place, the presumption should be that any hearing loss experienced by an employee is not work related unless it can be shown to be otherwise'' (Ex. 15: 119). A number of commenters agreed with the comment of the Edison Electric Group that ''OSHA should also establish a criteria of exposure to noise at or above the 85 dB(a) TWA action level of 30 or more days per year before the case is recordable'' because ''[a] single day's exposure at or below the PEL will not cause hearing loss'' (Ex. 15: 401), and NIOSH proposed that work-relationship be presumed ''if an employee is exposed to an 8-hour time-weighted sound level of noise equaling or exceeding 85 dB(A) or to peak sound levels equaling or exceeding 115 dB(A) regardless of brevity or infrequency'' (Ex. 15: 407).

In the final rule, OSHA has continued to rely on a presumption of work-relationship for workers who are exposed to noise at or above the action levels specified in the Occupational Noise standard (29 CFR 1910.95). In line with the overall concept of work relationship adopted in this final rule for all conditions, an injury or illness is considered work related if it occurs in the work environment. For workers who are exposed to the noise levels that require medical surveillance under § 1910.95 (an 8-hour time-weighted average of 85 dB(A) or greater, or a total noise dose of 50 percent), it is highly likely that workplace noise is the cause of or, at a minimum, has contributed to the observed STS. It is not necessary for the workplace to be the sole cause, or even the predominant cause, of the hearing loss in order for it to be work-related. Because the final recordkeeping rule relies upon the coverage of the Occupational Noise standard, it is also not necessary for OSHA to include a minimum time of exposure provision. The Occupational Noise standard does not require a baseline audiogram to be taken for up to six months after the employee is first exposed to noise in the workplace, and the next annual audiogram would not be taken until a year after that. For any worker to have an applicable change in audiogram results under the Occupational Noise standard, the worker would have been exposed to levels of noise exceeding 85 dB(A) for at least a year, and possibly even for 18 months.

In addition, the provisions allowing for review by a physician or other licensed health care professional allow for the exclusion of hearing loss cases that are not caused by noise exposure, such as off the job traumatic injury to the ear, infections, and the like. OSHA notes that this presumption is consistent with a similar presumption in OSHA's Occupational Noise standard (in both cases, an employer is permitted to rebut this presumption if he or she suspects that the hearing loss shown on an employer's audiogram in fact has a medical etiology and this is confirmed by a physician or other licensed health care professional).

Miscellaneous Issues

Other issues addressed by commenters to the rulemaking record on OSHA's proposed criterion for recording hearing loss included whether OSHA should treat hearing levels for each ear separately for recording purposes. Impact Health Services, Inc. (Ex. 15: 175) recommended that proposed Appendix B specify that shifts in hearing be calculated separately for each ear:

> Because an individual's left and right ears may be affected differently by noise or other occupational injury, it is important that Appendix B specifies that shifts in hearing are to be calculated separately for each ear.

Arguing along similar lines, the Chevron Companies raised the issue of revising baselines for both ears when a standard threshold shift is recorded in only one ear. They commented:

> The proposed rule discusses an average shift in one or both ears and establishing a new or revised baseline for future tests to be evaluated against. In discussing the new or revised baseline however the proposed rule does not give guidance on revision when only one ear meets the revision criteria (15 dB or 25 dB or whatever the final rule states). Are the baselines for both ears revised or only the ear meeting the criteria? This issue should be clearly addressed in the final rule. Usually noise induced hearing loss is a symmetrical event so it would be reasonable to revise the baselines for both ears. If the baselines are to be revised individually one could anticipate more hearing losses being recorded than if they are revised in unison. Therefore, for Hearing Conservation Program statistics to be meaningful and comparable, baseline revision must be handled the same across industries (Ex. 15: 343).

Shifts in hearing must be calculated separately for each ear, in accordance with the requirements of § 1910.95. However, if a single audiogram reflects a loss of hearing in both ears, only one hearing loss case must be entered into the records. The issue of revising baseline audiograms to evaluate the extent of future hearing loss pertains to a hearing loss case that has been entered on the Log. If a single-ear STS loss has been recorded on the Log, then the baseline audiogram should be adjusted for that ear, and that ear only. If an STS affecting both ears has been recorded on the Log, then the baseline audiogram may be revised and applied to both ears. This means that there should be no cases where the baseline audiogram has been adjusted and the case has not been recorded on the Log.

The Medical Educational Development Institute (Ex. 15: 25) made several recommendations for changing OSHA's noise standard, 29 CFR 1910.95, to add specific steps to be taken when a 10 dB STS occurs, such as employee interviews, reevaluations with medical personnel, physician referral, labeling of revised baseline audiograms, and reassignment to quieter work for workers with a second or subsequent STS. These are interesting

recommendations, but they address issues that are beyond the scope of this rulemaking. This rulemaking is concerned only with the Part 1904 requirements for recording occupational hearing loss on the OSHA 300 Log, and does not affect any provision of the OSHA Occupational Noise standard.

Phillips Petroleum (Ex. 15: 354) raised another miscellaneous issue when it suggested that OSHA phase in the recording of audiometric tests if a more protective definition of hearing loss was adopted in the final rule:

> [i]f OSHA insists on the recording of hearing loss at the 15 dB, it would artificially inflate the number of recordable hearing-loss cases and have a similar effect as that of the severity issue. We recommend that if the recordability bar is lowered from 25 dB], OSHA allow a transition period where a 15 dB shift is listed on the log, but is not counted in the recordable total. This should continue for a transition period of three years to allow facilities to identify all employees affected. Any employees who were not identified during the transition period would become recordables with a 15 dB hearing loss after the transition period.

OSHA does not believe that a transition period is needed for the recording of occupational hearing loss or any other type of injury or illness included in the records. Adding such a provision would add unnecessary complexity to the rule, and would also create an additional change in the data that would make it difficult to compare data between the two years at the end of the transition. OSHA finds that it is better to implement the recordkeeping changes as a single event and reduce the impacts on the data in future years.

As noted previously, OSHA is not making any changes to its noise standards in this Part 1904 rulemaking, and thus no additional protections are being provided in this final rule.

Section 1904.11 Additional Recording Criteria for Work-Related Tuberculosis Cases

Section 1904.11 of the final rule being published today addresses the recording of tuberculosis (TB) infections that may occur to workers occupationally exposed to TB. TB is a major health concern, and nearly one-third of the world's population may be infected with the TB bacterium at the present time. There are two general stages of TB, tuberculosis infection and active tuberculosis disease. Individuals with tuberculosis infection and no active disease are not infectious; tuberculosis infections are asymptomatic and are only detected by a positive response to a tuberculin skin test. Workers in many settings are at risk of contracting TB infection from their clients or patients, and some workers are at greatly increased risk, such as workers exposed to TB patients in health care settings. Outbreaks have also occurred in a variety of workplaces, including hospitals, prisons, homeless shelters, nursing homes, and manufacturing facilities (62 FR 54159).

The text of § 1904.11 of the final rule states:

(a) Basic requirement. If any of your employees has been occupationally exposed to anyone with a known case of active tuberculosis (TB), and that employee subsequently develops a tuberculosis infection, as evidenced by a positive skin test or diagnosis by a physician or other licensed health care professional, you must record the case on the OSHA 300 Log by checking the ''respiratory condition'' column.

(b) Implementation.

(1) Do I have to record, on the Log, a positive TB skin test result obtained at a pre-employment physical?

No, because the employee was not occupationally exposed to a known case of active tuberculosis in your workplace.

(2) May I line-out or erase a recorded TB case if I obtain evidence that the case was not caused by occupational exposure?

Yes. you may line-out or erase the case from the Log under the following circumstances:

(i) The worker is living in a household with a person who has been diagnosed with active TB;

(ii) The Public Health Department has identified the worker as a contact of an individual with a case of active TB unrelated to the workplace; or

(iii) A medical investigation shows that the employee's infection was caused by exposure to TB away from work, or proves that the case was not related to the workplace TB exposure.

The Proposal

The proposed rule included criteria for the recording of TB cases in proposed Appendix B. In that appendix, OSHA proposed to require the recording of cases of TB infection or disease at the time an employee first had a positive tuberculin skin test, except in those cases where the skin test result occurred before the employee was assigned to work with patients or clients. The proposal stated that cases of TB disease or TB infection would be presumed to be work-related if they occurred in an employee employed in one of the following industries: correctional facilities, health care facilities, homeless shelters, long-term care facilities for the elderly, and drug treatment centers. In other words, the proposal contained a ''special industries'' presumption for those industries known to have higher rates of occupational TB transmission. OSHA proposed to allow employers to rebut the presumption of work-relatedness if they could provide evidence that the employee had been exposed to active TB outside the work environment. Examples of such evidence would have included (1) the employee was living in a household with a person who had been diagnosed with active TB, or (2) the Public Health Department had identified the employee as a contact of an individual with a case of active TB. For employees working in industries other than the ''special'' industries, OSHA proposed that a positive skin test result be considered work-related when the employee had been exposed to a person within the work environment who was known to have TB disease. Under the proposal, an employee exhibiting a positive skin test and working in industries other than those listed would otherwise not be presumed to have acquired the infection in the work environment (61 FR 4041). As noted in the proposal, these recording criteria for TB were consistent with those published previously in OSHA directives to the field (February 26, 1993 memo to Regional Administrators). The final rule permits employers to rebut the presumption of work-relatedness in cases of TB infection among employees but does not rely on the ''special industries'' approach taken by OSHA in the proposal, for reasons explained below.

Positive Skin Tests

Several comments in the record supported OSHA's proposed recording criteria for occupational TB cases (see, *e.g.*, Exs. 15: 72, 133, 198). A number of commenters, however, questioned whether a positive tuberculin skin test reaction should be considered a recordable occupational illness (Ex. 15: 146, 188, 200). For example, BF Goodrich wrote:

> We disagree with a positive skin test reaction as the criterion for recording a TB case. Such tests are only indicative of a past exposure, not necessarily an illness or a condition. OSHA should allow diagnosing medical professionals to use their professional judgement to confirm active TB cases and restrict recordability to those cases (Ex. 15: 146).

Kaiser Permanente (Ex. 15: 200) argued:

> The presumption that an initial positive skin test result or diagnosed tuberculosis in a health care employee is occupationally based is not warranted. While there have been outbreaks in health care facilities

documented in the literature, and while skin test conversion does occur in health care workers and may in given cases be occupationally related, the Kaiser Permanente experience has not been characterized by outbreaks or significant rates of skin test conversion. Diagnosed cases of tuberculosis among Kaiser Permanente health care workers are extremely rare.

OSHA views the situation differently. A positive tuberculin skin test indicates that the employee has been exposed to Mycobacterium tuberculosis *and* has been infected with the bacterium. Although the worker may or may not have active tuberculosis disease, the worker has become infected. Otherwise, his or her body would not have formed antibodies against these pathogens. (OSHA is aware that, in rare situations, a positive skin test result may indicate a prior inoculation against TB rather than an infection.)

OSHA believes that TB infection is a significant change in the health status of an individual, and, if occupational in origin, is precisely the type of illness Congress envisioned including in the OSHA injury and illness statistics. Contracting a TB infection from a patient, client, detainee, or other person in the workplace would cause serious concern, in OSHA's view, in any reasonable person. Once a worker has contracted the TB infection, he or she will harbor the infection for life. At some time in the future, the infection can progress to become active disease, with pulmonary infiltration, cavitation, and fibrosis, and may lead to permanent lung damage and death. An employee harboring TB infection is particularly likely to develop the full-blown disease if he or she must undergo chemotherapy, contracts another disease, or experiences poor health. According to OSHA's proposed TB rule (62 FR 54159), approximately 10% of all TB infections progress at some point to active disease, and it is not possible to predict in advance which individuals will do so.

OSHA also believes that it is important to require employers to record TB cases when an employee experiences a positive skin test because doing so will create more timely and complete statistics. If, for example, OSHA were to require recording only when the worker develops active TB, many cases that were in fact occupational in origin would go unrecorded. In such cases, if the worker had retired or moved on to other employment, the employer would generally not know that the employee had contracted active TB disease, and the case would never be included in the Nation's occupational injury and illness statistics and important information would be lost. Thus, requiring the recording of a case at the infection stage will create more accurate, complete and useful statistics, one of the major goals of this rulemaking.

Several commenters suggested that TB should not be recorded at all because, in their view, acquiring TB infection is not within the control of the employer and is not amenable to control by an employer's safety and health program (see, *e.g.*, Exs. 15: 316, 348, 414, 423). For example, Raytheon Engineers & Constructors (Ex. 15: 414) argued that TB infection and disease should not be recorded because it ''is not due to a condition of the work environment under the control of the employer.'' Dupont argued along similar lines:

> It does not make sense to record tuberculosis cases where an infectious worker infects co-workers. That has nothing to do with job activity or with the workplace except as an accidental exposure. The same type of thinking could apply to flu symptoms, ''colds'', conjunctivitis, etc., where lack of personal hygiene or a strong ''germ'' migrated through the workplace. If the exposure is not part of the job activity, none of the cases mentioned, including tuberculosis, should be recorded (Ex. 15: 348).

As discussed elsewhere in this document (see the Legal Authority section above), Congress did not intend OSHA's recordkeeping system only to capture conditions over which the employer has complete control or the ability to prevent the condition. The Act thus supports a presumption of work-relatedness for illnesses resulting from exposure in the workplace, and the OSHA recordkeeping system has always reflected this position (although a few specific exceptions to that presumption are permitted, including an exception for common colds and flu). In accordance with that presumption, when an employee is exposed to an infectious agent in the workplace, such as TB, chicken pox, etc., either by a co-worker, client, patient, or any other person, and the employee becomes ill, workplace conditions have either caused or contributed to the illness and it is therefore work-related. Since, as discussed above, TB infection is clearly a serious condition, it is non-minor and must be recorded.

Employee-to-Employee Transmission

Two commenters argued that transmission from employee to employee should not be considered work-related (Exs. 15: 39, 348). The RR Donnelley & Sons Company (Ex. 15: 39) pointed out that an employer ''may never know that a fellow employee has tuberculosis. To record personal transmission from one employee to another goes beyond the scope of work relatedness.'' Other commenters agreed with OSHA that, at least under certain circumstances, employee-to-employee transmission should be considered work-related (see, *e.g.*, Exs. 15: 78, 218, 361, 398, 407). For example, Alliant Techsystems (Ex. 15: 78) stated that ''[i]f a worker with infectious tuberculosis disease infected their co-worker, the co-workers' infection/disease would be recordable.''

Again, as discussed above, OSHA believes, under the positional theory of causality, that non-minor illnesses resulting from an exposure in the work environment are work-related and therefore recordable unless a specific exemption to the presumption applies. Infection from exposure to another employee at work is no different, in terms of the geographic presumption, from infection resulting from exposure to a client, patient, or any other person who is present in the workplace. The transmission of TB infection from one employee to another person at work, including a co-worker, clearly is non-minor and is squarely within the presumption.

Special Industry Presumptions

Many of the commenters supported OSHA's proposed approach of assuming work-relatedness for TB cases if the infection occurred in workers employed in certain special industries (see, *e.g.*, Exs. 24, 15: 78, 345, 376, 407). Other commenters suggested that OSHA abandon the proposed special industry presumption (see, *e.g.*, Exs. 15: 197, 200, 225, 259, 279, 302, 341, 431, 436). In the proposed rule, OSHA proposed different work-relatedness criteria for different work environments, *i.e.,* in industries in which published reports of TB outbreaks were available from the Centers for Disease Control and Prevention (CDC), a special presumption would prevail, while in industries in which occupational transmission had not been documented it would not.

Kaiser Permanente commented that the CDC ''Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health-Care Facilities establish facility risk levels for occupational transmission of tuberculosis based upon assessment of a range of relevant criteria such as job duties, incidence of TB patients treated, and community TB rates'' and urged OSHA to follow these in the final rule (Ex. 15: 200).

Two commenters objected to the inclusion of nursing homes in the list of

industries in which the special industry presumption would apply (Exs. 15: 259, 341). For example, the American Health Care Association (AHCA) suggested:

> [i]t should not be presumed that exposure is work-related in all long term care facilities for the elderly. Depending upon the facility and/or its location, the incidence of TB infection/disease in the facility may be less than that of the general public. The Centers for Disease Control and Prevention recognizes that even within certain settings, there are varying levels of risk (minimal to high). TB linkage to the facility should be based on the level of risk using the CDC assessment system, with work relatedness assigned to facilities within the moderate to high risk classification (Ex. 15: 341).

Two commenters suggested OSHA add more industries to the proposed list of industries to which the special industry presumption would apply. The American Nurses Association (ANA) told the Agency that ''There should be no question on the inclusion of the home health arena under the rubric of health care facilities. The risk of transmission exists in all health care work sites including home health sites and must not be limited to traditional health care facilities' (Ex. 15: 376). Alliant Techsystems (Ex. 15: 78) suggested adding ''Industries that causes exposure outside the United States such as the airline sector.''

Some commenters argued that recording should be limited only to TB cases occurring in workers in specific industries, *i.e.,* that no case of TB in other industries, no matter how transmitted or when diagnosed, should be recordable (see, *e.g.*, Exs. 15: 351, 378, 396). Westinghouse Electric Corporation recommended that ''Tuberculosis exposure or disease cases outside of listed industries where cases would be prevalent (such as health care facilities, long-term care facilities, etc.) should not be recordable as an occupational illness. The logical source of exposure would be non work-related and outside the premises of the employer's establishment.'' Likewise, the Air Transport Association (Ex. 15: 378) suggested that TB recording ''[s]hould be limited to medical work environments rather than general industry. The administrative burden far exceeds the expected benefits.''

OSHA is aware that the relative risk of TB, and of all occupational injuries and illnesses, varies widely from industry to industry and from occupation to occupation. However, OSHA does not consider this circumstance relevant for recordkeeping purposes. The fact that ironworkers experience a higher incidence of falls from elevation than do carpenters does not mean that carpenters' injuries from such falls should not be recorded. Congress clearly intended information such as this to be used by individual employers and to be captured in the national statistical program. Again, because TB infection is a significant illness wherever in the workplace it occurs, and because no exemption applies, it must be recorded in all covered workplaces. Accordingly, in the final rule being published today, TB cases are recordable without regard to the relative risk present in a given industry, providing only that the employee with the infection has been occupationally exposed to someone with a known case of active tuberculosis. Employers may rebut the presumption only if a medical investigation or other special circumstances reveal that the case is not work-related.

In the final rule, OSHA has not adopted the ''special industries'' presumption, for several reasons. First, doing so would be inconsistent with the approach taken by the Agency in other parts of the rule, *i.e.,* specific industries have not been singled out for special treatment elsewhere. Second, a ''special industries'' presumption is not needed because the approach OSHA has taken in this section will provide employers with better ways of rebutting work-relatedness when that is appropriate. Finally, the special industries approach is not sufficiently accurate or well enough targeted to achieve the intended goal. Many cases of occupationally transmitted TB occur among employees in industries other than the ''special industries,'' and evidence shows that the risk of TB infection varies greatly among facilities in the special industries.

Other Suggestions for Determining the Work-Relatedness of TB Cases

A number of commenters provided other suggestions for determining the work-relatedness of TB cases (see, *e.g.*, Exs. 15: 39, 154, 181, 188, 200, 218, 226, 335, 393, 407, 431, 436).

The Society for Human Resource Management stated:

> Workers are exposed to tuberculosis in many places other than the work site: it would be unduly burdensome to require employers to provide evidence that the employee has had non-work exposure. Since the employee is in the best position to retrace his or her activities, he or she should be required to provide evidence to establish work-relatedness (Ex. 15: 431).

OSHA does not agree that the employee is in a better position than the employer to know whether an employee has been exposed to TB at work. For example, the worker is not as likely to know whether a co-worker, patient, client, or other work contact has an active TB case. To determine whether exposure to an active case of TB has occurred at work, the employer may interview the employee to obtain additional information, or initiate a medical investigation of the case, but it would be inappropriate to place the burden of providing evidence of work-relationship on the employee.

The American Ambulance Association (Ex. 15: 226) did not support the proposed approach of reporting an employee's positive tuberculin skin test reaction ''unless there has [also] been documentation of a work-related exposure.'' The American Network of Community Options and Resources (ANCOR) argued ''ANCOR strongly opposes the inclusion of tuberculosis unless the infection is known to have been caused at work due to a known, active carrier'' (Ex. 15: 393). The American Association of Occupational Health Nurses (AAOHN) proposed that the criteria for recording TB infection or illness be ''[a]n employee tests positive for tuberculosis infection after being exposed to a person within the work environment known to have tuberculosis disease and the positive test results are determined to be caused by the person in the workplace with tuberculosis disease'' (Ex. 15: 188).

Several commenters suggested that the first case of TB occurring in the workplace should not be recordable (see, *e.g.*, Exs. 15: 218, 361, 398). In two separate comments, the Association for Professionals in Infection Control (APIC) recommended:

> [a]s an acceptable rebuttal to the presumption of work relationship when an employee is found to be infected with tuberculosis or to have active disease. The employer is able to demonstrate that no other employee with similar duties and patient assignments as the infected employee was found to have tuberculosis infection or active disease (Exs. 15: 361, 398).

In addition, Bell Atlantic (Ex. 15: 218) proposed that public health agencies be charged with determining the work-relationship of cases of TB in the workplace. Bell Atlantic's comments to the rulemaking record were as follows:

> Bell Atlantic does not agree that tuberculosis cases should be inherently reported. The first identified incidence of tuberculosis in an employee group probably was not contracted in the workplace. However, if Public Health Officials deem it necessary to require TB testing in the facility as a preventive measure, and new cases are found, these may be recordable. The criteria here is one of public health, and where the disease initiated. The Public Health Agencies

would be charged with investigation of family members, friends, and the community away from work.

A number of commenters misunderstood the proposal as allowing the geographic presumption of work-relationship only to be rebutted in certain ''high risk'' industries. For example, Alcoa commented that ''OSHA seems to conclude * * * that if someone in your workforce has TB then each person in the workplace who tests positive is now considered as having work-related TB due to the incidental exposure potential'' (Ex. 15: 65). ALCOA suggested that the final rule allow the geographic presumption of work-relationship to be rebutted for ''all other industries.''

OSHA agrees that a case of TB should be recorded only when an employee has been exposed to TB in the workplace (*i.e.,* that the positional theory of causation applies to these cases just as it does to all others). OSHA has added an additional recording criterion in this case: for a TB case occurring in an employee to be recordable, that employee must have been exposed at work to someone with a known case of active tuberculosis. The language of the final rule addresses these concerns: ''If any of your employees has been occupationally exposed to anyone with a known case of active tuberculosis, * * *'' Under the final rule, if a worker reports a case of TB but the worker has not been exposed to an active case of the disease at work, the case is not recordable. However, OSHA sees no need for the employer to document such workplace exposure, or for the Agency to require a higher level of proof that workplace exposure has occurred in these compared with other cases. Further, OSHA knows of no justification for excluding cases simply because they are the first or only case discovered in the workplace. If a worker contracted the disease from contact with a co-worker, patient, client, customer or other work contact, the case would be work-related, even though it was the first case detected. Many work-related injury and illness cases would be excluded from the recordkeeping system if cases were only considered to be work-related when they occurred in clusters or epidemics. This was clearly not Congress's intent.

The final rule's criteria for recording TB cases include three provisions designed to help employers rule out cases where occupational exposure is not the cause of the infection in the employee (*i.e.,* where the infection was caused by exposure outside the work environment). An employer is not required to record a case involving an employee who has a positive skin test and who is exposed at work if (1) the worker is living in a household with a person who has been diagnosed with active TB, (2) the Public Health Department has identified the worker as a contact of a case of active TB unrelated to the workplace, or (3) a medical investigation shows that the employee's infection was caused by exposure to TB away from work or proves that the case was not related to the workplace TB exposure.

The final rule thus envisions a special role for public health departments that may investigate TB outbreaks but does not permit employers to wait to record a case until a public health department confirms the work-relatedness of the case. In addition, the final rule's provisions for excluding cases apply in all industries covered by the recordkeeping rule, just as the recording requirements apply to all industries. The final rule thus does not include the ''special industries'' approach of the proposal. As discussed above, the Agency has rejected this proposed approach because it would not have been consistent with the approach OSHA has taken elsewhere in the rule, which is not industry-specific; it is not necessary to attain the intended goal; and it would not, in any case, have achieved that goal with the appropriate degree of accuracy or specificity.

A few commenters stressed that employers should not be required to record cases where the employee was infected with TB before employment (see, *e.g.*, Exs. 15: 65, 407, 414). For example, Alcoa (Ex. 15: 65) proposed that employers not be required to consider as work-related any case where ''the employee has previously had a positive PPD [Purified Protein Derivative] test result.'' In response to this suggestion, OSHA has added an implementation question to the final rule to make sure that employers understand that pre-employment skin test results for TB are not work-related and do not have to be recorded. These results are not considered work-related for the purposes of the current employer's Log because the test result cannot be the result of an event or exposure in the current employer's work environment.

NIOSH proposed to expand the recording criteria for TB infection or disease to include the criterion that ''regardless of the industry or source of infection, a case of active TB disease is presumed to be work-related if the affected employee has silicosis attributable to crystalline silica exposure in the employer's establishment'' (Ex. 15: 407). OSHA has chosen not to include this criterion in the final rule because in NIOSH's example the case would previously have been entered into the records as a case of silicosis. Adopting the NIOSH criterion would result in the same illness being recorded twice.

Kaiser Permanente recommended that OSHA adopt a method for determining the work relationship of TB cases that Kaiser Permanente currently uses in California to evaluate whether cases are recordable, in accordance with an agreement with the California Division of Occupational Safety and Health (Ex. 15: 200):

1. The employer shall promptly investigate all tuberculin skin test conversions according to the ''Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Facilities'' published by the Centers for Disease Control and Prevention (CDC Guidelines).
2. Probable exposure to Mycobacterium tuberculosis unrelated to work environment. The conversion shall not be recorded on the log if, after investigation, the employer reasonably determines that the employee probably converted as a result of exposure unrelated to the employee's work duties.
3. Probable exposure to Mycobacterium tuberculosis related to work environment. The conversion shall be recorded on the log if, after investigation, the employer reasonably determines that the employee probably converted as a result of exposure related to the employee's work duties.
4. Inability to determine probable cause of exposure. If, after reasonably thorough investigation, the employer is unable to determine whether the employee probably converted as a result of exposure related to the employee's work duties, the following shall be done:
   a. The conversion shall not be recorded on the log if the employee was, at all times during which the conversion could have occurred, assigned to a unit or job classification, which met the minimal risk, low risk, or very low risk criteria specified in the CDC Guidelines.
   b. In all other cases, the conversion shall be recorded on the log.

As an initial matter, OSHA notes that the States are not authorized to provide employers with variances to the Part 1904 regulations, under either the rule being published today or the former rule. The issuing of such variances is exclusively reserved to Federal OSHA, to help ensure the consistency of the data nationwide and to make the data comparable from state-to-state. OSHA has not adopted the approach suggested by Kaiser Permanente because the approach is too complex, does not apply equally to health care and non-health care settings, and does not provide the clear guidance needed for a regulatory requirement. However, because the final rule allows employers to rebut the presumption of work-relatedness if a

medical evaluation concludes that the TB infection did not arise as a result of occupational exposure, a physician or other licensed health care professional could use the CDC Guidelines or another method to investigate the origin of the case. If such an investigation resulted in information that demonstrates that the case is not related to a workplace exposure, the employer need not record the case. For example, such an investigation might reveal that the employee had been vaccinated in childhood with the BCG vaccine. The employer may wish, in such cases, to keep records of the investigation and determination.

Section 1904.12 Recording Criteria for Cases Involving Work-Related Musculoskeletal Disorders

Section 1904.12, entitled ''Recording criteria for cases involving work-related musculoskeletal disorders,'' provides requirements for recording work-related musculoskeletal disorders (MSDs). MSDs are defined in the final recordkeeping rule as ''injuries and disorders of the muscles, nerves, tendons, ligaments, joints, cartilage, and spinal discs.''

Paragraph 1904.12(a) establishes the employer's basic obligation to enter recordable musculoskeletal disorders on the Log and to check the musculoskeletal disorder column on the right side of the Log when such a case occurs. The paragraph states that, ''[i]f any of your employees experiences a recordable work-related musculoskeletal disorder (MSD), you must record it on the OSHA 300 Log by checking the ''musculoskeletal disorder'' column.'' Paragraph 1904.12(b)(1) contains the definition of 'musculoskeletal disorder' used for recordkeeping purposes. Paragraphs 1904.12(b)(2) and 1904.12(b)(3) provide answers to questions that may arise in implementing the basic requirement, including questions on the work-relatedness of MSDs.

The Proposal

The proposal defined MSDs as ''injuries and illnesses * * * result[ing] from ergonomic hazards,'' such as lifting, repeated motion, and repetitive strain and stress on the musculoskeletal system. (61 FR 4046) This language was derived, in part, from the definition of the term ''cumulative trauma disorders (CTDs),'' used in OSHA's *Ergonomics Program Management Guidelines For Meatpacking Plants* (hereafter ''*Meatpacking Guidelines*''). The 1990 *Meatpacking Guidelines* used the term CTDs to cover ''health disorders arising from repeated biomechanical stress due to ergonomic hazards.'' (Ex. 11 at p. 20.)

Appendix B to the recordkeeping rule proposed requirements for employers to follow when recording MSDs. The proposed requirements would have required recording: (1) whenever an MSD was diagnosed by a health care provider, or (2) whenever an employee presented with one or more of the objective signs of such disorders, such as swelling, redness indicative of inflammation, or deformity. When either of these two criteria was met, or when an employee experienced subjective symptoms, such as pain, and one or more of the general criteria for recording injuries and illnesses (i.e., death, loss of consciousness, days away from work, restricted work, job transfer, or medical treatment) were met, an MSD case would have been recordable under the proposal.

The proposal also contained special provisions for determining whether hot and cold treatments administered to alleviate the signs and symptoms of MSDs would be considered first aid or medical treatment. Under the former recordkeeping rule, the application of hot and cold treatment on the first visit to medical personnel was considered first aid, while the application of such treatment on the second or subsequent visit was considered to constitute medical treatment. OSHA proposed to revise this provision to consider hot or cold therapy to be first aid for all injuries and illnesses except MSDs, but to consider two or more applications of such therapy medical treatment if used for an MSD case (61 FR 4064). Whether hot and cold therapies constitute first aid or medical treatment is addressed in detail in section 1904.7 of the final recordkeeping rule. As discussed in that section, under the final rule, hot and cold therapies are considered first aid, regardless of the type of injury or illness to which they are applied or the number of times such therapy is applied.

The Final Rule's Definition of Musculoskeletal Disorder

The preamble to the proposal described an MSD as an injury or disorder ''resulting from'' ergonomic hazards. However, OSHA has not carried this approach forward in the final rule because it would rely on an assessment of the cause of the injury, rather than the nature of the injury or illness itself.

Paragraph 1904.12(b)(1) of the final rule therefore states, in pertinent part, that MSDs ''are injuries and disorders of the muscles, nerves, tendons, ligaments, joints, cartilage and spinal discs. MSDs do not include injuries caused by slips, trips, falls, or other similar accidents.'' This language clarifies that, for recordkeeping purposes, OSHA is not defining MSDs as injuries or disorders caused by particular risk factors in the workplace. Instead, the Agency defines MSDs as including all injuries to the listed soft tissues and structures of the body regardless of physical cause, unless those injuries resulted from slips, trips, falls, motor vehicle accidents, or similar accidents. To provide examples of injuries and disorders that are included in the definition of MSD used in the final rule, Section 1904.12(b)(1) contains a list of examples of MSDs; however, musculoskeletal conditions not on this list may also meet the final rule's definition of MSD.

Determining the Work-Relatedness of MSDs

Section 1904.12(b)(2) provides that ''[t]here are no special criteria for determining which musculoskeletal disorders to record. An MSD case is recorded using the same process you would use for any other injury or illness.'' This means that employers must apply the criteria set out in sections 1904.5–1904.7 of the final rule to determine whether a reported MSD is ''work-related,'' is a ''new case,'' and then meets one or more of the general recording criteria. The following discussion supplements the information provided in the summary and explanation accompanying section 1904.5, to assist employers in deciding which MSDs are work-related.

For MSDs, as for all other types of injuries and illnesses, the threshold question is whether the geographic presumption established in paragraph 1904.5(a) applies. The presumption applies whenever an MSD or other type of injury or illness ''results from an event or exposure in the work environment.'' For recordkeeping purposes, an ''event'' or ''exposure'' includes any identifiable incident, occurrence, activity, or bodily movement that occurs in the work environment. If an MSD can be attributed to such an event or exposure, the case is work related, regardless of the nature or extent of the ergonomic risk factors present in the workplace or the worker's job.

This position is not new to the final rule; it is clearly reflected in the 1986 BLS *Recordkeeping Guidelines.* The *Guidelines* contain the following discussion of the applicability of the work-relatedness presumption to back injuries and hernia cases, which reflects OSHA's position under this final rule:

> Back and hernia cases should be evaluated in the same manner as any other case.

Questions concerning the recordability of these cases usually revolve around: (1) The impact of a previous back or hernia condition on the recordability of the case, or (2) whether or not the back injury or hernia was work-related.

Preexisting conditions generally do not impact the recordability of cases under the OSHA system. * * * For a back or hernia case to be considered work-related, it must have resulted from a work-related event or exposure in the work environment. Employers may sometimes be able to distinguish between back injuries that result from an event in the work environment, and back injuries that are caused elsewhere and merely surface in the work environment. The former are recordable; the latter are not. This test should be applied to all injuries and illnesses, not just back and hernia cases. *Guidelines* at p. 32 (emphasis in original).

The *Guidelines* provide the following question and answer to illustrate that MSDs may be attributable to events or exposures in the work environment that pose little apparent ergonomic risk:

B–16 Q. An employee's back goes out while performing routine activity at work. Assuming the employee was not involved in any stressful activity, such as lifting a heavy object, is the case recordable?

A. Particularly stressful activity is not required. If an event (such as a * * * sharp twist, etc.) occurred in the work environment that caused or contributed to the injury, the case would be recordable, assuming it meets the other requirements for recordability. *Guidelines* at p. 32 (emphasis in original).

OSHA believes that, in most cases, an employee who reports an MSD at work will be able to identify the activity or bodily movements (such as lifting, twisting, or repetitive motions) that produced the MSD. If the activity or movements that precipitated the disorder occurred at work, the presumption of work-relatedness is established without the need for further analysis. However, cases may arise in which it is unclear whether the MSD results from an event or exposure in the work environment. In these cases, paragraph 1904.5(b)(3) of the final rule directs the employer to evaluate the employee's work activities to determine whether it is likely that one or more events or exposures in the work environment caused or contributed to the disorder. In this situation the employer would consider the employee report, the ergonomic risk factors present in the employee's job, and other available information to determine work-relationship.

In evaluating job activities and work conditions to identify whether ergonomic risk factors are present, employers may turn to readily available sources of information for assistance, such as materials made available by OSHA on its web site, current scientific evidence, available industry guidelines, and other pertinent sources. This final rule does not establish new or different criteria for determining whether an MSD is more likely than not to have resulted from work activities or job conditions, i.e., from exposure to ergonomic risk factors at work. As is the case for all injuries and illnesses, the employer must make a good faith determination about work-relatedness in each case, based on the available evidence.

The preamble discussion for paragraph 1904.5(b)(3) contains some examples to assist employers in making this determination. In addition, the BLS *Guidelines* contain the following examples:

Q. Must there be an identifiable event or exposure in the work environment for there to be a recordable case? What if someone experiences a backache, but cannot identify the particular movement which caused the injury?

A. Usually, there will be an identifiable event or exposure to which the employer or employee can attribute the injury or illness. However, this is not necessary for recordkeeping purposes. If it seems likely that an event or exposure in the work environment either caused or contributed to the case, the case is recordable, even though the exact time or location of the particular event or exposure cannot be identified.

If the backache is known to result from some nonwork-related activity outside the work environment and merely surfaces at work, then the employer need not record the case. In these situations, employers may want to document the reasons they feel the case is not work related. (BLS *Guidelines,* p. 32.)

Comments on Other Approaches to Recording MSDs

Commenters provided OSHA with several suggestions for recording musculoskeletal disorders: requiring diagnosis by a health care professional, recording symptoms lasting seven days, and eliminating special criteria for recording MSD cases. These are discussed below.

Eliminating Special Criteria for Recording MSD Cases

A large number of commenters suggested that the recordkeeping rule should not contain criteria for recording MSD cases that were different from those for recording all injuries and illnesses, arguing that they should be captured using the criteria for all other types of injuries and illnesses (see, *e.g.*, Exs. 15: 9, 44, 76, 109, 122, 123, 130, 145, 146, 176, 188, 199, 201, 218, 235, 272, 273, 288, 289, 301, 303, 304, 347, 351, 359, 368, 386, 392, 395, 396, 409, 425, 427). The comments of PPG Industries, Inc. (Ex. 15: 109) are representative of these views: ''The system for evaluating all cases should be consistent. When evaluating musculoskeletal disorders, the normal recordkeeping criteria should be used.'' The Voluntary Protection Programs Participants' Association (VPPPA) also recommended that ''MSDs should be treated as any other injury or illness. If the problem arises to the level of seriousness that it is a recordable injury or illness, then it should be recorded on the log'' (Ex. 15: 425). The National Safety Council (Ex. 15: 359) recommended that ''if an employee has pain, he or she should report it. It then becomes recordable or not recordable based on the usual criteria. The employer makes a decision on a case by case basis.''

OSHA agrees with these commenters that MSD cases should be recorded in the same way as other injuries and illnesses, and should not have separate recordability criteria. Using the same criteria for these cases, which constitute one-third of all occupational injuries and illnesses, simplifies the final rule and makes the system easier for employers and employees to use. Employing consistent recording criteria thus helps to achieve one of OSHA's major goals in this rulemaking, simplification. Section 1904.12 has been included in the final rule not to impose different recording criteria on MSDs, but to emphasize that employers are to record MSD cases like all other injuries and illnesses. OSHA believes that this approach to the recording of MSDs will yield statistics on musculoskeletal disorders that are reliable and complete.

Requiring Diagnosis by a Health Care Professional

A number of commenters recommended that OSHA require the recording of musculoskeletal disorders only when they are diagnosed by a health care professional or identified by a medical test result (see, *e.g.*, Exs. 15: 20, 22, 39, 42, 44, 57, 60, 78, 82, 121, 126, 146, 173, 199, 201, 218, 225, 242, 246, 247, 248, 259, 272, 288, 289, 303, 318, 324, 332, 335, 341, 342, 348, 351, 355, 356, 357, 364, 366, 378, 384, 397, 414, 424, 440, 441). The National Electrical Contractors Association (NECA) requested that ''OSHA modify the current criteria to state ''Positive x-ray showing broken bones or fracture, diagnosis of broken teeth, or diagnosis of acute soft tissue damages'' (Ex. 15: 126). The United Technologies Company (UTC) agreed that ''MSDs should only be recorded if the diagnosis is made by a health care provider operating within the scope of his or her specialty'' (Ex. 15: 440). The National

Coalition on Ergonomics (Ex. 15: 366) urged OSHA to limit the recording of MSD cases to those diagnosed by highly qualified health care professionals:

> [O]SHA should not encourage unqualified individuals to ''diagnose'' musculoskeletal disorders given the present state of medical knowledge of their causes and cures. * * * Therefore, OSHA should limit in the definition of musculoskeletal disorders the diagnosis to qualified and trained physicians, and such other practitioners as are accepted by the medical community as having the training and skill necessary to adequately and appropriately treat these cases.

Other commenters expressed similar opinions, arguing that the work relationship of a given case should be determined by a health care professional (see, *e.g.*, Exs. 15: 9, 105, 248, 249, 250, 262, 272, 288, 303, 304, 324, 366, 397, 408, 440). The Footwear Industries of America (Ex. 15: 249) recommended that ''An MSD should be recordable only if it is diagnosed by a health-care provider based on a determination that the MSD is clearly work-related—that is, caused by the work environment.'' The American Dental Association (Ex. 15: 408) suggested that ''OSHA should not require employers to keep records of musculoskeletal disorders unless and until a physician identifies work as the ''predominant cause'' in a given case.'' United Technologies Company recommended that the health care provider use a check list to make this determination: ''UTC also believes that the provider should be required to complete a check list regarding work relatedness with the language changed to include predominantly caused by the work environment and the submittal of information by the employer'' (Ex. 15: 440).

The Northrop Grumman Association (Ex. 15: 42) suggested that ''Recordability should only be based on objective, documented findings by a licensed physician. In [proposed] mandatory Appendix B, recordability is defined as diagnosis by a health care provider and/or objective findings. The 'or' should be deleted. Only positive test findings should denote recordability. There are physicians who diagnose cases without any objective tests to confirm their diagnosis.'' Other commenters (see, *e.g.*, Exs. 15: 44, 386, 330, 332) recommended that MSD cases be recorded only when they are diagnosed by a health care provider and/or are identified by a positive test result *and* meet the general recording criteria.

A few commenters argued that a health care professional's diagnosis should not be considered evidence of work-relatedness (see, *e.g.*, Exs. 15: 347, 363, 409). For example, the American Automobile Manufacturers Association (AAMA) remarked that ''[w]e strongly oppose the recording of a musculoskeletal disorder based solely on the diagnosis by a health care provider. A diagnosis, in and of itself, does not reflect whether a musculoskeletal disorder is significant or serious in nature. Health care providers record a description or diagnosis of an employee's complaint whether minor or serious.'' On the other hand, the American Federation of State, County, and Municipal Employees (Ex. 15: 362) argued that ''[w]orkers may not see a health care professional until after they have endured symptoms for an extended period * * * The reality of the situation is that a great number of workers who suffer from symptoms will not be diagnosed by a health care provider unless or until their condition becomes severe and/or disabling.''

As discussed in the preamble to the work relationship section of the final rule (§ 1904.5), an employer is always free to consult a physician or other licensed health care professional to assist in making the determination of work relationship in individual injury or illness cases, including musculoskeletal disorders. If a physician or other licensed health care professional has knowledge of the employee's current job activities and work conditions, work history, and the work environment, he or she can often use that information, along with the results of a medical evaluation of the worker, to reach a conclusion about the work-relatedness of the condition. Relying on the expertise of a knowledgeable health care professional can be invaluable to the employer in those infrequent cases for which it is not clear whether workplace events or exposures caused or contributed to the MSD or significantly aggravated pre-existing symptoms. Employers may also obtain useful information from ergonomists, industrial engineers, or other safety and health professionals who have training and experience in relevant fields and can evaluate the workplace for the presence of ergonomic risk factors.

However, OSHA does not require employers to consult with a physician or other licensed health care professional or to have the employee undergo medical tests when making work-relationship determinations. The Agency finds that doing so would be both unnecessary and impractical in the great majority of cases and would result both in delaying the recording of occupational MSD cases and increasing medical costs for employers.

In most situations, an evaluation by a physician or other licensed health care professional is simply not needed in order to make a recording decision. For example, if a worker strains a muscle in his or her back lifting a heavy object, and the back injury results in days away from work, there is no doubt either about the work-relationship of the case or its meeting of the recording criteria. Similarly, if a worker performing a job that has resulted in MSDs of the wrist in other employees reports wrist pain and restricted motion, and the employer places the employee on restricted work, the case is recordable and there is no need to await a clinical diagnosis.

Recording of MSD Symptoms

In the preamble to the proposed rule (61 FR 4047), OSHA asked:

> There is a concern that the proposed criteria [for recording MSDs] will result in a situation where workers could be working with significant pain for an extended period of time, without their case being entered into the records. OSHA has been asked to consider an additional recording criterion for these cases: record when the employee reports symptoms (pain, tingling, numbness, etc.) persisting for at least 7 calendar days from the date of onset. OSHA asks for input on this criterion.

Some commenters urged OSHA to require employers to record MSD cases where an employee reports symptoms that have persisted for at least 7 calendar days (see, *e.g.*, Exs. 15: 87, 129, 186, 362, 369, 371, 374, 380). The American Federation of State County and Municipal Employees, AFL–CIO (AFSCME) recommended:

> Under-reporting of MSDs will increase if OSHA adopts this proposal. It has been AFSCME's experience that workers experiencing pain, soreness, tenderness, numbness, tingling and other sensations in their extremities or back do not immediately report these symptoms to their employer. Rather, most employees first attempt to alleviate their symptoms on their own: they ingest medications, use topical solutions, apply heat or cold to affected areas, or utilize other remedies in their attempt to relieve pain, aches, stiffness, or other symptoms. OSHA should require that these cases be recorded when symptoms last for seven consecutive days.
>
> Investigations conducted by AFSCME repeatedly demonstrate that inclusion of the additional criterion is necessary in order to ascertain accurately the number of work-related MSDs. Employer records typically show MSD rates at or even well below ten percent of employees at risk for these injuries. However, results of AFSCME-conducted symptom surveys show that it is common for a third or more of the employees to respond that they have felt pain, numbness, tingling, or other symptoms that have persisted for more than seven days.* * *

AFSCME wishes to emphasize that accurate and complete recording of MSDs is critically important. Early detection, proper medical intervention, and appropriate measures to address ergonomic risk factors in the workplace are all necessary to prevent and manage MSDs (Ex. 15: 362).

Many commenters objected to the proposed 7-day symptom recording concept (see, *e.g.*, Exs. 15: 9, 20, 39, 122, 127, 128, 170, 230, 246, 248, 281, 289, 324, 330, 332, 341, 359, 378, 397, 406, 434). David E. Jones of the law firm of Ogletree, Deakins, Nash, Smoak & Stewart (Ex. 15: 406) stated that this provision was unnecessary because ''[t]he prevalent experience has shown that employers typically record those symptoms when they result in medical treatment, restricted work activity, or days away from work.'' The Eli Lilly Company (Ex. 15: 434) also observed that ''[b]ased on input from [our] occupational health physicians, the vast majority of MSD-type cases would manifest into objective findings or a MSD diagnosis after 7 calendar days of legitimate subjective symptoms.''

Other objections to the proposal's 7-day symptom trigger were based on practical considerations. Many commenters were opposed to recording undiagnosed conditions that persist for seven days on the grounds that the seriousness or veracity of the complaint of pain or other symptoms could not be established by the employer (see, *e.g.*, Exs. 15: 9, 20, 39, 121, 122, 127, 128, 170, 218, 230, 246, 248, 281, 289, 359, 366, 397). For example, the Dayton Hudson Corporation (Ex. 15: 121) stated: ''[s]elf-reporting of symptoms with no medical findings or evaluation is an invitation for abuse. Are these cases work-related or serious? Are they even real?'' Clariant Corporation held the view that ''[d]isgruntled employees could use subjective findings as a means of avoidance. It could be used to prevent them from doing a job or task they do not like'' (Ex. 15: 217). The National Coalition on Ergonomics (Ex. 15: 366) opposed any recordation based on symptoms alone, stating:

First, persistent pain is a symptom, not a disorder, and therefore cannot be a case. There is often no indication that persistent pain is work-related, except that as the person becomes more fatigued, the pain may appear or become more intense. Further, because pain is subjective, there is no way to quantify it so as to focus only on serious cases. Finally, pain can exist without an underlying pathology. Pain in and of itself cannot be a case in the absence of a diagnosis by a qualified medical practitioner, provided that the case is serious, disabling or significant.

Second, other symptoms mentioned in OSHA's question do not represent cases either. As we discuss below, individual symptoms are not illnesses; symptoms, in conjunction with appropriate signs and/or laboratory results are essential to diagnose specific conditions.

Since symptoms do not define cases, OSHA cannot—indeed, should not—require employers to record complaints of uncertain validity and non-specific origin. It is perhaps true that such employees should see a trained physician or other practitioner, but only after this event will there be a case to record, if one exists at all.

Linda Ballas & Associates (Ex. 15: 31) expressed a different concern, namely that ''[i]f an employee is experiencing pain, or reports symptoms—the clock should not have to click to 7 days before the case is recordable. This will lead to under recording and under reporting * * *.''

In response to the comments on this issue, OSHA finds that pain and/or other MSD symptoms, of and by themselves, may indicate an injury or illness. In this regard, MSD cases are not different from other types of injury or illness. As discussed in the preamble to the definitions section of the final rule (Subpart G), symptoms such as pain are one of the primary ways that injuries and illnesses manifest themselves. If an employee reports pain or other symptoms affecting the muscles, nerves, tendons, etc., the incident must be evaluated for work-relatedness, and, if determined by the employer to be work-related, must be tested against the recording criteria to determine its recordability. If it is determined by the employer to be recordable, it must be recorded as an MSD on the OSHA 300 Log.

The ICD–9–CM manual, the *International Classification of Diseases, Clinical Modification* (ICD–CM), the official system of assigning codes to diagnoses of disease, injury and illness, lists several MSD conditions that consist only of pain. That is, when health care professionals diagnose these disease states, they do so on the basis of employee-reported pain (health care professionals often evaluate and confirm such reports by physical examination when making a diagnosis). According to the National Center for Health Statistics (NCHS), the agency responsible for the coordination of all official disease classification activities in the United States relating to the International Classification of Diseases (ICD), the ICD–CM is the official system of assigning codes to diagnoses and procedures associated with hospital utilization in the United States, and is used to code and classify morbidity data from inpatient and outpatient records, physicians' offices, and most NCHS surveys. The following table includes a few illustrative examples of ICD illness codes for pain-related disorders that would be considered MSD cases under OSHA's definition and would thus warrant an evaluation of work-relatedness by the employer.

ICD code	Name and description
723.1	Cervicalgia—Pain in neck.
724.1	Pain in thoracic spine.
724.2	Lumbago—Low back pain.
724.5	Backache, unspecified.

(NCHS Internet home page, http://www.cdc.gov/nchswww/about/otheract/icd9)

Pain is a symptom that generally indicates the existence of some underlying physiological condition, such as inflammation, damage to a spinal disc, or other biomechanical damage. The occurrence of pain or other symptoms (such as, in the case of MSDs, tingling, burning, numbness, etc.) is thus indicative of an incident that warrants investigation by the employer for work-relatedness, the first step in the injury and illness reporting and recording process. The occurrence of pain or other symptoms, however, is not enough, in the absence of an injury or illness that meets one or more of the recording criteria, to make any injury or illness (including an MSD case) recordable under Part 1904. Employers are not required to record symptoms unless they are work-related and the injury or illness reaches the seriousness indicated by the general recording criteria, which for MSD cases will almost always be days away from work, restricted work, medical treatment, or job transfer. Thus, the requirements governing the recording of all injuries and illnesses will work to ensure that symptoms such as the aches and pains that most people experience from time to time during their lives, are not automatically recorded on the OSHA Log. These same recording requirements will also ensure that those MSDs that are determined by the employer to be work-related and that also meet one or more of the recording criteria will be captured in the national statistics.

If the employer is concerned that the case is not work-related, he or she can refer the employee to a health care professional for a determination, evaluation, or treatment. In this situation, or when the employee has already obtained medical attention, the physician or other licensed health care professional can help to differentiate between work-related and non-work-related cases, minor aches and pains, or inappropriate employee reports. This is no different for MSD cases than for

other types of injuries and illnesses, and does not represent a new problem in the determination of work-related injury and illness. There have always been disputes between workers and employers over the existence of an injury or illness and whether it is work-related. If an employer subsequently demonstrates that a worker is malingering or determines that an injury or illness or is not work-related (using OSHA's definition of work-related), the employer may remove the recorded entry from the OSHA 300 Log.

Although OSHA believes that pain or other symptoms indicate an injury or illness that warrants additional analysis, the final rule has not adopted persistent symptoms alone, whether lasting for 7 days or any other set time period, as an automatic recording criterion. OSHA is concerned about workers who experience persistent pain for any reason, and such pain, if work-related, may well warrant an inquiry into the employee's work conditions and the taking of administrative actions. However, pain or other symptoms, standing alone, have not ordinarily been captured by the OSHA recordkeeping system, and OSHA has accordingly not adopted persistent musculoskeletal pain as a recording criterion, for the following reasons.

First, as discussed earlier, OSHA does not believe that MSD cases should receive differential treatment for recording purposes, and the final rule does not contain different criteria for recording MSD cases; instead, it relies on the general criteria of § 1904.7 to capture MSD cases. OSHA finds that, for recordkeeping purposes, MSD pain is no different in nature than the pain caused by a bruise, cut, burn or any other type of occupational injury or illness. For example, the OSHA rule does not contain a criterion requiring that if a burn, cut or bruise results in pain for seven days it is automatically recordable. Creating a special provision for MSD pain would create an inconsistency in the rule.

Further, OSHA believes that the provisions of the final recordkeeping rule, taken together will appropriately capture reliable, consistent, and accurate data on MSD cases. Incorporating a clear definition of MSDs, clarifying the rule's requirements for determining work-relatedness; and refining the definitions of restricted work, first aid and medical treatment; will all work together to improve the quality of the Log data on MSDs. OSHA concludes, based on an analysis of the record evidence on MSDs, that the general recording criteria will enhance the data on work-related, non-minor MSDs occurring in the workplace, and that an additional ''persistent pain'' criterion is unnecessary for purposes of the recordkeeping system.

New hires

Some commenters encouraged OSHA to find a way to exclude MSD cases that involve minor muscle soreness in newly hired employees, i.e., to allow employers to not record MSDs occurring during a ''break-in'' period (see, *e.g.*, Exs. 15: 27, 31, 39, 82, 87, 105, 186, 198, 204, 221, 239, 272, 283, 289, 303, 330, 359, 374, 412, 440). For example, the American Meat Institute (Ex. 15: 330) remarked: ''Employees returning from vacation, or other extended break periods from the job function, could have normal muscle aches to which hot/cold packs could provide relief. Recording such cases would not meet the purpose [of the OSHA Act] either.'' On the same topic, the National Safety Council (Ex. 15: 359) wrote:

> The concept of forgiveness for a short period of adjustment to return to work makes good sense in industries that are traditionally very resistant to early return to work programs. If allowing for a short ''break-in'' period helps get workers safely and comfortably back to full productivity and earning capacity it should be seriously considered. The Council recommends, however, that no specific method be developed in the proposed rule because situations may vary greatly from industry to industry.

The Harsco Corporation (Ex. 15: 105) suggested ''Construction activities can be a physically demanding occupation. If a person hasn't worked in a period of time, the first couple of days can be very tough. To transfer a person to a different task which would allow for the affected body part to rest should have no bearing on recordability if no other treatment is required.''

Other commenters disagreed, however, that a recording exemption for injuries occurring during a break-in period was appropriate (see, *e.g.*, Exs. 15: 68, 359, 371). For example, the State of New York Workers' Compensation Board (Ex. 15: 68) stated that:

> As to the exclusion of minor soreness commonly occurring to newly hired employees or employees on a rehab assignment during a ''break-in stage'', we do not envision any reason to exclude reporting solely on this basis. The criteria should not be to whom the injury happens, but rather whether the injury would otherwise be reportable regardless of who is injured.

The United Food and Commercial Workers Union (UFCW) argued:

> We could not disagree more with the agency. The current proposal in fact screens out all fleeting cases, and includes only those cases that are serious, have progressed and become debilitating. Only those cases with serious medical findings, lost workdays, restricted days and those receiving medical treatment are currently recordable—not those with fleeting pain that goes away with a good nights rest (Ex. 15: 371).

After a review of the record on this topic, OSHA finds that no special provision for newly hired or transferred workers should be included in the final rule. As the National Safety Council stated, it would be very difficult to identify a single industry-wide method for dealing with break-in or work conditioning periods. Any method of exempting such cases would risk excluding legitimate work-related, serious MSD cases. A newly hired employee can be injured just as easily as a worker who has been on the job for many years. In fact, inexperience on the job may contribute to an MSD injury or illness. For example, a new worker who is not aware of the need to get assistance to move a heavy load or perform a strenuous function may attempt to do the task without help and be hurt in the process. Cases of this type, if determined to be work-related, are appropriately included in national statistics on occupational injuries and illnesses.

OSHA notes that minor muscle soreness, aches, or pains that do not meet one or more of the general recording criteria will not be recorded on the OSHA 300 Log. Therefore, the system already excludes minor aches and pains that may occur when employees are newly hired, change jobs, or return from an extended absence. These cases will be recorded only if they reach the level of seriousness that requires recording. The final rule's definition of first aid includes hot/cold treatments and the administration of non-prescription strength analgesics, two of the most common and conservative methods for treating minor muscle soreness. Thus, the final rule allows newly hired workers to receive these first aid treatments for minor soreness without the case being recordable.

The Ergonomics Rulemaking

Many of the comments OSHA received on the proposed recordkeeping rule referred to OSHA's efforts to develop an ergonomics standard. Several commenters argued that OSHA was trying, through the recordkeeping rule, to collect data to support an ergonomics standard (see, *e.g.*, Exs. 22, 183, 215, 304, 346, 397). Typical of these views was that of the National Beer Wholesalers Association (NBWA) (Ex. 15: 215):

NBWA is especially troubled by the likelihood that the new definitions of what injuries must be recorded and reported in the current proposed rule are intended artificially to inflate the number of reported musculoskeletal disorders, whether work-related or not. Such a surge in MSDs could be used to justify additional work on a workplace ergonomics rule despite the notable lack of a scientific basis for regulation in this area.

Other commenters believed that OSHA was using the recordkeeping rule to conduct a ''backdoor rulemaking'' to control ergonomics hazards in the workplace (see, *e.g.*, Exs. 15: 86, 215, 287, 304, 404, 412, 426). For example, the Reynolds Aluminum Company stated that:

Reynolds supports the inclusion of musculo-skeletal disorders (MSDs) on the OSHA log, but does not support the industry-wide application of the Ergonomics Program Management Guidelines For Meatpacking Plants as the criteria for determining recordability. By incorporating these guidelines into Appendix B, OSHA would be implementing an ergonomics program. It would be inappropriate and without legal or scientific basis to burden all industries with ergonomic guidelines designed for a specific, unique industry (Ex. 15: 426).

Several commenters stated that the injury and illness recordkeeping rules should not address musculoskeletal disorders until after an ergonomics standard has been completed (see, *e.g.*, Exs. 15: 13, 95, 393). For example, Entergy Services, Inc. (Ex. 15: 13) expressed the following concerns:

This area is of concern since there is no standard that really covers this issue except the meat packers standard * * * It is believed that to record this type case, a standard should be in place or language should be written to look at true disorders with long term effect as compared to short term symptoms.

Many commenters also made comments on the overall debate about ergonomics, *i.e.,* that the medical community has not reached consensus on what constitutes an MSD (see, *e.g.*, Exs. 15: 116, 1267, 323, 355), that there is too much scientific uncertainty about the issue of ergonomics (see, *e.g.*, Exs. 15: 57, 215, 304, 312, 342, 344, 355, 393, 397, 412, 424), that science and medicine cannot tell what is work-related and what is not (see, *e.g.*, Exs. 15: 204, 207, 218, 323, 341, 342, 3546, 408, 412, 424, 443), that OSHA needs to do more research before issuing a rule (Ex. 15: 234), that ''musculoskeletal disorder'' is a vague category (Ex. 15: 393), and that OSHA should drop the issue until the science is better (Ex. 15: 204).

OSHA does not agree that the provisions on the recording of MSDs contained in this recordkeeping rule would conflict in any way with OSHA's ergonomics rulemaking. Unlike the proposed ergonomics standard, the final ergonomics standard does not use an OSHA recordable case as a ''trigger'' that would require an employer to implement an ergonomics program. As a result, a recordable musculoskeletal disorder does not necessarily mean that the employer is required to implement an ergonomics program. The recordkeeping rule's provisions on the reporting of MSDs simply address the most consistent and appropriate way to record injury and illness data on these disorders. MSDs, like all other injuries and illnesses, must be evaluated for their work-relatedness and their recordability under the recordkeeping rule's general recording criteria; only if the MSD meets these tests is the case recordable. Additionally, OSHA has required the recording of MSDs for many years.

The recordkeeping rule and the ergonomics standard treat MSDs somewhat differently because the purpose of the two rules is different. Thus, although many of the requirements in the two rules are the same, some requirements reflect the different purposes of the two rulemakings. For example, the recordkeeping rule defines MSDs more broadly than the ergonomics rule because one of the purposes of the Part 1904 recordkeeping system is to gather broad information about injuries and illnesses; the ergonomics standard, in contrast, is designed to protect workers from those MSD hazards the employer has identified in their job. Another difference between the two rules is that the ergonomics standard requires employers to evaluate employee reports of MSD signs and symptoms that last for seven consecutive days, although the recordkeeping rule does not require employers to record signs and symptoms that last for seven consecutive days unless such signs or symptoms involve medical treatment, days of restricted work, or days away from work. The record in the ergonomics rulemaking strongly supported early reporting of MSD signs and symptoms because such early reporting reduces disability, medical costs, and lost productivity. However, evidence in the recordkeeping rulemaking did not support a requirement that persistent signs and symptoms of all occupational injuries and illnesses be recorded on the OSHA Log, and the final recordkeeping rule accordingly contains no such requirement.

Section 1904.29 Forms

Section 1904.29, titled ''Forms,'' establishes the requirements for the forms (OSHA 300 Log, OSHA 300A Annual Summary, and OSHA 301 Incident Report) an employer must use to keep OSHA Part 1904 injury and illness records, the time limit for recording an injury or illness case, the use of substitute forms, the use of computer equipment to keep the records, and privacy protections for certain information recorded on the OSHA 300 Log.

Paragraph 1904.29(a) sets out the basic requirements of this section. It directs the employer to use the OSHA 300 (Log), 300A (Summary), and 301 (Incident Report) forms, or equivalent forms, to record all recordable occupational injuries and illnesses. Paragraph 1904.29(b) contains requirements in the form of questions and answers to explain how employers are to implement this basic requirement. Paragraph 1904.29(b)(1) states the requirements for: (1) Completing the establishment information at the top of the OSHA 300 Log, (2) making a one- or two-line entry for each recordable injury and illness case, and (3) summarizing the data at the end of the year. Paragraph 1904.29(b)(2) sets out the requirements for employers to complete the OSHA 301 Incident Report form (or equivalent) for each recordable case entered on the OSHA 300 Log. The requirements for completing the annual summary on the Form 300A are found at Section 1904.32 of the final rule.

Required Forms

OSHA proposed to continue to require employers to keep both a Log (Form 300) and an Incident Report form (Form 301) for recordkeeping purposes, just as they have been doing under the former rule. OSHA received no comments on the use of two forms for recordkeeping purposes, i.e., a Log with a one-line entry for each case and a supplemental report that requires greater detail about each injury or illness case. OSHA has therefore continued to require two recordkeeping forms in the final rule, although these have been renumbered (they were formerly designated as the OSHA 200 Log and the OSHA 101 Supplementary Report).

In addition to establishing the basic requirements for employers to keep records on the OSHA 300 Log and OSHA 301 Incident Report and providing basic instructions on how to complete these forms, this section of the rule states that employers may use two lines of the OSHA 300 Log to describe

an injury or illness, if necessary. Permitting employers to use two lines when they need more space and specifying this information in the rule and on the Log responds to several comments (see, *e.g.*, Exs. 37; 15: 138, 389) about the lack of adequate space for descriptive information on the proposed OSHA 300 Log form. OSHA believes that most injury and illness cases can be recorded using only one line of the Log. However, for those cases requiring more space, this addition to the Log makes it clear that two lines may be used to describe the case. The OSHA 300 Log is designed to be a scannable document that employers, employees and government representatives can use to review a fairly large number of cases in a brief time, and OSHA believes that employers will not need more than two lines to describe a given case. Employers should enter more detailed information about each case on the OSHA 301 form, which is designed to accommodate lengthier information.

Deadline for Entering a Case

Paragraph 1904.29(b)(3) establishes the requirement for how quickly each recordable injury or illness must be recorded into the records. It states that the employer must enter each case on the OSHA 300 Log and OSHA 301 Form within 7 calendar days of receiving information that a recordable injury or illness has occurred. In the vast majority of cases, employers know immediately or within a short time that a recordable case has occurred. In a few cases, however, it may be several days before the employer is informed that an employee's injury or illness meets one or more of the recording criteria.

The former recordkeeping rule required each injury or illness to be entered on the OSHA Log and Summary no later than six working days after the employer received information about the case. OSHA proposed to change this interval to 7 calendar days. Several commenters agreed that allowing 7 calendar days would simplify the reporting time requirement and reduce confusion for employers (see, *e.g.*, Exs. 36; 15: 9, 36, 65, 107, 154, 179, 181, 203, 332, 369, 387). Other commenters (see, *e.g.*, Exs. 15: 46, 60, 82, 89, 184, 204, 225, 230, 239, 283, 288, 305, 348, 375, 390, 346, 347, 348, 358, 389, 409, 423, 424, 431) objected to the proposed 7 calendar-day requirement, principally on the grounds that the proposed 7 calendar-day time limit would actually be shorter than the former rule's 6 working-day limit in some situations, such as if a long holiday weekend intervened (see, *e.g.*, Exs. 15: 9, 60, 230, 272, 375).

One commenter urged OSHA to adopt a 21-day period because conducting a thorough investigation to determine whether a case is work-related or a recurrence of an old case can sometimes take longer than 7 or even 10 days (Ex. 15: 184). In the final rule, OSHA is adopting a 7 calendar-day time limit for the recording of an injury or illness that meets the rule's recording criteria. For many employers, the 7 day calendar period will be longer than the former 6 working day period. Although it is true that, in other cases, a 7 calendar-day limit may be slightly shorter than the former rule's 6 working-day limit, the Agency believes that the 7 calendar-day rule will provide employers sufficient time to receive information and record the case. In addition, a simple ''within a week'' rule will be easier for employers to remember and apply, and is consistent with OSHA's decision, in this rule, to move from workdays to calendar days whenever possible. The Agency believes that 7 calendar days is ample time for recording, particularly since the final rule, like the former rule, allows employers to revise an entry simply by lining it out or amending it if further information justifying the revision becomes available. The final rule does contain one exception for the 7 day recording period: if an employee experiences a recordable hearing loss, and the employer elects to retest the employee's hearing within 30 days, the employer can wait for the results of the retest before recording.

Equivalent Forms and Computerized Records

Commenters were unanimous in urging OSHA to facilitate the use of computers and to allow the use of alternative forms in OSHA recordkeeping (see, *e.g.*, Exs. 21, 22, 15:9, 11, 45, 72, 95, 111, 184, 262, 271, 288, 305, 318, 341, 346, 389, 390, 396, 405, 424, 434, 438). The comments of the U.S. West Company (Ex. 15:184) are representative of these views:

> U S WEST strongly supports provisions in the proposed rule that allow ''equivalent'' forms instead of the OSHA Forms 300 and 301. U S WEST also supports the provisions that would allow use of data processing equipment and computer printouts of equivalent forms. These provisions allow employers considerable flexibility and greatly reduced paperwork burdens and costs, especially for larger multi-site employers.

Accordingly, paragraphs 1904.29(b)(4) and (b)(5) of the final rule make clear that employers are permitted to record the required information on electronic media or on paper forms that are different from the OSHA 300 Log, provided that the electronic record or paper forms are equivalent to the OSHA 300 Log. A form is deemed to be ''equivalent'' to the OSHA 300 Log if it can be read and understood as easily as the OSHA form and contains at least as much information as the OSHA 300 Log. In addition, the equivalent form must be completed in accordance with the instructions used to complete the OSHA 300 Log. These provisions are intended to balance OSHA's obligation, as set forth in Section 8(d) of the OSH Act, to reduce information collection burdens on employers as much as possible, on the one hand, with the need, on the other hand, to maintain uniformity of the data recorded and provide employers flexibility in meeting OSHA's recordkeeping requirements. These provisions also help to achieve one of OSHA's goals for this rulemaking: to allow employers to take full advantage of modern technology and computers to meet their OSHA recordkeeping obligations.

Several commenters were concerned that computerized records would make it more difficult for employees to access the records (see, *e.g.*, Exs. 15:379, 380, 418, 438). Representative of these views is a comment from the United Auto Workers (UAW):

> Electronic data collection is an essential step to moving forward, especially regarding data analysis for large worksites. However, as it works today electronic collection can also be an obstacle to prompt availability to persons without direct access to the computer system. For this reason, OSHA should require the availability of electronic information to employees and employee representatives in the same time interval as hard copy information, regardless of whether the computer system is maintained at the site (Ex. 15: 438).

OSHA does not believe that computerization of the records will compromise timely employee, employer or government representative access to the records. To ensure that this is the case, paragraph § 1904.29(b)(5) of the final rule allows the employer to keep records on computer equipment only if the computer system can produce paper copies of equivalent forms when access to them is needed by a government representative, an employee or former employee, or an employee representative, as required by §§ 1904.35 or 1904.40, respectively. Of course, if the employee requesting access to the information agrees to receive it by e-mail, this is acceptable under the 1904 rule.

OSHA also proposed specifically to require that, on any equivalent form, three of the questions on the form asking for details of the injury or illness

(proposed questions 16, 17, and 18) be positioned on the form in the same order and be phrased in identical language to that used on the OSHA 301 Incident Report. The three questions were all designed to obtain more detailed information about how the injury or illness occurred, what equipment or materials the employee was using at the time of the injury or illness, and the activity the employee was engaged in at the time of the injury or illness.

A number of commenters objected to the proposed requirement that, on any equivalent form, these three questions be asked in the same order and be phrased in the same language as on the OSHA Incident Report (see, *e.g.*, Exs. 33; 37; 15: 9, 41, 44, 59, 60, 119, 132, 156, 176, 201, 231, 281, 283, 301, 312, 318, 322, 329, 334, 335, 346). In addition to arguing that such a requirement would be burdensome and prescriptive, these commenters pointed out that the proposed OSHA recordkeeping form was not identical to many State workers' compensation forms (the forms most often used as alternatives to the OSHA forms), which would mean that employers in these States would, in effect, be forced to use the OSHA forms (Ex. 15: 334). Other commenters argued that being required to use a certain format would hamper employers' internal accident investigations (see, *e.g.*, Exs. 15: 44, 176, 322). For example, the Kodak Company remarked:

> In [proposed] section 1904.5(b)(2)—''Questions 16, 17 & 18 must be asked in the same order and using identical language from the Form 301.'' Companies, like Kodak, have well established techniques to ascertain the cause of the injury and illness. This requirement would actually hamper our ability to find the root cause of an accident. This requirement should be eliminated from the rule. (Ex. 15: 322)

The final rule does not include a requirement that certain questions on an equivalent form be asked in the same order and be phrased in language identical to that used on the OSHA 301 form. Instead, OSHA has decided, based on a review of the record evidence, that employers may use any substitute form that contains the same information and follows the same recording directions as the OSHA 301 form, and the final rule clearly allows this. Although the consistency of the data on the OSHA 301 form might be improved somewhat if the questions asking for further details were phrased and positioned in an identical way on all employers' forms, OSHA has concluded that the additional burden such a requirement would impose on employers and workers' compensation agencies outweighs this consideration.

OSHA has revised the wording of these three questions on the final OSHA 301 form to match the phraseology used by the Bureau of Labor Statistics (BLS) in its Annual Survey of Occupational Injuries and Illnesses. By ensuring consistency across both the BLS and OSHA forms, this change will help those employers who respond both to the BLS Annual Survey and keep OSHA records.

Handling of Privacy Concern Cases

Paragraphs 1904.29(b)(6) through (b)(10) of the final rule are new and are designed to address privacy concerns raised by many commenters to the record. Paragraph 1904.29(b)(6) requires the employer to withhold the injured or ill employee's name from the OSHA 300 Log for injuries and illnesses defined by the rule as ''privacy concern cases'' and instead to enter ''privacy concern case'' in the space where the employee's name would normally be entered if an injury or illness meeting the definition of a privacy concern case occurs. This approach will allow the employer to provide OSHA 300 Log data to employees, former employees and employee representatives, as required by § 1904.35, while at the same time protecting the privacy of workers who have experienced occupational injuries and illnesses that raise privacy concerns. The employer must also keep a separate, confidential list of these privacy concern cases, and the list must include the employee's name and the case number from the OSHA 300 Log. This separate listing is needed to allow a government representative to obtain the employee's name during a workplace inspection in case further investigation is warranted and to assist employers to keep track of such cases in the event that future revisions to the entry become necessary.

Paragraph 1904.29(b)(7) defines ''privacy concern cases'' as those involving: (i) An injury or illness to an intimate body part or the reproductive system; (ii) an injury or illness resulting from a sexual assault; (iii) a mental illness; (iv) a work-related HIV infection, hepatitis case, or tuberculosis case; (v) needlestick injuries and cuts from sharp objects that are contaminated with another person's blood or other potentially infectious material, or (vi) any other illness, if the employee independently and voluntarily requests that his or her name not be entered on the log. Paragraph 1904.29(b)(8) establishes that these are the only types of occupational injuries and illnesses that the employer may consider privacy concern cases for recordkeeping purposes.

Paragraph 1904.29(b)(9) permits employers discretion in recording case information if the employer believes that doing so could compromise the privacy of the employee's identity, even though the employee's name has not been entered. This clause has been added because OSHA recognizes that, for specific situations, coworkers who are allowed to access the log may be able to deduce the identity of the injured or ill worker and obtain innapropriate knowledge of a privacy-sensitive injury or illness. OSHA believes that these situations are relatively infrequent, but still exist. For example, if knowing the department in which the employee works would inadvertently divulge the person's identity, or recording the gender of the injured employee would identifying that person (because, for example, only one woman works at the plant), the employer has discretion to mask or withhold this information both on the Log and Incident Report.

The rule requires the employer to enter enough information to identify the cause of the incident and the general severity of the injury or illness, but allows the employer to exclude details of an intimate or private nature. The rule includes two examples; a sexual assault case could be described simply as ''injury from assault,'' or an injury to a reproductive organ could be described as ''lower abdominal injury.'' Likewise, a work-related diagnosis of post traumatic stress disorder could be described as ''emotional difficulty.'' Reproductive disorders, certain cancers, contagious diseases and other disorders that are intimate and private in nature may also be described in a general way to avoid privacy concerns. This allows the employer to avoid overly graphic descriptions that may be offensive, without sacrificing the descriptive value of the recorded information.

Paragraph 1904.29(b)(10) protects employee privacy if the employer decides voluntarily to disclose the OSHA 300 and 301 forms to persons other than those who have a mandatory right of access under the final rule. The paragraph requires the employer to remove or hide employees' names or other personally identifying information before disclosing the forms to persons other than government representatives, employees, former employees or authorized representatives, as required by paragraphs 1904.40 and 1904.35, except in three cases. The employer may disclose the forms, complete with personally identifying information, (2) only: (i) to an auditor or consultant

hired by the employer to evaluate the safety and health program; (ii) to the extent necessary for processing a claim for workers' compensation or other insurance benefits; or (iii) to a public health authority or law enforcement agency for uses and disclosures for which consent , an authorization, or opportunity to agree or object is not required under section 164.512 of the final rule on Standards for Privacy of Individually Identifiable Health Information, 45 CFR 164.512.

These requirements have been included in § 1904.29 rather than in § 1904.35, which establishes requirements for records access, because waiting until access is requested to remove identifying information from the OSHA 300 Log could unwittingly compromise the injured or ill worker's privacy and result in unnecessary delays. The final rule's overall approach to handling privacy issues is discussed more fully in the preamble discussion of the employee access provisions in § 1904.35.

The Treatment of Occupational Illness and Injury Data on the Forms

The treatment of occupational injury and illness data on the OSHA forms is a key issue in this rulemaking. Although the forms themselves are not printed in the Code of Federal Regulations (CFR), they are the method OSHA's recordkeeping regulation uses to meet the Agency's goal of tracking and reporting occupational injury and illness data. As such, the forms are a central component of the recordkeeping system and mirror the requirements of the Part 1904 regulation. The final Part 1904 rule requires employers to use three forms to track occupational injuries and illnesses: the OSHA 300, 300A, and 301 forms, which replace the OSHA 200 and 101 forms called for under the former recordkeeping rule, as follows:

1. The OSHA Form 300, Log of Work-Related Injuries and Illnesses, replaces the Log portion of the former OSHA Form 200 Log and Summary of Occupational Injuries and Illnesses. The OSHA 300 Log contains space for a description of the establishment name, city and state, followed by a one-line space for the entry for each recordable injury and illness.

2. The OSHA Form 300A, Summary of Work-Related Injuries and Illnesses, replaces the Summary portion of the former OSHA Form 200 Log and Summary of Occupational Injuries and Illnesses. The Form 300A is used to summarize the entries from the Form 300 Log at the end of the year and is then posted from February 1 through April 30 of the following year so that employees can be aware of the occupational injury and illness experience of the establishment in which they work. The form contains space for entries for each of the columns from the Form 300, along with information about the establishment, and the average number of employees who worked there the previous year, and the recordkeeper's and corporate officer's certification of the accuracy of the data recorded on the summary. (These requirements are addressed further in Section 1904.32 of the final rule and its associated preamble.)

3. The OSHA Form 301, Injury and Illness Report, replaces the former OSHA 101 Form. Covered employers are required to fill out a one-page form for each injury and illness recorded on the Form 300. The form contains space for more detailed information about the injured or ill employee, the physician or other health care professional who cared for the employee (if medical treatment was necessary), the treatment (if any) of the employee at an emergency room or hospital, and descriptive information telling what the employee was doing when injured or ill, how the incident occurred, the specific details of the injury or illness, and the object or substance that harmed the employee. (Most employers use a workers' compensation form as a replacement for the OSHA 301 Incident Report.)

The use of a three-form system for recordkeeping is not a new concept. The OSHA recordkeeping system used a separate summary form from 1972 to 1977, when the Log and Summary forms were combined into the former OSHA Form 200 (42 FR 65165). OSHA has decided that the three-form system (the 300 Log, the 300A summary, and the 301 Incident Report) has several advantages. First, it provides space for more cases to be entered on the Log but keeps the Log to a manageable size. Second, it helps to ensure that an injured or ill employee's name is not posted in a public place. When the forms were combined in 1977 into a single form, employers occasionally neglected to shield an employee's name on the final sheet of the 200 Log, even though the annual summary form was designed to mask personal identifiers. The use of a separate 300A summary form precludes this possibility. Third, the use of a separate summary form (the final rule's Form 300A) allows the data to be posted in a user-friendly format that will be easy for employees and employers to use. Fourth, a separate 300A Form provides extra space for information about an employee's right to access the Log, information about the establishment and its employees, and the dual certifications required by § 1904.32 of the rule. Finally, a separate 300A Form makes it easier to attach to the reverse side of the form worksheets that are designed to help the employer calculate the average number of employees and hours worked by all employees during the year.

The majority of the changes to the final forms (compared with the forms used with the former rule and the proposed forms) have been made to reflect the requirements of the final rule and are needed to align the forms with the final regulatory requirements. All of the other changes to the forms reflect formatting and editorial changes made to simplify the forms, make them easier to understand and complete, and facilitate use of the data. The forms have been incorporated into an information package that provides individual employers with several copies of the OSHA 300, 300A, and 301 forms; general instructions for filling out the forms and definitions of key terms; an example showing how to fill out the 300 Log; a worksheet to assist employers in computing the average number of employees and the total number of hours worked by employees at the establishment in the previous year; a non-mandatory worksheet to help the employer compute an occupational injury and illness rate; and instructions telling an employer how to get additional help by (1) accessing the OSHA Internet home page, or (2) by calling the appropriate Federal OSHA regional office or the OSHA approved State-Plan with jurisdiction. The package is included in final rule Section VI, Forms, later in this preamble.

The Size of the OSHA Recordkeeping Forms

The OSHA recordkeeping forms required by the final Part 1904 recordkeeping rule are printed on legal size paper (8½″ x 14″). The former rule's Log was an 11 by 17-inch form, the equivalent of two standard 8½ by 11-inch pages. The former 200 Log was criticized because it was unwieldy to copy and file and contained 12 columns for recording occupational injury and occupational illness cases. The proposed OSHA 300 Log and Summary would have fit on a single 8½ by 11-inch sheet of paper (61 FR 4050), a change that would have been made possible by the proposed elimination of redundancies on the former 200 Log and of certain data elements that provided counts of restricted workdays and separate data on occupational injury and illness cases. The proposed OSHA 300 Form was favorably received by a

large number of commenters (see, *e.g.*, Exs. 19, 44, 15: 48, 157, 246, 307, 347, 351, 373, 374, 378, 384, 391, 395, 396, 427, 434, 441, 443). For example, the National Association of Plumbing-Heating-Cooling Contractors (NAPHCC) stated:

> NAPHCC applauds the Agency's efforts to simplify the Injury and Illness Log and Summary in the form of a new Form 300 and Form 301. Employers will be more comfortable with the one-page forms—they appear less ominous than the oversized 200 Form and therefore have a better chance of being completed in a timely and accurate manner (Ex. 15: 443, p. 6).

A number of commenters were concerned that proposed the 300 form would fail to capture important data and argued that the former Log should be retained (see, *e.g.*, Exs. 15:15, 47, 283, 369, 429, 438). The primary argument of this group of commenters was that the size of the form should not determine which data elements were included on the Log and which were not. The comment of the International Union, United Automobile, Aerospace & Agricultural Implement Workers of America—UAW summed up this position: ''The UAW uses this data on a yearly basis when it becomes available at the national level, and on a daily basis at the plant level. Compared to the value of the summary data and data series, the goal of reducing the size of the form to something easily Xeroxed is silly'' (Ex. 15: 438, p. 2). The International Brotherhood of Teamsters commented ''OSHA believes the change results in a simplified form that fits on a standard sheet of paper that can be easily copied and kept on a personal computer. * * * The storage capacity of an additional page in a personal computer is hardly burdensome. The amount of information that can be collected should always be need based, and never be limited to what an 8½″ x 11″ sheet of paper can hold'' (Ex. 15: 369, p. 49).

OSHA agrees that the proposed Log would have resulted in a significant loss of useful data and has therefore maintained several data fields on the final OSHA 300 Log to capture counts of restricted work days and collect separate data on occupational injuries and several types of occupational illness. However, there is a limit to the information that can be collected by any one form. OSHA wishes to continue to make it possible for those employers, especially smaller employers, who wish to keep records in paper form to do so. It is also important that the Log be user-friendly, easily copied and filed, and otherwise manageable. Although a form 8½ x 11 inches in size would be even easier to manage, OSHA has concluded that a form of that size is too small to accommodate the data fields required for complete and accurate reporting.

Accordingly, OSHA has redesigned the OSHA 300 Log to fit on a legal size (8½ x 14 inches) piece of paper and to clarify that employers may use two lines to enter a case if the information does not fit easily on one line. The OSHA forms 300A and 301, and the remainder of the recordkeeping package, have also been designed to fit on the same-size paper as the OSHA 300 Log. For those employers who use computerized systems (where handwriting space is not as important) equivalent computer-generated forms can be printed out on 8½ x 11 sheets of paper if the printed copies are legible and are as readable as the OSHA forms.

Commenters raised four major issues concerning the OSHA 300 Log: (1) Defining lost workdays (discussed below); (2) collecting separate data on occupational injury and occupational illness (discussed below); (3) collecting separate data on musculoskeletal disorders (discussed below and in the summary and explanation associated with § 1904.12; and (4) recurrences (discussed in the summary and explanation associated with § 1904.6, Determination of new cases). In addition, commenters raised numerous minor issues concerning the 300 Log data elements and forms design; these are discussed later in this section.

Defining Lost Workdays

OSHA proposed to eliminate the term ''lost workdays,'' by replacing it with ''days away from work'' (61 FR 4033). The OSHA recordkeeping system has historically defined lost workdays as including both days away from work and days of restricted work activity, and the *Recordkeeping Guidelines* discussed how to properly record lost workday cases with days away from work and lost workday cases with days of restricted work activity (Ex. 2, p. 47, 48). However, many use the term ''lost workday'' in a manner that is synonymous with ''day away from work,'' and the term has been used inconsistently for many years. Many commenters on the proposal agreed that the term ''lost workday'' should be deleted from the forms and the recordkeeping system because of this confusion (see, *e.g.*, Exs. 33; 37; 15: 9, 26, 69, 70, 105, 107, 136, 137, 141, 146, 176, 184, 204, 224, 231, 266, 271, 272, 273, 278, 281, 287, 288, 301, 303, 305, 347, 384, 414, 428). The Akzo Nobel Chemicals Company (Ex. 37) simply commented ''[a] big ATTA BOY for removing restricted work cases from under the lost time umbrella. They never really belonged there.'' William K. Principe of the law firm of Constangy, Brooks & Smith, LLC, stated that:

> The elimination of the term ''lost work days'' is a good idea, because its use under the existing recordkeeping regulations has been confusing. Recordkeepers have equated ''lost work days'' with ''days away from work,'' but have not thought that ''lost work days'' included days of ''restricted work activity.'' Thus, the elimination of ''lost work days'' will result in more understandable terminology.

The Hoffman-La Roche, Inc. company agreed with OSHA's proposal to eliminate the term lost workdays from the system, stating that ''[t]he term ''lost workdays'' is confusing and does not clearly define whether the case involved days away from work or restricted days. However, the term ''lost workday case'' still has a place in defining a case that has either days away from work or restricted days.'' The Jewel Coal and Coke Company (Ex. 15: 281) remarked that:

> [w]e believe that the listing of restricted work injuries/illnesses has its purpose as to the consideration of the seriousness of the injury or illness. However, we believe that restricted work duty injuries/illnesses should be placed in a separate category from days away from work and should not be considered as serious as accidents with days away from work but are in fact more serious than first Aid cases or other medically reportable cases. We believe that the listing of the date of return of the employee to full work activities may very well have it's place on the OSHA Form 301 or other supplemental forms.

In the final rule, OSHA has eliminated the term ''lost workdays'' on the forms and in the regulatory text. The use of the term has been confusing for many years because many people equated the terms ''lost workday'' with ''days away from work'' and failed to recognize that the former OSHA term included restricted days. OSHA finds that deleting this term from the final rule and the forms will improve clarity and the consistency of the data.

The 300 Log has four check boxes to be used to classify the case: death, day(s) away from work, days of restricted work or job transfer; and case meeting other recording criteria. The employer must check the single box that reflects the most severe outcome associated with a given injury or illness. Thus, for an injury or illness where the injured worker first stayed home to recuperate and then was assigned to restricted work for several days, the employer is required only to check the box for days away from work (column I). For a case with only job transfer or restriction, the employer must check the

box for days of restricted work or job transfer (Column H). However, the final Log still allows employers to calculate the incidence rate formerly referred to as a ''lost workday injury and illness rate'' despite the fact that it separates the data formerly captured under this heading into two separate categories. Because the OSHA Form 300 has separate check boxes for days away from work cases and cases where the employee remained at work but was temporarily transferred to another job or assigned to restricted duty, it is easy to add the totals from these two columns together to obtain a single total to use in calculating an injury and illness incidence rate for total days away from work and restricted work cases.

Counting Days of Restricted Work or Job Transfer

Although the final rule does not use the term ''lost workday'' (which formerly applied both to days away from work and days of restricted or transferred work), the rule continues OSHA's longstanding practice of requiring employers to keep track of the number of days on which an employee is placed on restricted work or is on job transfer because of an injury or illness. OSHA proposed to eliminate the counting of the number of days of restricted work from the proposed 300 Log (61 FR 4046). The proposal also asked whether the elimination of the restricted work day count would provide an incentive for employers to temporarily assign injured or ill workers to jobs with little or no productive value to avoid recording a case as one involving days away from work (61 FR 4046).

A large number of commenters supported OSHA's proposal to eliminate the counting of restricted work days (see, *e.g.*, Exs. 21; 26; 27; 28; 33; 37; 51; 15: 9, 19, 26, 39, 44, 60, 65, 67, 69, 70, 76, 79, 82, 83, 85, 87, 100, 105, 107, 111, 119, 121, 123, 136, 137, 141, 145, 146, 154, 156, 159, 170, 171, 173, 176, 184, 188, 194, 199, 203, 204, 205, 218, 224, 225, 229, 230, 231, 234, 235, 239, 246, 247, 260, 262, 265, 266, 271, 272, 273, 278, 281, 283, 287, 288, 289, 298, 301, 303, 304, 305, 307, 317, 321, 332, 334, 336, 337, 341, 345, 346, 347, 351, 364, 368, 373, 384, 390, 391, 392, 401, 405, 409, 413, 414, 423, 424, 426, 427, 428, 430, 434, 437, 440, 442). For example, the Union Carbide Corporation (Ex. 15: 391) argued that their:

> [e]xperience with tracking lost or restricted workdays the way it is being done today indicates that it is fruitless. The interest is in the number of lost workday or restricted workday cases with only minor attention being given to the number of days involved. Elimination of the term ''lost workdays'' in regard to restricted workdays would surely be a step in the direction of simplicity and focus. The severity of an injury/illness is more clearly indicated by the number of days away from work than by any other means. The inclusion of cases involving restricted work only clouds the issue.

The Monsanto Corporation (Ex. 28) urged the Agency to do away with *all* day counts, noting that Monsanto:

> [u]ses the recordable case as the basis of our performance measurement system. We measure the number of days away and restricted but rarely look at them. We agree that OSHA should eliminate the number of days of restricted work from the requirements but we would also delete the number of days away as well. While the number of days are some measure of ''severity'', we think a better and simpler measure is just the cases rate for fatalities and/or days away cases.

The commenters who argued for eliminating the counting of restricted workdays offered several reasons: (1) Doing away with the counting would simplify the recordkeeping system and reduce burden on employers (see, *e.g.*, Exs. 33; 15: 69, 105, 136, 137, 141, 146, 156, 176, 184, 188, 203, 224, 231, 239, 266, 272, 273, 278, 288, 289, 301, 303, 304, 336, 337, 345, 346, 347, 390, 391, 409, 424, 426, 428, 430, 442); (2) eliminating the day counts would make it easier to computerize the records (see, *e.g.*, Exs. 15: 136, 137, 141, 224, 266, 278); (3) limiting counts of restricted work would match workers' compensation insurance requirements, which typically count only days away from work (see, *e.g.*, Exs. 15: 225, 336); (4) counts of restricted work have little or no value (see, *e.g.*, Exs. 21; 15: 65, 105, 119, 154, 170, 203, 205, 235, 260, 262, 265, 332, 347, 391, 401, 405, 409, 430); (5) restricted workday counts are not used in safety and health programs and their evaluation (see, *e.g.*, Exs. 15: 65, 119, 154, 159, 194, 239, 271, 347, 409, 426, 428); (6) restricted workday counts are not a good measure of injury and illness severity (see, *e.g.*, Exs. 15: 336, 345); and (7) restricted workday counts are not a uniform or consistent measure (see, *e.g.*, Exs. 15: 235, 288, 289, 347, 409, 442).

For example, the National Grain and Feed Association (Ex. 15: 119) argued that ''[t]here is no evidence that the current restricted work activity day counts are being used in safety and health programs and there is no purpose in continuing the restricted work activity count requirement.'' The Tennessee Valley Authority (Ex. 15: 235) argued that ''[o]nly days away from work or death should be recorded on the 300 log. Recording of restricted work-day cases is difficult to consistently record, thereby, not providing a good data base for comparison.''

However, a number of commenters opposed the proposal to eliminate the counting of restricted days (see, *e.g.*, Exs. 35; 15: 31, 34, 41, 61, 72, 74, 181, 186, 281, 310, 350, 359, 369, 371, 380, 438). For example, Linda Ballas & Associates (Ex. 15: 31) argued that:

> [r]estricted work days should be counted. A restricted case with 1 restricted day would be less severe than a restricted work case with 30 days. The elimination of the restricted work activity day count will provide an incentive for employers to temporarily assign injured or ill workers to jobs with little or no productive value to avoid recording a case as one involving days away from work.* * *

Most of these commenters argued that restricted work day data are needed to gauge the severity of an occupational injury or illness (see, *e.g.*, Exs. 15: 31, 34, 41, 181, 186, 310, 369, 371, 438) or that such data are a measure of lost productivity (see, *e.g.*, Exs. 15: 41, 61, 281). The American Association of Occupational Health Nurses stated that ''[O]SHA should be aware that modifications to recording restricted work days will result in the loss of valuable information related to the severity of the injuries/illnesses.'' The Jewel Coal and Coke Company (Ex. 15: 281) stated that:

> We believe that the listing of restricted work injuries/illnesses has its purpose as to the consideration of the seriousness of the injury or illness. However, we believe that restricted work duty injuries/illnesses should be placed in a separate category from days away from work and should not be considered as serious as accidents with days away from work but are in fact more serious than first Aid cases or other medically reportable cases.* * *

The North Carolina Department of Labor (Ex. 15: 186) recommended that:

> [r]estricted work day counts as well as lost work day counts can be measures of the severity of individual illnesses/injuries. In addition through trend analysis lost work day rates and restricted work day rates may be calculated by job, department, etc. to identify higher risk jobs, departments, etc. and/or measure the effectiveness of interventions and progress in the development of a comprehensive ergonomics program.

As to OSHA's question in the proposal about the incentive for employers to offer restricted work to employee's in order to avoid recording a case with days away from work, a number of commenters questioned whether such an incentive exists (see, *e.g.*, Exs. 15: 13, 26, 27, 39, 79, 136, 137, 141, 156, 181, 199, 218, 224, 229, 242, 263, 266, 269, 270, 278, 283, 341, 364, 377, 409, 426, 434, 440). For example,

the United Technologies Company (UTC) stated that ''[U]TC does not believe that the recording or not recording of restricted days will influence management's decision to temporarily assign employees to restricted work. The decision to place an employee on restricted work is driven by workers' compensation costs rather than OSHA incidence rates'' (Ex. 15: 440). The American Textile Manufacturers Association (ATMI) agreed:

> [A]TMI believes that this will not provide an incentive for employers to temporarily assign injured or ill workers to jobs with little or no productive value to avoid recording a case as one involving days away from work. The restricted work activity day count is in no way related to an employer wanting to avoid having days away from work. Workers' compensation claims and, for the most part, company safety awards are based on the number of ''lost-time accidents.'' The counting of restricted work days has never been an incentive or disincentive for these two key employer safety measures and ATMI believes that this will not change. (Ex. 15: 156)

Other commenters, however, believed there could be incentive effects (see, *e.g.*, Exs. 15: 13, 31, 74, 111, 359, 369).

In the final rule, OSHA has decided to require employers to record the number of days of restriction or transfer on the OSHA 300 Log. From the comments received, and based on OSHA's own experience, the Agency finds that counts of restricted days are a useful and needed measure of injury and illness severity. OSHA's decision to require the recording of restricted and transferred work cases on the Log was also influenced by the trend toward restricted work and away from days away from work. In a recent article, the BLS noted that occupational injuries and illnesses are more likely to result in days of restricted work than was the case in the past. From 1978 to 1986, the annual rate in private industry for cases involving only restricted work remained constant, at 0.3 cases per 100 full-time workers. Since 1986, the rate has risen steadily to 1.2 cases per 100 workers in 1997, a fourfold increase. At the same time, cases with days away from work declined from 3.3 in 1986 to 2.1 in 1997 (Monthly Labor Review, June 1999, Vol. 122. No. 6, pp. 11–17). It is clear that employers have caused this shift by modifying their return-to-work policies and offering more restricted work opportunities to injured or ill employees. Therefore, in order to get an accurate picture of the extent of occupational injuries and illnesses, it is necessary for the OSHA Log to capture counts of days away from work *and* days of job transfer or restriction.

The final rule thus carries forward OSHA's longstanding requirement for employers to count and record the number of restricted days on the OSHA Log. On the Log, restricted work counts are separated from days away from work counts, and the term ''lost workday'' is no longer used. OSHA believes that the burden on employers of counting these days will be reduced somewhat by the simplified definition of restricted work, the counting of calendar days rather than work days, capping of the counts at 180 days, and allowing the employer to stop counting restricted days when the employees job has been permanently modified to eliminate the routine job functions being restricted (see the preamble discussion for 1904.7 General Recording Criteria).

Separate 300 Log Data on Occupational Injury and Occupational Illness

OSHA proposed (61 FR 4036–4037) to eliminate any differences in the way occupational injuries, as opposed to occupational illnesses, were recorded on the forms. The proposed approach would not, as many commenters believed, have made it impossible to determine the types and number of cases of occupational illnesses at the aggregated national level, although it would have eliminated the distinction between injuries and illnesses at the individual establishment level. In other words, the proposed approach would have involved a coding system that the BLS could use to project the incidences of several types of occupational illnesses nationally, but would not have permitted individual employers to calculate the incidence of illness cases at their establishments.

Many commenters reacted with concern to the proposal to eliminate, for recording purposes, the distinction between occupational injuries and occupational illnesses, and to delete the columns on the Log used to record specific categories of illnesses (see, *e.g.*, Exs. 15: 213, 288, 359, 369, 407, 418, 429, 438). For example, Con Edison stated that ''Distinguishing between injuries and illness is a fundamental and essential part of recordkeeping'' (Ex. 15: 21), and the National Institute for Occupational Safety and Health (NIOSH) discussed the potentially detrimental effects on the Nation's occupational injury and illness statistics of such a move, stating ''For occupational health surveillance purposes * * * NIOSH recommends that entries on the OSHA log continue to be categorized separately as illnesses and injuries'' (Ex. 15: 407).

Many commenters also criticized OSHA's proposal to delete from the Log the separate columns for 7 categories of occupational illnesses (see, *e.g.*, Exs. 20, 35, 15: 27, 283, 371). These commenters pointed out that these categories of illnesses have been part of the recordkeeping system for many years and that they captured data on illness cases in 7 categories: occupational skin diseases or disorders, dust diseases of the lungs, respiratory conditions due to toxic agents, poisoning (systemic effects of toxic materials), disorders due to physical agents, disorders associated with repeated trauma, and all other occupational illnesses. Typical of the views of commenters concerned about the proposal to delete these columns from the Log was the comment of the United Auto Workers: ''OSHA should abandon the plan to change the OSHA 200 form to eliminate illness categories. The illness categories in the summary presently provide critically necessary information about cumulative trauma disorders, and useful information about respiratory conditions'' (Ex: 15: 348).

Several commenters supported the proposed concept of adding a single column to the form on which employers would enter illness codes that would correspond to the illness conditions listed in proposed Appendix B, which could then be decoded by government classifiers to project national illness incidence rates for coded conditions (see, *e.g.*, Exs. 20, 15: 27, 369, 371). For example, the United Brotherhood of Carpenters and Joiners of America stated:

> The UBC would recommend [that].* * * A column should be added for an identification code for recordable conditions from Appendix B. (Eg. 1 = hearings loss, 2 = CTD's. 3 = blood lead. Etc.) (Ex. 20).

After a thorough review of the comments in the record, however, OSHA has concluded that the proposed approach, which would have eliminated, for recording purposes, the distinction between work-related injuries and illnesses, is not workable in the final rule. The Agency finds that there is a continuing need for separately identifiable information on occupational illnesses and injuries, as well as on certain specific categories of occupational illnesses. The published BLS statistics have included separate estimates of the rate and number of occupational injuries and illnesses for many years, as well as the rate and number of different types of occupational illnesses, and employers, employees, the government, and the public have found this information useful and worthwhile. Separate illness

and injury data are particularly useful at the establishment level, where employers and employees can use them to evaluate the establishment's health experience and compare it to the national experience or to the experience of other employers in their industry or their own prior experience. The data are also useful to OSHA personnel performing worksite inspections, who can use this information to identify potential health hazards at the establishment.

Under the final rule, the OSHA 300 form has therefore been modified specifically to collect information on five types of occupational health conditions: musculoskeletal disorders, skin diseases or disorders, respiratory conditions, poisoning, and hearing loss. There is also an ''all other illness'' column on the Log. To record cases falling into one of these categories, the employer simply enters a check mark in the appropriate column, which will allow these cases to be separately counted to generate establishment-level summary information at the end of the year.

OSHA rejected the option suggested by the UBC and others (see, *e.g.*, Exs. 20, 15: 27, 369, 371)—to add a single column that would include a code for different types of conditions—because such an approach could require employers to scan and separately tally entries from the column to determine the total number of each kind of illness case, an additional step that OSHA believes would be unduly burdensome. Because the scanning and tallying are complex, this approach also would be likely to result in computational errors.

In the final rule, two of the illness case columns on the OSHA 300 Log are identical to those on the former OSHA Log: a column to capture cases of skin diseases or disorders and one to capture cases of systemic poisoning. The single column for respiratory conditions on the new OSHA Form 300 will capture data on respiratory conditions that were formerly captured in two separate columns, i.e., the columns for respiratory conditions due to toxic agents (formerly column 7c) and for dust diseases of the lungs (formerly column 7b). Column 7g of the former OSHA Log provided space for data on all other occupational illnesses, and that column has also been continued on the new OSHA 300 Log. On the other hand, column 7e from the former OSHA Log, which captured cases of disorders due to physical agents, is not included on the new OSHA Log form. The cases recorded in former column 7e primarily addressed heat and cold disorders, such as heat stroke and hypothermia; hyperbaric effects, such as caisson disease; and the effects of radiation, including occupational illnesses caused by x-ray exposure, sun exposure and welder's flash. Because space on the form is at a premium, and because column 7e was not used extensively in the past (recorded column 7e cases accounted only for approximately five percent of all occupational illness cases), OSHA has not continued this column on the new OSHA 300 Log.

OSHA has, however, added a new column specifically to capture hearing loss cases on the OSHA 300 Log. The former Log included a column devoted to repeated trauma cases, which were defined as including noise-induced hearing loss cases as well as cases involving a variety of other conditions, including certain musculoskeletal disorders. Several commenters recommended that separate data be collected on hearing loss (see, *e.g.*, Exs. 20, 53X, p.76, 15: 31). Dedicating a column to occupational hearing loss cases will provide a valuable new source of information on this prevalent and often disabling condition. Although precise estimates of the number of noise-exposed workers vary widely by industry and the definition of noise dose used, the EPA estimated in 1981 that about 9 million workers in the manufacturing sector alone were occupationally exposed to noise levels above 85 dBA. Recent risk estimates suggest that exposure to this level of noise over a working lifetime would cause material hearing impairment in about 9 percent, or approximately 720,000, U.S. workers (NIOSH, 1998). A separate column for occupational hearing loss is also appropriate because the BLS occupational injury and illness statistics only report detailed injury characteristics information for those illness cases that result in days away from work. Because most hearing loss cases do not result in time off the job, the extent of occupational hearing loss has not previously been accurately reflected in the national statistics. By creating a separate column for occupational hearing loss cases, and clearly articulating in section 1904.10 of the final rule the level of hearing loss that must be recorded, OSHA believes that the recordkeeping system will, in the future, provide accurate estimates of the incidence of work-related loss of hearing among America's workers.

Column on the Log for Musculoskeletal Disorders

Column 7f of the former Log also was intended to capture cases involving repetitive motion conditions, such as carpal tunnel syndrome, tendinitis, etc. These conditions have been called by many names, including repetitive stress injuries, cumulative trauma disorders, and overuse injuries. OSHA has decided to include a separate column on the Log for musculoskeletal disorders (MSDs), the preferred term for injuries and illnesses of the muscles, nerves, tendons, ligaments, joints, cartilage and spinal discs, including those of the upper extremities, lower extremities, and back. Many MSDs are caused by workplace risk factors, such as lifting, repetitive motion, vibration, overexertion, contact stress, awkward or static postures, and/or excessive force. The repeated trauma column on the former OSHA Log did not permit an accurate count of musculoskeletal disorders, both because other conditions, such as occupational hearing loss, were included in the definition of repeated trauma and because many musculoskeletal disorders—including lower back injuries—were excluded. The column was limited to disorders classified as illnesses, but OSHA instructed employers to record all back cases as injuries rather than illnesses, even though back disorders are frequently associated with exposure to occupational stresses over time (Ex. 2, p. 38).

In its proposal, OSHA asked for comment on the need for a separate column containing information on musculoskeletal disorder (MSD) cases such as low back pain, tendinitis and carpal tunnel syndrome. OSHA received numerous comments opposing the addition of an MSD column to the Log (see, *e.g.*, Exs. 15: 9, 60, 78, 105, 122, 136, 137, 141, 201, 218, 221, 224, 266, 278, 305, 308, 318, 346, 395, 397, 406, 414, 430). These commenters objected on several grounds: because they believed that including such a column would make the forms more complex (Ex. 15: 414), because the column would have ''no utility'' (Ex. 15: 397), or because the column would only capture a small percentage of total MSD cases (Ex. 15: 210). Several commenters objected because they believed that an MSD column would duplicate information already obtained through the case description (see, *e.g.*, Exs. 15: 9, 105, 210, 221, 406). For example, the law firm of Ogletree, Deakins, Nash, Smoak & Stewart offered comments on behalf of a group of employers known as the ODNSS Coalition, remarking that ''The log and system of OSHA recordkeeping would not benefit from a separate column for musculoskeletal disorders. The proposed rules for recording these disorders are clear, and

the revisions to the ''case description'' column appearing on the OSHA Form 300 provide for the ample identification of the disorders, which will enable all interested parties to track and analyze entries of that nature'' (Ex. 15: 406). Another group of commenters contended that a separate MSD column would result in an inaccurate picture of MSD incidence because the numbers recorded would increase as a result of the inclusion of lower back MSDs in the cases to be entered in the column (see, *e.g.*, Exs. 15: 305, 308, 318, 346). Representative of these comments is one from the National Association of Manufacturers (NAM):

> Given the over-inclusive definitions of the terms ''work-related,'' ''injury or illness,'' ''medical treatment'' and ''MSDs'' (in Appendix B), and the fact that, for the first time, back injuries would be included as MSDs, we strongly objected to that idea. Under that approach, the MSD numbers probably would have been huge, would have painted a grossly inaccurate and misleading picture as to the current prevalence of MSDs, and would have been cited as justification for an ergonomics standard. Unless and until those deficiencies are completely eliminated, the NAM remains unalterably opposed to the inclusion of an MSD column on the OSHA Form 300 (Ex. 15: 305).

OSHA also received numerous comments supporting the addition of a separate MSD column on the Log (see, *e.g.*, Exs. 35; 15: 32, 156, 371, 379, 380, 415, 418, 438). For example, the United Food and Commercial Workers stated that:

> Of key concern to our membership is the lack of any categorization for musculoskeletal disorders (MSD). A major concern in meatpacking and poultry plants, our committees will now be forced to spend endless hours poring over the logs, reading each individual definition and deciding whether it is a MSD. The logs are often hand written and xerox copies of these are difficult to read. This is a real burden for workers, companies, joint committees and anyone using the logs (Ex. 15: 371).

After a thorough review of the record, and extensive consultation with NIOSH and the BLS to establish the need for such statistics, OSHA has concluded that including a separate column on the final OSHA 300 Log for MSD cases is essential to obtain an accurate picture of the MSD problem in the United States. In 1997, more than 600,000 MSDs resulting in days away from work were reported to the BLS by employers, although determining this number has required close cooperation between OSHA and the BLS and several ''special runs'' by the BLS (i.e., computer analyses performed especially for OSHA) (see on the Internet at ftp://146.142.4.23/pub/special.requests/ocwc/osh/). OSHA believes that such a column on the OSHA 300 Log will not only permit more complete and accurate reporting of these disorders and provide information on the overall incidence of MSDs in the workplace, it will provide a useful analytical tool at the establishment level. OSHA recognizes that the column will add some complexity to the form, but believes that the additional complexity will be more than offset by the fact that all recordable MSDs will be captured in a single entry on the Log. Thus, the total count of cases in the MSD column will allow employers, employees, authorized representatives, and government representatives to determine, at a glance, what the incidence of these disorders in the establishment is. OSHA does not agree with those commenters who stated that entries in the MSD column will duplicate information recorded in the injury/illness description; the case description column will include additional information, *e.g.*, on the particular type of MSD (back strain, carpal tunnel syndrome, wrist pain, tendinitis, etc.).

OSHA also does not agree with those commenters who argued that including a separate column for MSDs would introduce error into the national statistics on the incidence of MSDs. The views of these commenters are not persuasive because the number of reportable lost-workday MSDs is already being captured in national statistics, albeit under two categories (''injuries'' and ''illnesses'') that are difficult to interpret. In response to comments that including a separate column on the Log will provide OSHA with ''justification for an ergonomics standard,'' the Agency notes that it has already developed and proposed an ergonomics standard despite the absence of a single MSD column on employers' Logs.

Miscellaneous 300 Form Issues

The proposed OSHA Form 300 contained a column designated as the ''Employer Use'' column. Many employers keep two sets of injury and illness records; one for OSHA Part 1904 purposes and another for internal safety management system purposes. OSHA envisioned that the proposed Employer Use column would be used to tailor the Log to meet the needs of the establishment's particular safety and health program and reduce the practice some employers have adopted of keeping multiple sets of occupational injury and illness records for various purposes. For example, OSHA envisioned that an employer could enter codes in this column to collect data on occupational injuries and illnesses beyond what is required by the OSHA Part 1904 regulation, such as the results of accident investigations, whether the case was accepted by workers' compensation, or whether or not the employee was hospitalized for treatment.

A number of commenters supported the proposed Employer Use column (see, *e.g.*, Exs. 15: 87, 136, 137, 141, 170, 224, 266, 278, 359). Some stated that employers could utilize the column to identify cases based on specific criteria that could be used in their internal safety and health evaluations (see, *e.g.*, Exs. 15: 136, 137, 141, 170, 224, 266, 278, 359). For example, the National Safety Council stated ''The Council believes that adding the employer use column to the log will effectively reduce the adverse effects of accountability systems. This will allow employers to identify cases for which supervisors and managers should be held accountable, using company specific criteria'' (Ex. 15: 359, p. 14). Another commenter, Kathy Mull, stated ''The comment on possible use of the 'employer use column' to note cases not included in internal safety statistics is a possible mechanism to defer pressures on internal performance measures as tied strictly to OSHA recordkeeping'' (Ex. 15: 278, p. 4).

Several commenters opposed the addition to the Log of an Employer Use column, however (see, *e.g.*, Exs. 15: 28, 82, 109, 132, 375). Among these was the American Petroleum Institute, which stated ''If the revised regulation meets API's recommended system objectives, the 'employer use' column would not be needed. Cases recorded would then be credible, reasonable and meaningful to employers, employees (and to OSHA). * * * OSHA should consider the employer as the primary user of the system'' (Ex. 15: 375A, p. 55). Commenters also expressed concern that an Employer Use column could have a negative effect on the use of the data. For example, the Sherman Williams Company stated ''It is not necessary to provide column j, for ''other'' information that may be provided by the employer. It will lead to inconsistent utilization of the proposed form. Delete column j of the proposed Form 300'' (Ex. 15: 132, p. 1).

Several other commenters argued for the addition of new data requirements to the OSHA 300 Log, as follows:

Commenter	Suggested addition to the 300 Log
G. Neil Companies (Ex. 15: 29)	Information explaining which employers must keep the Log should be added to the form.
Atlantic Dry Dock Corp. (Ex. 15: 179)	A line to carry over the totals from previous page should be added at the top of the form.
Maine Department of Labor (Ex. 15: 41)	The form should include three columns for case type: a column for days away only, a column for days away and restricted, and a column for restricted only to differentiate the three different types of cases.
Ford Motor Company (Ex. 15: 347)	''To facilitate identification, Ford proposes that the employee's last four numbers of his or her social security number be included on the OSHA 300 and 301 Forms * * * The last four numbers of the social security number will greatly assist in employee identification and at the same time offer some measure of confidentiality.''
American Trucking Associations (Ex. 15: 397)	''OSHA should add a new column to the proposed OSHA 300 form allowing employers to indicate whether an injury occurred off-site. This recommendation is not novel [ ] the current OSHA 101 form asks if the injury or illness occurred on the employer's premises * * * the inclusion of the 'off-site' column is crucial in determining which fixed facilities maintain abnormally high rates of workplace injuries/illnesses. In addition, this recommendation furthers the goal of requiring motor carriers to record injuries and illnesses to their employees as well as provides valuable information to OSHA and others regarding the employer's lack of control over the site of the injury.''

OSHA has not added the fields or columns suggested by commenters to the final 300 or 301 forms because the available space on the form has been allocated to other data that OSHA considers more valuable. In addition, there is no requirement in the final rule for employers to enter any part of an employee's social security number because of the special privacy concerns that would be associated with that entry and employee access to the forms. However, employers are, of course, free to collect additional data on occupational injury and illness beyond the data required by the Agency's Part 1904 regulation.

The OSHA 301 Form

Although the final OSHA 300 Log presents information on injuries and illnesses in a condensed format, the final OSHA 301 Incident Record allows space for employers to provide more detailed information about the affected worker, the injury or illness, the workplace factors associated with the accident, and a brief description of how the injury or illness occurred. Many employers use an equivalent workers' compensation form or internal reporting form for the purpose of recording more detailed information on each case, and this practice is allowed under paragraph 1904.29(b)(4) of the final rule.

The OSHA Form 301 differs in several ways from the former OSHA 101 form it replaces, although much of the information is the same as the information on the former 101 Form, although it has been reworded and reformatted for clarity and simplicity. The final Form 301 does not require the following data items that were included on the former OSHA 101 to be recorded:

—The employer name and address;
—Employee social security number;
—Employee occupation;
—Department where employee normally works;
—Place of accident;
—Whether the accident occurred on the employer's premises; and
—Name and address of hospital.

OSHA's reasons for deleting these data items from the final 301 form is that most are included on the OSHA Form 300 and are therefore not necessary on the 301 form. Eliminating duplicate information between the two forms decreases the redundancy of the data collected and the burden on employers of recording the data twice. The employee social security number has been removed for privacy reasons. OSHA believes that the information found in several other data fields on the 301 Form (*e.g.*, the employee's name, address, and date of birth) provides sufficient information to identify injured or ill individuals while protecting the confidentiality of social security numbers.

OSHA has also added several items to the OSHA Form 301 that were not on the former OSHA No. 101:

—The date the employee was hired;
—The time the employee began work;
—The time the event occurred;
—Whether the employee was treated at an emergency room; and
—Whether the employee was hospitalized overnight as an in-patient (the form now requires a check box entry rather than the name and address of the hospital).

OSHA concludes that these data fields will provide safety and health professionals and researchers with important information regarding the occurrence of occupational injuries and illnesses. The questions pertaining to what the employee was doing, how the injury or illness occurred, what the injury or illness was, and what object or substance was involved have been reworded somewhat from those contained on the former OSHA No. 101, but do not require employers or employees to provide additional information.

Proposed Form 301

The proposed OSHA 301 Injury and Illness Incident Record differed in minor respects from the former OSHA 101. For example, a number of fields would have been eliminated to reduce redundancy between the Log and the Incident Report, and several items would have been added to the Incident Report to obtain additional information about occupational injuries and illnesses. OSHA proposed to add to the Form 301 the following:

—The date the employee was hired;
—The time the employee began work;
—The time the event occurred;
—Whether the employee was treated at an emergency room;
—Whether the employee was hospitalized overnight as an in-patient;
—The equipment, materials or chemicals the employee was using when the event occurred; and
—The activity the employee was engaged in when the event occurred.

In addition, the proposed regulation would have required the employer to ask several questions (questions 16 through 18) in the same order and using the same language as used on the OSHA forms, in order to obtain more consistent and accurate data about these data items.

A number of commenters approved of the proposed Form 301 (see, *e.g.*, Exs. 21; 15: 32, 153, 246, 324, 369, 374, 380, 396, 427, 441). For example, the International Brotherhood of Teamsters (Ex. 15: 369) stated that the union ''[s]upports the [proposed] modifications of the OSHA Injury and Illness Incident Record (OSHA Form

301) to collect more useful information.'' Other commenters preferred the former OSHA 101 form and urged OSHA to retain it (see, *e.g.*, Exs. 15: 47, 48, 122, 242). For example, the Boiling Springs Fire District (Ex. 15: 47) opposed any changes to the Log or 101 forms, stating ''[W]e like the forms we are presently using and feel that the information in these forms is adequate. I am a great believer in the old saying 'if it is not broke—why fix it'?''

Many of the commenters who specifically addressed the proposed 301 form were concerned about the privacy implications of providing employees, former employees, and employee representatives with access to the OSHA 301 forms. These concerns are addressed in detail in the section of this summary and explanation associated with section 1904.35, Employee involvement. Many other commenters were concerned with the use of equivalent forms (discussed above) and with the requirement to ask certain questions in the same order and using the same language (also discussed above). The remaining comments relating to the proposed forms are grouped into three categories: comments about the proposed case detail questions (proposed questions 9, 10, 16, 17 and18) and the data they would collect; the other fields OSHA proposed to add to the form 101/301; and comments urging the Agency to place additional data fields on the 301 form.

Rewording of the Proposed Case Detail Questions (questions 9, 10, 16, 17, and 18)

OSHA proposed to include five questions on the final OSHA 301 form to gather information about the details of each work-related injury or illness case:

—Proposed question 9 asked for information about the specific injury or illness (*e.g.*, second degree burn or toxic hepatitis);
—Proposed question 10 asked for information on the body part or parts affected (*e.g.*, lower right forearm);
—Proposed question 16 asked for information on all equipment, materials or chemicals the employee was using when the event occurred;
—Proposed question 17 asked for information on the specific activity the employee was engaged in when the event occurred;
—Proposed question 18 asked for information on how the injury or illness occurred, including a description of the sequence of events that led up to the incident and the objects or substances that directly injured or made the employee ill.

OSHA received only one comment about the contents of the proposed questions: George R. Cook, Jr., of the Hearing Conservation Services Company, stated:

> Questions 9, 10, and 16 on the OSHA 301 form should be worded so that the combination of the answers to these three questions could be used as the answer to Question F. on the OSHA 300. Therefore, if a form 301 is filled out in computerized form, that information could then be carried over to the form 300 thus eliminating the need for duplicate entry (Ex. 15: 188).

As discussed above, final Form 301 no longer requires the employer to include these questions on any equivalent form in the same format or language as that used by the OSHA 301 form. However, any employer wishing to take the approach suggested by Mr. Cook is free to do so.

Several commenters objected to proposed question 16 and questioned why information on all of the materials, equipment or chemicals the employee was using when the event occurred was needed (see, *e.g.*, Exs. 15: 35, 205, 318, 334, 375, 424). For example, the Chocolate Manufacturers Association and the National Confectioners Association, in a joint comment (Ex. 15: 318, p. 9) , stated:

> [W]e strongly disagree with the approach reflected in Question 16. We believe the additional information sought by Question 16 (and not by Question 18) is irrelevant and would not, in any event, justify a second set of reporting forms for every recordable incident subject to federal or state OSHA jurisdiction. Requiring a listing of ''all'' equipment, materials or chemicals an employee might have been using—without regard to whether they contributed to the injury or illness—would serve no useful purpose.

OSHA agrees with this assessment and has not included this question from the final 301 form.

The final form solicits information only on the object or substance that directly harmed the employee. The final 301 form contains four questions eliciting case detail information (*i.e.,* what was the employee doing just before the incident occurred?, what happened?, what was the injury or illness?, and what object or substance directly harmed the employee?). The language of these questions on the final 301 form has been modified slightly from that used in the proposed questions to be consistent with the language used on the BLS Survey of Occupational Injuries and Illnesses collection form. The BLS performed extensive testing of the language used in these questions while developing its survey form and has subsequently used these questions to collect data for many years. The BLS has found that the order in which these questions are presented and the wording of the questions on the survey form elicit the most complete answers to the relevant questions. OSHA believes that using the time-tested language and ordering of these four questions will have the same benefits for employers using the OSHA Form 301 as they have had for employers responding to the BLS Annual Survey. Matching the BLS wording and order will also result in benefits for those employers selected to participate in the BLS Annual Survey. To complete the BLS survey forms, employers will only need to copy information from the OSHA Injury and Illness Incident Report to the BLS survey form. This should be easier and less confusing than researching and rewording responses to the questions on two separate forms.

The Data Fields OSHA Proposed to Change on the Proposed 301 Form

Proposed field 5, Date hired. OSHA proposed to add this data field to collect additional data about the work experience of the injured or ill worker. Such data can be very useful for employers, employees, and OSHA because it enables researchers to discover, for example, whether newly hired or inexperienced workers experience relatively more injuries and illnesses than more experienced workers. Several commenters questioned the value of the data OSHA proposed to collect in field 5 (see, *e.g.*, Exs. 15: 151, 152, 179, 180, 201, 347, 409). For example, Caterpillar Inc. (Ex. 15: 201) recommended that ''[i]tem 5 of Form 301 be deleted. The date hired is not a significant factor in analyzing injury causation. If any similar data is necessary, it should be the time on the current job, which is a better indicator of relative job skills or work experience.'' Several commenters asked for clarification of the ''date hired'' phrase (see, *e.g.*, Exs. 15: 151, 152, 179, 180). For example, Atlantic Marine, Inc. (Ex. 15: 180) asked ''What date shall be recorded as the ''Date Hired'' if an employee is laid off, is terminated, or resigns and then is rehired? Should the date of initial hire or the date of rehire be recorded?'

OSHA continues to believe that the data gathered by means of the ''date hired'' field will have value for analyzing occupational injury and illness data and has therefore included this data field on the final OSHA 301 form. These data are useful for analyzing the incidence of occupational injury and illness among newly hired

workers and those with longer tenure. OSHA is aware that the data collected are not a perfect measure of job experience because, for example, an employee may have years of experience doing the same type of work for a previous employer, and that prior experience will not be captured by this data field. Another case where this data field may fail to capture perfect data could occur in the case of an employee who has worked for the same employer for many years but was only recently reassigned to new duties. Despite cases such as these, inclusion of this data field on the Form 301 will allow the Agency to collect valid data on length of time on the job for most employment situations.

For the relatively infrequent situation where employees are hired, terminated, and then rehired, the employer can, at his or her discretion, enter the date the employee was originally hired, or the date of rehire.

Proposed field 6, Name of health care provider; proposed field 7, If treatment off site, facility name and address; and proposed field 8, Hospitalized overnight as in-patient? The former OSHA Form 101 included similar data fields: former field 18 collected the ''name and address of physician,'' while former field 19 collected data on ''if hospitalized, name and address of hospital.'' Several commenters discussed these data fields and questioned their usefulness for analytical purposes (see, *e.g.*, Exs. 15: 95, 151, 152, 179, 180, 347, 409). The Pacific Maritime Association (Ex. 15: 95) noted the difficulty of collecting the data requested by proposed data fields 5, 6, 7, and 13 as they pertain to longshoremen:

> Items 5, 6, 7, and 13 on the OSHA Form 301 presents problems for direct employers of longshoremen. Longshoremen are hired on a daily basis, select their own health care provider; may be treated at a facility of their choice, and may not return to the same employer when returning to work.

Several commenters asked OSHA to clarify the data that OSHA was asking for in these data fields (see, *e.g.*, Exs. 15: 51, 152, 179, 180, 347, 409). For example, the Ford Motor Company (Ex. 15: 347) asked:

> [I]tem 6, ''Name of health care provider'' is unclear in terms of the general instructions. Who is considered the primary health care provider? Is it the individual who sees the employee on the initial medical visit, the individual who renders the majority of care for a case, or the individual who renders care if the employee is referred to an off-site provider on the initial visit? We feel that the last choice is the correct response. We also question the benefit of providing this information. The criteria for OSHA recordability focuses on the care provided, and not on the individual providing the care.
>
> Item 7, ''If treated off-site, facility name and address'' requires more specific instructions as to when this field must be completed. Is this to be completed if the employee is referred to an outside provider on the initial visit, or is this to be completed should the individual be referred out later in the course of the injury or illness? We feel that the former is the correct response. We also question the benefit of providing this information.

OSHA has decided to continue to collect information on final Form 301 concerning the treatment provided to the employee (proposed data field 7). OSHA's experience indicates that employers have not generally had difficulty in providing this information, either in the longshoring or any other industry. The data in this field is particularly useful to an OSHA inspector needing additional information about the medical condition of injured or ill employees. (OSHA does not request this medical information without first obtaining a medical access order under the provisions of 29 CFR part 1913, Rules Concerning OSHA Access to Employee Medical Records.) The final OSHA 301 Form therefore includes a data field for information on the off-site treating facility.

The final 301 Form also includes a data field requesting the name of the health care professional seen by the injured or ill employee. The employer may enter the name either of the physician or other health care professional who provided the initial treatment or the off-site treatment. If OSHA needs additional data on this point, the records of the health care professional listed will include both the name of the referring physician or other health care professional as well as the name of the health care professional to whom the employee was referred for specialized treatment.

Several commenters asked OSHA to collect data on whether a hospitalization involved in-patient treatment or was limited to out-patient treatment (see, *e.g.*, Exs. 15: 151, 152, 179, 180). For example, Alabama Shipyard, Inc. recommended ''Instead of asking in [proposed] item 8 if an employee is hospitalized overnight as in-patient, have a check box to record whether the treatment was as an in-patient or outpatient status'' (Ex. 15: 152). OSHA agrees that the additional information suggested by this commenter would be useful, and final OSHA Form 301 asks two hospitalization-related questions: Was employee treated in an emergency room?, and Was employee hospitalized overnight as an in-patient?

Proposed question 13, date of return to work at full capacity: The proposed Injury and Illness Incident Report (Form 301) contained a data field requiring the date the employee returned to work at full capacity if the case involved restricted work activity or days away from work. This field was included to provide information regarding the length of time the employee was partially or fully incapacitated by the injury or illness. However, because the final rule requires employers to record day counts both for cases involving days away from work and cases involving job transfer or restriction (see discussion above), the date at which an employee returned to work at full capacity field is no longer necessary and does not appear on the final form.

Proposed questions 14, Time of event and 15, Time employee began work: No commenter objected to the inclusion of proposed data field 14, Time of event, and only two commenters objected to proposed data field 15, Time employee began work (see, *e.g.*, Exs. 15: 347, 409). Both of these commenters, the Ford Motor Company and the American Automobile Manufacturers Association, stated that:

> ''Time employee began work,'' is of questionable benefit. Many employees perform a variety of jobs during the day or may have their job changed during the day (work added or subtracted). This question is burdensome and offers little benefit for data analysis.

Several commenters discussed the way the proposed form collected the new information on the time of the accident (see, *e.g.*, Exs. 15: 151, 152, 179, 180, 260, 262, 265, 347, 401, 409). Several of these commenters suggested that OSHA do away with the am/pm designation and use a 24-hour clock instead (see, *e.g.*, Exs. 15: 151, 152, 179, 180). The comments of Atlantic Marine (Ex. 15: 152) are representative:

> Change the form from using A.M. or P.M. to using a 24-hour clock. A 24-hour clock is much easier to use in drawing conclusions on the relationship between injuries/illnesses and the time of day that they occurred. OSHA may find that many employers are currently using a 24-hour clock system.

Another group of commenters suggested that OSHA add am/pm boxes the employer could simply check off as an easier way to collect the data (see, *e.g.*, Exs. 15: 260, 262, 265, 401). For example, the Edison Electric Institute (Ex. 15: 401) suggested that ''Questions 14 and 15 should include a box which can be checked for AM and PM to reduce the possibility that this information will be omitted.''

OSHA has included on the final 301 form the two questions asking for data on the time of the event and the time the employee began work so that employers, employees and the government can obtain information on the role fatigue plays in occupational injuries and illness. Both questions (*i.e.,* on time of event and time employee began work) must be included to conduct this analysis. Thus, OSHA has included both fields on the final Form 301. In addition, the form has been designed so that the employer can simply circle the a.m. or p.m. designation. OSHA believes that this approach will provide the simplest, least burdensome method for capturing these data, and that using a 24 hour clock system would be cumbersome or confusing for most employers.

Data fields for the name and phone number of the person completing the form. Both the former and proposed Incident Report forms included fields designed to obtain information on the person who completed the form. The former OSHA 101 form asked for the date of report, the name of the preparer, and that person's official position. The proposed form would have carried forward the name and title of the preparer and the date, and added the person's phone number. OSHA received very little comment on these proposed data fields. The Ford Motor Company (Ex. 15: 347) and the American Automobile Manufacturers Association (Ex. 15: 409) both made the following comment:

> The ''Completed by'' field could be modified to consolidate name and title. This would be consistent with the manner in which most health care professionals routinely sign their name.
>
> The ''Phone number required'' item should refer to the medical department's number or the general number of the establishment, and be included with the establishment's name and address at the top of the form. This would decrease the paperwork burden by allowing the use of a stamp or a pre-typed format as opposed to completing a phone number on each OSHA Form 301.

The final OSHA Form 301 permits the employer to include the name and title in either field, as long as the information is available. As to the phone number, the employer may use whatever number is appropriate that would allow a government representative accessing the data to contact the individual who prepared the form.

Case File number: The former OSHA 101 form did not include a method for linking the OSHA 300 and 301 forms. Any linking had to be accomplished via the employee's name, department, occupation, and the other information from the forms. OSHA proposed to add a field to the OSHA 301 form that would use the same case number as that on the OSHA 300 form, thus making it easier for employers, employees and government representatives to match the data from the two forms. Two commenters objected to the addition of such a case file number (Exs. 15: 217, 334). The American Forest & Paper Association (AF&PA) argued:

> Another issue of concern to AF&PA is the requirement for a unique case or file number on the Form 300 and Form 301 to facilitate cross-referencing between the forms. We believe there is sufficient data (employee name, date of birth, date of injury) on all existing state First Report of Injury forms to readily cross-reference the First Report to the entry on the Form 300. A uniform requirement for employers to create an indexing system would serve no useful purpose. Furthermore, it would be unduly burdensome for many affected companies except in those cases when there is a reason to maintain the confidentiality of the affected employee's name (Ex. 15: 334).

OSHA continues to believe that easy linkage of the Forms 300 and 301 will be beneficial to all users of these data. Thus, the final Form 301 contains a space for the case file number. The file/case number is required on both forms to allow persons reviewing the forms to match an individual OSHA Form 301 with a specific entry on the OSHA Form 300. Access by authorized employee representatives to the information contained on the OSHA Form 301 is limited to the information on the right side of the form (see § 1904.35(b)(2)(v)(B) of the final rule). The case/file number is the data element that makes a link to the OSHA Form 300 possible. OSHA believes that this requirement will add very little burden to the recordkeeping process, because the OSHA Log has always required a unique file or case number. The final Form 301 requirement simply requires the employer to place the same number on the OSHA 301 form.

Suggested Fields

Commenters submitted suggestions for other data fields that they believed should be included on the OSHA Form 301, as follows.

Commenter(s)	Suggested addition to the 301 incident report, and OSHA response
American Industrial Hygiene Association (AIHA) (Ex. 15: 153).	''AIHA suggests a corrective action box on the OSHA 301. This form is often used as an employer's accident report, and this would encourage employers to seek action as appropriate to prevent reoccurrence.''
	OSHA has not included this suggested change because the 301 form is not designed to be an accident investigation form, but is used to gather information on occupational injuries and illnesses. Corrective actions would thus not be an appropriate data field for this form.
(Exs. 15: 179, 180, 151, 152).	''A space is needed for recording an employee identification number. This number is important for maintaining records. Some employers use the employee's social security number, while others have a unique, employer generated identifier for each employee.''
.....	OSHA believes the combination of other data fields (case number, employee name, address and date of birth) provides the user the ability to identify individuals when necessary.
Ogletree, Deakins, Nash, Smoak & Stewart (Ex. 15: 406).	Substituting ''regular job title'' would provide for effective use of Form 301 in conducting safety and health analysis of the workplace.
	The OSHA 300 Log asks for the employee's job title. OSHA does not believe there is a need to ask for the data on both forms.

Commenter(s)	Suggested addition to the 301 incident report, and OSHA response
American Petroleum Institute (Ex. 15: 375).	"[t]he supplemental data should contain all information necessary to make recordkeeping decisions, and to facilitate certification of the logs at year end. For this reason, the following should be added to what OSHA proposes for the supplemental data: company name, establishment name, employee social security number, regular job title, "new injury or illness?", "loss of consciousness?", days away from work, first date absent, est. duration of absence, "date days-away cases returned to work?," "result in restricted activity?", "job transfer?", "termination of employment?" OSHA has not included these data fields on the final form because the Agency believes that doing so would duplicate the information on the OSHA 300 form. There is also no need to use the OSHA 301 form to document all the employer's recordkeeping decisions.
Ford Motor Company and the American Automobile Manufacturers Association (Exs. 15: 347, 409).	"AAMA proposes the OSHA Form 301 include the establishment name and address at the top of the form. This will assist not only the employer, but OSHA as well, to avoid any confusion over records in which one medical department may serve several establishments. Also, it will be helpful in those cases where a company employee, who works predominately at one particular facility, sustains an injury or illness at another company establishment." The establishment name and location are included on the OSHA Form 300. In an effort to identify and eliminate duplication of data, OSHA has not included this data item on the OSHA Form 301.
Building and Construction Trades Department, AFL–CIO (Ex.15: 394).	For every potentially recordable injury or illness, the employer shall record: case number, date case reported and name of employee. —Job title of employee. —Date of injury or illness. —Time of event or exposure. —Time employee began work. —Specific description of injury or illness. —Location where the accident or exposure occurred (*e.g.* loading dock). —Facility or Project (*e.g.* Hackensack factory, or Dreamwood Subdevelopment). —Body part affected. —Equipment, tools, materials, or chemicals being used. —Specific activity when injured or upon onset of illness. —How injury or illness occurred. OSHA notes that the final OSHA 301 form contains many of these data elements. The Agency believes that the remaining fields are unnecessary or duplicative of information already found on the OSHA 300 Log.

Summary

The final forms employers will use to keep the records of those occupational injuries and illnesses required by the final rule to be recorded have been revised to reflect the changes made to the final rule, the record evidence gathered in the course of this rulemaking, and a number of changes designed to simplify recordkeeping for employers. In addition, the forms have been revised to facilitate the use of equivalent forms and employers' ability to computerize their records.

Subpart D. Other OSHA injury and illness recordkeeping requirements

Subpart D of the final rule contains all of the 29 CFR Part 1904 requirements for keeping OSHA injury and illness records that do not actually pertain to entering the injury and illness data on the forms. The nine sections of Subpart D are:

—Section 1904.30, which contains the requirements for dealing with multiple business establishments;

—Section 1904.31, which contains the requirements for determining which employees' occupational injuries and illnesses must be recorded by the employer;

—Section 1904.32, which requires the employer to prepare and post the annual summary;

—Section 1904.33, which requires the employer to retain and update the injury and illness records;

—Section 1904.34, which requires the employer to transfer the records if the business changes owners;

—Section 1904.35, which includes requirements for employee involvement, including employees' rights to access the OSHA injury and illness information;

—Section 1904.36, which prohibits an employer from discriminating against employees for exercising their rights under the Act;

—Section 1904.37, which sets out the state recordkeeping regulations in OSHA approved State-Plan states; and

—Section 1904.38, which explains how an employer may seek a variance from the recordkeeping rule.

Section 1904.30 Multiple Establishments

Section 1904.30 covers the procedures for recording injuries and illnesses occurring in separate establishments operated by the same business. For many businesses, these provisions are irrelevant because the business has only one establishment. However, many businesses have two or more establishments, and thus need to know how to apply the recordkeeping rule to multiple establishments. In particular, this section applies to businesses where separate work sites create confusion as to where injury and illness records should be kept and when separate records must be kept for separate work locations, or establishments. OSHA recognizes that the recordkeeping system must accommodate operations of this type, and has adopted language in the final rule to provide some flexibility for employers in the construction, transportation, communications, electric and gas utility, and sanitary services industries, as well as other employers with geographically dispersed operations. The final rule provides, in part, that operations are not considered separate establishments unless they continue to be in operation for a year or more. This length-of-site-operation provision increases the chances of discovering patterns of occupational injury and illness, eliminates the burden of creating OSHA 300 Logs for transient work sites, and ensures that useful records are generated for more permanent facilities.

OSHA's proposed rule defined an establishment as a single physical location that is in operation for 60 calendar days or longer (61 FR 4059), but did not provide specific provisions covering multiple establishments. In the final rule, the definition of

establishment is included in Subpart G, Definitions.

The basic requirement of § 1904.30(a) of this final rule states that employers are required to keep separate OSHA 300 Logs for each establishment that is expected to be in business for one year or longer. Paragraph 1904.30(b)(1) states that for short-term establishments, i.e., those that will exist for less than a year, employers are required to keep injury and illness records, but are not required to keep separate OSHA 300 Logs. They may keep one OSHA 300 Log covering all short-term establishments, or may include the short-term establishment records in logs that cover individual company divisions or geographic regions. For example, a construction company with multi-state operations might have separate OSHA 300 Logs for each state to show the injuries and illnesses of its employees engaged in short-term projects, as well as a separate OSHA 300 Log for each construction project expected to last for more than one year. If the same company had only one office location and none of its projects lasted for more than one year, the company would only be required to have one OSHA 300 Log.

Paragraph 1904.30(b)(2) allows the employer to keep records for separate establishments at the business' headquarters or another central location, provided that information can be transmitted from the establishment to headquarters or the central location within 7 days of the occurrence of the injury or illness, and provided that the employer is able to produce and send the OSHA records to each establishment when § 1904.35 or § 1904.40 requires such transmission. The sections of the final rule are consistent with the corresponding provisions of the proposed rule.

Paragraph 1904.30(b)(3) states that each employee must be linked, for recordkeeping purposes, with one of the employer's establishments. Any injuries or illnesses sustained by the employee must be recorded on his or her home establishment's OSHA 300 Log, or on a general OSHA 300 Log for short-term establishments. This provision ensures that all employees are included in a company's records. If the establishment is in an industry classification partially exempted under § 1904.2 of the final rule, records are not required. Under paragraph 1904.30(b)(4), if an employee is injured or made ill while visiting or working at another of the employer's establishments, then the injury or illness must be recorded on the 300 Log of the establishment at which the injury or illness occurred.

How Long Must an Establishment Exist to Have a Separate OSHA Log

As previously stated, the final rule provides that an establishment must be one that is expected to exist for a year or longer before a separate OSHA log is required. Employers are permitted to keep separate OSHA logs for shorter term establishments if they wish to do so, but the rule does not require them to do so. This is a change from the proposed rule, which would have required an establishment to be in operation for 60 days to be considered an ''establishment'' for recordkeeping purposes. The proposed 60-day threshold would have changed the definition of ''establishment'' used in OSHA's former recordkeeping rule, because that rule included a one-year-in-operation threshold for defining a fixed establishment required to keep a separate OSHA Log (Ex. 2, p. 21). The effect of the proposed change in the threshold would have been to increase the number of short-duration operations required to maintain separate injury and illnesses records.

The majority of the comments OSHA received on this issue opposed the decrease in the duration of the threshold from one year to 60 calendar days, primarily because commenters felt that requiring temporary facilities to maintain records would be burdensome, costly and would not increase the utility of the records (see, *e.g.*, Exs. 21, 15: 21, 43, 78, 116, 122, 123, 145, 170, 199, 213, 225, 254, 272, 288, 303, 304, 305, 308, 338, 346, 349, 350, 356, 358, 359, 363, 364, 375, 389, 392, 404, 412, 413, 423, 424, 433, 437, 443, 475). For example, the Associated Builders and Contractors, Inc. (ABC):

> [d]isagrees that sites in existence for as little as 60 days need separate injury and illness records. The redefinition of ''establishment'' will cause enormous problems for subcontractors in a variety of construction industries. Even employers with small workforces could be on the site of several projects at any one time, and in the course of the year could have sent crews to hundreds of sites. Though they may be on such sites for only brief periods of time, they will be required under this proposal to create separate logs for each site, increasing greatly their paperwork requirements without increasing the amount of information available to their employees (Ex. 15: 412).

In addition, many of these commenters argued that a 60-day threshold would be especially burdensome because it would capture small work sites where posting of the annual summary or mailing the summary to employees would make little sense because so few cases would be captured on each Log. The majority of these commenters suggested that OSHA retain the former one-year duration threshold in the definition of establishment (see, *e.g.*, Exs. 15: 78, 123, 225, 254, 305, 356, 389, 404).

Other commenters expressed concern that the proposed 60-day threshold would create an unreasonable burden on employers in service industries like telecommunications and other utilities, whose employees typically report to a fixed location, such as a service center or garage, but perform tasks at transient locations that remain in existence for more than 60 days. These commenters felt that classifying such locations as ''establishments'' and creating thousands of new OSHA Logs, would have ''no benefit to anyone'' (Ex. 15: 199) (*see also* Exs. 15: 65, 170, 213, 218, 332, 336, 409, 424).

In contrast, commenters who supported the 60-day threshold worried that injuries and illnesses occurring at transient locations would never be accounted for without such a provision (see, *e.g.*, Exs. 15: 9, 133, 310, 369, 425). Some urged OSHA to adopt an even shorter time-in-operation threshold (see, *e.g.*, Exs. 15: 369, 418, 429). For example, the International Brotherhood of Teamsters (IBT) stated that they ''[w]ould strongly support reducing the requirement to thirty days to cover many low level housing construction sites, and transient operations, similar to mobile amusement parks'' (Ex. 15: 369). The AFL–CIO agreed: ''* * * the 60-day time period is still too long. We believe that to truly capture a majority of these transient work sites, a 30-day time period would be more realistic. A 30-day time period as the trigger would capture construction activities such as trenching, roofing, and painting projects which will continue to be missed if a 60-day time period is used'' (Ex. 15: 418). OSHA agrees that under the proposed provisions there was a potential for injuries and illnesses to be missed at short term establishments and for employees who did not report to fixed establishments. Therefore, §§ 1904.30(b)(1) and (b)(3) have been added to make it clear that records (but not a *separate* log) must be kept for short-term establishments lasting less than one year, and that each employee must be linked to an establishment.

The United Parcel Service (UPS) recommended that OSHA craft its rule to coincide with a company's personnel records system, stating ''[t]he unit for which an employer maintains personnel records is presumptively appropriate and efficient; accordingly, OSHA should not mandate a rule that conflicts with a company's current personnel units policy'' (Ex. 15: 424). OSHA recognizes

that employers would prefer OSHA to allow companies to keep records in any way they choose. However, OSHA believes that allowing each company to decide how and in what format to keep injury and illness records would erode the value of the injury and illness records in describing the safety and health experience of individual workplaces and across different workplaces and industries. OSHA has therefore decided not to adopt this approach in the final rule, but to continue its longstanding requirement requiring records to be kept by establishment.

OSHA has reviewed all of the comments on this issue and has responded by deleting any reference to a time-in-operation threshold in the definition of establishment but specifying a one-year threshold in section 1904.30(a) of the final rule. OSHA finds, based on the record evidence, that the one-year threshold will create useful records for stable establishments without imposing an unnecessary burden on the many establishments that remain in existence for only a few months.

Centralized Recordkeeping

As previously stated, the proposed rule did not include a specific section covering multiple establishments. The proposal did require that records for employees not reporting to any single establishment on a regular basis should be kept at each transient work site, or at an established central location, provided that records could be obtained within 4 hours if requested as proposed.

Most commenters supported provisions that would allow the employer to keep records at a centralized location (see, *e.g.*, Exs. 20, 21, 15: 9, 38, 48, 136, 137, 141, 154, 173, 203, 213, 224, 234, 235, 254, 260, 262, 265, 266, 272, 277, 278, 288, 303, 321, 336, 350, 367, 373, 375, 401, 409). Many, however, disagreed with the requirement that records be produced within 4 hours if requested by an authorized government official. Those comments are discussed in the preamble for § 1904.40, Providing records to government representatives. The only other concern commenters expressed about centralized recordkeeping was that centralized records, like computerized records, would make it more difficult for employees to access the records (see, *e.g.*, Exs. 15:379, 380, 418, 438).

OSHA does not believe that centralization of the records will compromise timely employee or government representative access to the records. To ensure that this is the case, centralization under § 1904.30(b)(2) is allowed only if the employer can produce copies of the forms when access to them is needed by a government representative, an employee or former employee, or an employee representative, as required by §§ 1904.35 and 40.

Recording Injuries and Illnesses Where They Occur

Proposed section 1904.7, Location of records, and section 1904.11, Access to records, covered recordkeeping requirements for employees who report to one establishment but are injured or made ill at other locations of the same company. Specifically, these sections required that records for employees reporting to a particular establishment but becoming ill or injured at another establishment within the same company be kept at the establishment in which they became injured or ill. This was derived from OSHA's longstanding interpretation that employees' cases should be recorded where they occur, if it is at a company establishment (April 24, 1992 letter of interpretation to Valorie A. Ferrara of Public Service Electric and Gas Company). Several commenters objected to the proposed requirement that an employee's injury or illness be recorded on the log of the establishment where the injury occurred, rather than on the log of the establishment they normally report to (see, *e.g.*, Exs.15: 60, 107, 146, 184, 199, 200, 232, 242, 263, 269, 270, 329, 335, 343, 356, 375, 377). The comments of the B.F. Goodrich Company (Ex. 15: 146) are representative:

> [t]he requirement for a company to log a visiting employee's injury or illness on the log of the company establishment that they are visiting rather than on the log of their normal work establishment, is not consistent with the data collection process. As proposed, the rule requires the facility to record the injury or illness and not the hours worked by the visiting employee. These individuals would not normally be counted in the number of employees at the visited site nor in the manhours worked at that site. Recording of cases from visiting employees would improperly skew the incidence rates of both facilities. This approach is particularly inappropriate in the case of an illness, since the case may be a result of accumulated exposures which have nothing to do with the site visited during the onset of the illness. Alternately, an injury or illness could manifest after the visitor leaves the facility.

OSHA disagrees with these commenters about where the injuries and illnesses should be recorded. For the vast majority of cases, the place where the injury or illness occurred is the most useful recording location. The events or exposures that caused the case are most likely to be present at that location, so the data are most useful for analysis of that location's records. If the case is recorded at the employee's home base, the injury or illness data have been disconnected from the place where the case occurred, and where analysis of the data may help reveal a workplace hazard. Therefore, OSHA finds that it is most useful to record the injury or illness at the location where the case occurred. Of course, if the injury or illness occurs at another employer's workplace, or while the employee is in transit, the case would be recorded on the OSHA 300 Log of the employee's home establishment.

For cases of illness, two types of cases must be considered. The first is the case of an illness condition caused by an acute, or short term workplace exposure, such as skin rashes, respiratory ailments, and heat disorders. These illnesses generally manifest themselves quickly and can be linked to the workplace where they occur, which is no different than most injury cases. For illnesses that are caused by long-term exposures or which have long latency periods, the illness will most likely be detected during a visit to a physician or other health care professional, and the employee is most likely to report it to his or her supervisor at the home work location.

Recording these injuries and illnesses could potentially present a problem with incidence rate calculations. In many situations, visiting employees are a minority of the workforce, their hours worked are relatively inconsequential, and rates are thus unaffected to any meaningful extent. However, if an employer relies on visiting labor to perform a larger amount of the work, rates could be affected. In these situations, the hours of these personnel should be added to the establishment's hours of work for rate calculation purposes.

Section 1904.31 Covered employees

Final Rule Requirements and Legal Background

Section 1904.31 requires employers to record the injuries and illnesses of all their employees, whether classified as labor, executive, hourly, salaried, part-time, seasonal, or migrant workers. The section also requires the employer to record the injuries and illnesses of employees they supervise on a day-to-day basis, even if these workers are not carried on the employer's payroll.

Implementing these requirements requires an understanding of the Act's definitions of ''employer'' and

''employee.'' The statute defines ''employer,'' in relevant part, to mean ''a person engaged in a business affecting interstate commerce who has employees.'' 29 U.S.C. 652 (5). The term ''person'' includes ''one or more individuals, partnerships, associations, corporations, business trusts, legal representatives, or any organized group of persons.'' 29 U.S.C. 652 (4). The term ''employee'' means ''an employee of an employer who is employed in a business of his employer which affects interstate commerce.'' 29 U.S.C. 652(6). Thus, any individual or entity having an employment relationship with even one worker is an employer for purposes of this final rule, and must fulfill the recording requirements for each employee.

The application of the coverage principles in this section presents few issues for employees who are carried on the employer's payroll, because the employment relationship is usually well established in these cases. However, issues sometimes arise when an individual or entity enters into a temporary relationship with a worker. The first question is whether the worker is an employee of the hiring party. If an employment relationship exists, even if temporary in duration, the employee's injuries and illnesses must be recorded on the OSHA 300 Log and 301 form. The second question, arising in connection with employees provided by a temporary help service or leasing agency, is which employer—the host firm or the temporary help service—is responsible for recordkeeping.

Whether an employment relationship exists under the Act is determined in accordance with established common law principles of agency. At common law, a self-employed ''independent contractor'' is not an employee; therefore, injuries and illnesses sustained by independent contractors are not recordable under the final Recordkeeping rule. To determine whether a hired party is an employee or an independent contractor under the common law test, the hiring party must consider a number of factors, including the degree of control the hiring party asserts over the manner in which the work is done, and the degree of skill and independent judgment the hired party is expected to apply. *Loomis Cabinet Co.* v. *OSHRC,* 20 F.3d 938, 942 (9th Cir. 1994).

Other individuals, besides independent contractors, who are not considered to be employees under the OSH Act are unpaid volunteers, sole proprietors, partners, family members of farm employers, and domestic workers in a residential setting. See 29 CFR § 1975.4(b)(2) and § 1975.6 for a discussion of the latter two categories of workers. As is the case with independent contractors, no employment relationship exists between these individuals and the hiring party, and consequently, no recording obligation arises.

A related coverage question sometimes arises when an employer obtains labor from a temporary help service, employee leasing firm or other personnel supply service. Frequently the temporary workers are on the payroll of the temporary help service or leasing firm, but are under the day-to-day supervision of the host party. In these cases, Section 1904.31 places the recordkeeping obligation upon the host, or utilizing, employer. The final rule's allocation of recordkeeping responsibility to the host employer in these circumstances is consistent with the Act for several reasons.

First, the host employer's exercise of day-to-day supervision of the temporary workers and its control over the work environment demonstrates a high degree of control over the temporary workers consistent with the presence of an employment relationship at common law. See *Loomis Cabinet Co.,* 20 F.3d at 942. Thus, the temporary workers will ordinarily be the employees of the party exercising day-to-day control over them, and the supervising party will be their employer.

Even if daily supervision is not sufficient alone to establish that the host party is the employer of the temporary workers, there are other reasons for the final rule's allocation of recordkeeping responsibility. Under the OSH Act, an employer's duties and responsibilities are not limited only to his own employees. Cf. *Universal Constr. Co.* v. *OSHRC,* 182 F.3d 726, 728–731 (10th Cir. 1999). Assuming that the host is *an* employer under the Act (because it has an employment relationship with someone) it reasonably should record the injuries of all employees, whether or not its own, that it supervises on a daily basis. This follows because the supervising employer is in the best position to obtain the necessary injury and illness information due to its control over the worksite and its familiarity with the work tasks and the work environment. As discussed further below, the final rule is sensible and will likely result in more accurate and timely recordkeeping.

The Proposed Rule

The final rule's coverage rules are consistent with the basic principles embodied in the former rule and in the proposal. The proposed rule would have continued to require employers to record the injuries and illnesses of employees over whose work they exert ''day-to-day supervision'' (61 FR 4058/3). OSHA proposed to codify this longstanding interpretation by adding a definition of ''employee'' together with a note explaining its application to Part 1904 recordkeeping. The proposed definition restated the definition of employee in the OSH Act. It then explained that, for recordkeeping purposes, an employer should consider as its employees any persons who are supervised on a day-to-day basis at the establishment. The proposal noted that this was the test regardless of whether the persons were labeled as ''independent contractors,'' ''migrant workers,'' or workers provided by a temporary help service.

The proposal further explained that day-to-day supervision occurs ''when, in addition to specifying the output, product or result to be accomplished by the person's work, the employer supervises the details, means, methods and processes by which the work is to be accomplished'' (61 FR 4059/1). OSHA also noted that other classes of workers would not be covered because they were not considered employees, either as defined in the OSH Act or as set forth in regulatory interpretations. These included sole proprietors, partners, family members of farm employers, and domestic workers in a residential setting.

Response To the Proposal

A number of commenters agreed with OSHA's approach to differentiate between employees and true independent contractors, and to require employers to keep records for employees they supervise on a day-to-day basis (see, *e.g.*, Exs. 15: 61, 65, 205, 305, 322, 333, 346, 348, 351, 369, 390, 429). The National Association of Manufacturers (NAM) stated:

> [f]or purposes of recordkeeping, OSHA has consistently taken the position that the term ''employee'' includes all personnel who are supervised on a day-to-day basis by the employer using their services (not only with respect to the result to be achieved, but also the means, methods and processes by which the work is to be accomplished). While this is a fact-intensive determination that must be made on a case-by-case basis, we commend the Agency for attempting to clarify the matter by making that approach an explicit part of the rule, presumably for purposes of both recordkeeping and records access (Ex. 15: 305).

The National Association of Temporary Staffing Services (NATSS)) supported:

[c]ontinuation of ''utilizing employer'' rule for maintaining records for temporary employees. Temporary help and staffing service firms recruit individuals with a broad range of training, education and skills, and then assign them to work at customer locations on a variety of assignments and projects. The fundamental nature of the service relationship is such that while staffing service firms are the general employers of their workers and assume a broad range of employer responsibilities, those responsibilities generally do not include direct supervision of the employees at the worksite. Hence, staffing firms have a limited ability to affect conditions at the worksite.

In recognition of the above, OSHA's long-standing policy has been to require the worksite employer, not the staffing firm, to maintain illness and injury records of temporary workers supervised by the worksite employer. The proposed rules continue this policy. In a special ''note'' in section 1904.3, ''employee'' for record keeping purposes is defined to include temporary workers ''when they are supervised on a day-to-day basis by the employer utilizing their services.'' Under this definition, the worksite employer, not the staffing firm, would be required to maintain records for temporary employees supplied by a staffing firm, provided they are supervised by the worksite employer. As stated in the background section of the proposed rule, ''this is consistent with case law and the interpretation currently used by OSHA'' (61 F.R. 4034). NATSS strongly supports this proposed definition. (Ex. 15: 333)

A number of commenters opposed OSHA's proposed approach on this issue (see, *e.g.*, Exs. 15: 9, 23, 26, 64, 67, 82, 92, 119, 154, 159, 161, 184, 185, 198, 203, 204, 225, 259, 287, 297, 299, 312, 335, 336, 338, 341, 356, 363, 364, 370, 404, 423, 424, 427, 431, 437, 443). Several of these commenters thought that including temporary employees from temporary services, independent contractors and other leased personnel within the definition of employee would impose new burdens on employers (see, *e.g.*, Exs. 15: 35, 67, 356, 423, 437). However, the proposal did not alter the long-standing meanings of the terms employee, employer or employment relationship. The day-to-day supervision test for identifying the employer who is responsible for compliance with Part 1904 is a continuation of OSHA's former policy, and is consistent with the common law test. The comments indicate that many employers are not aware that they need to keep records for leased workers, temporary workers, and workers who are inaccurately labeled ''independent contractors'' but are in fact employees. However, these workers are employees under both the former rule and the final rule. Incorporating these requirements into the regulatory text can only help to improve the consistency of the data by clarifying the employer's responsibilities.

Several commenters erroneously believed that they might need to keep records for all employees of independent contractors performing work in their establishment (see, *e.g.*, Exs. 15: 161, 203, 312). The Battery Council International remarked:

[i]t is unclear how this clarification would apply to employers in the battery industry who hire independent contractors to perform construction and other activities on their manufacturing facilities. Often times, battery manufacturers will provide the contractors with an orientation to the facility (which includes the facility's safety and health rules and location of MSDSs) [material safety data sheets], and monitor the work of the contractor to ensure that work contracted for has been completed, but do not otherwise supervise the details, means, methods and processes by which the work is to be accomplished. In these relationships, the contractors certify to the battery manufacturers that they comply with all OSHA requirements including training, which must be completed as part of the work contract.

If the intent of the proposed clarification is to not require the reporting of injuries and illnesses to independent contractors under similar conditions as described above, then BCI supports this concept and requests further clarification on this issue. BCI will oppose, however, any attempt by OSHA to require the reporting of injuries or illnesses that occur to ''independent contractors'' where the employer has not otherwise supervised the details, means, methods and processes by which the work was accomplished (Ex. 15: 161).

The International Dairy Foods Association (IDFA) was concerned that if a dairy processing facility hired an electrical contractor to install new lighting and the electrical contractor's employee were injured while installing the lighting, the dairy might have to record the incident in its Part 1904 records (Ex. 15: 203).

The 1904 rule does not require an employer to record injuries and illnesses that occur to workers supervised by independent contractors. However, the label assigned to a worker is immaterial if it does not reflect the economic realities of the relationship. For example, an employment contract that labels a hired worker as an independent contractor will have no legal significance for Part 1904 purposes if in fact the hiring employer exercises day-to-day supervision over that worker, including directing the worker as to the manner in which the details of the work are to be performed. If the contractor actually provides day-to-day supervision for the employee, then the contractor is responsible for compliance with Part 1904 as to that employee. In the IDFA example, unless the dairy exercised supervisory control over the time and manner of the electrician's work, the dairy would not be considered the electrician's employer and would not be required to record the incident.

Some commenters argued that the injury and illness statistics would be more accurate or useful if the payroll employer recorded the injuries and illnesses, regardless of which employer controlled the work or the hazard (see, *e.g.*, Exs. 15: 9, 26, 92, 161, 198, 259, 287, 297, 299, 333, 341, 356, 364, 443). The Sandoz Corporation stated that ''[t]he control and responsibility for reporting these injuries should be with the employer, i.e. the establishment that pays the employee. This simplifies the control and reporting. It also allows a company that utilizes temporary or contract services to look at the OSHA record of the supplier as part of the purchasing decision and thus put pressure on the supplier for better safety performance, thus using market forces to improve safety'' (Ex. 15: 299). The Battery Council International added ''[r]equiring employers to record the injuries and illnesses of independent contractors under such circumstances is unfair and will result in the over recording of injuries and illnesses by the battery industry. This will result in more OSHA inspections on the lead battery industry, which will in turn impose additional costs and burdens on BCI members'' (Ex. 15: 161). The Fertilizer Institute stated ''[a]dopting compensation as the basis for determining the employer/employee relationship results in simplification that is not afforded when one must look at day-to-day supervision'' (Ex. 15: 154).

A few commenters recommended that the employer responsible for workers' compensation insurance also be required to record the injuries and illnesses (Ex. 15: 204, 225, 336, 364). The American Gas Association (Ex. 15: 225) stated that OSHA should:

[s]trive to parallel Workers' Compensation law. The employer may have supervision of some types of temporary workers, *e.g.*, daily office workers. However, the employer may have no control over a crew of construction contractors. In this case, the employer does not supervise the details, means, methods and processes by which the work accomplished. The definition of employee, along with the note to the definition proposed by OSHA requires a subjective determination to be made. 61 Fed. Reg. at 4058. We recommend OSHA follow a more objective test. The responsibility of reporting injuries and illnesses should turn on the fact of who provides the Workers' Compensation insurance, not necessarily daily supervision. This would then be an objective, rather than

subjective test, less likely open to interpretation and mistakes.

OSHA has rejected the suggestions that either the payroll or workers' compensation employer keep the OSHA 1904 records. The Agency believes that in the majority of circumstances the payroll employer will also be the workers' compensation employer and there is no difference in the two suggestions. Temporary help services typically provide the workers' compensation insurance coverage for the employees they provide to other employers. Therefore, our reasons for rejecting these suggestions are the same. OSHA agrees that there are good arguments for both scenarios: 1. Including injuries and illnesses in the records of the leasing employer (the payroll or workers' compensation employer and 2. For including these cases in the records of the controlling employer. Requiring the payroll or workers' compensation employer to keep the OSHA records would certainly be a simple and objective method. There would be no doubt about who keeps the records. However, including the cases in the records of the temporary help agency erodes the value of the injury and illness records for statistical purposes, for administering safety and health programs at individual worksites, and for government inspectors conducting safety and health inspections or consultations. The benefits of simplification and clarity do not outweigh the potential damage to the informational value of the records, for the reasons discussed below.

First, the employer who controls the workers and the work environment is in the best position to learn about all the injuries and illnesses that occur to those workers. Second, when the data are collected for enforcement and research use and for priority setting, the injury and illness data are clearly linked to the industrial setting that gave rise to them. Most important, transferring the recording/reporting function from the supervising employer to the leasing firm would undermine rather than facilitate one of the most important goals of Part 1904—to assure that work-related injury and illness information gets to the employer who can use it to abate work-related hazards. If OSHA were to shift the recordkeeping responsibility from the controlling employer to the leasing firm, the records would not be readily available to the employer who can make best use of them. OSHA would need to require the leasing firm to provide the controlling employer with copies of the injury and illness logs and other reports to meet this purpose. This would be both burdensome and duplicative.

Requiring the controlling (host) employer to record injuries and illnesses for employees that they control has several advantages. First, it assigns the injuries and illnesses to the individual workplace with the greatest amount of control over the working conditions that led to the worker's injury or illness. Although both the host employer and the payroll employer have safety and health responsibilities, the host employer generally has more control over the safety and health conditions where the employee is working. To the extent that the records connect the occupational injuries and illnesses to the working conditions in a given workplace, the host employer must include these cases to provide a full and accurate safety and health record for that workplace.

If this policy were not in place, industry-wide statistics would be skewed. Two workplaces with identical numbers of injuries and illnesses would report different statistics if one relied on temporary help services to provide workers, while the other did not. Under OSHA's policy, when records are collected to generate national injury and illness statistics, the cases are properly assigned to the industry where they occurred. Assigning these injuries and illnesses to temporary help services would not accurately reflect the type of workplace that produced the injuries and illnesses. It would also be more difficult to compare industries. To illustrate this point, consider a hypothetical industry that relies on temporary help services to provide 10% of its labor force. Assuming that the temporary workers experience workplace injury and illness at the same rate as traditional employees, the Nation's statistics would underrepresent that industry's injury and illness numbers by 10%. If another industry only used temporary help services for 1% of the labor force, its statistics would be closer to the real number, but comparisons to the 10% industry would be highly suspect.

The policy also makes it easier to use an industry's data to measure differences that occur in that industry over time. Over the last 20 years, the business community has relied increasingly on workers from temporary help services, employee leasing companies, and other temporary employees. If an industry sector as a whole changed its practices to include either more or fewer temporary workers over time, comparisons of the statistics over several years might show trends in injury and illness experience that simply reflected changing business practices rather than real changes in safety and health conditions.

Some commenters objected to this aspect of the proposal because they thought it would require both the personnel leasing firm and the host employer to record injuries and illnesses. Double recording would lead to inaccurate statistics when both employers reported their data to BLS (see, *e.g.*, Exs. 15: 9, 26, 92, 198, 259, 287, 297, 333, 341, 356, 364, 443). The National Association of Temporary Staffing Services Stated:

> [i]f the exemption is not retained in the case of SIC 7363 [Help Supply Services] employers, it would be especially important for the final rules to expressly provide * * * that there is no intent to impose a dual reporting requirement. At least one state OSH office already has construed the proposed lifting of the partial exemption as creating an obligation on the part of staffing firms to maintain records for all of its employees, including temporary employees supervised by the worksite employer. This is clearly inconsistent with the intent of the proposed rule and should be clarified (Ex. 15: 333).

The Society of the Plastics Industry added:

> [b]ecause statistics are required to be collected for several years, it would take a significant effort to contact several independent companies on a continual basis to obtain such information. This would only result in a serious duplication of records, as both the host employer and the temporary leasing employer record the case. This will increase the recordkeeping burden for both the employer and those independent companies hired for a specific job by that employer (Ex. 15: 364).

OSHA agrees with these commenters that there is a potential for double counting of injuries and illnesses for workers provided by a personnel supply service. We do not intend to require both employers to record each injury or illness. To solve this problem, the rule, at § 1904.31(b)(4), specifically states that both employers are not required to record the case, and that the employers may coordinate their efforts so that each case is recorded only once—by the employer who provides day-to-day supervision. When the employers involved choose to work with each other, or when both employers understand the Part 1904 regulations as to who is required to record the cases and who is not, there will not be duplicative recording and reporting. This policy will not completely eliminate double recording of these injuries and illnesses, but it provides a mechanism for minimizing the error in the BLS statistics.

OSHA believes that many employers already share information about these

injuries and illnesses to help each other with their own respective safety and health responsibilities. For example, personnel service employers need information to process workers' compensation claims and to determine how well their safety and health efforts are working, especially those involving training and the use of personal protective equipment. The host employer needs information on conditions in the workplace that may have caused the injuries or illnesses.

Many commenters objected to the requirement that the employer who controls the work environment record injuries and illnesses of temporary workers because that employer does not have adequate information to record the cases accurately (see, *e.g.*, Exs. 15: 9, 23, 184, 341, 363, 364, 370). These commenters contended that temporary workers supplied by personnel agencies may not have been at any given assignment long enough for the controlling employer to count days away from work accurately or to make informed judgments about the recordability of ongoing or recurring cases. The comments also contended that the controlling employer may have difficulty judging whether an injury or illness is related to that employer's work environment, to other places of employment, or is totally non-work related. These drawbacks in turn affect the recording employer's ability to certify to the completeness and accuracy of the annual summary of the Log. U.S. West, Inc. (Ex. 15: 184) remarked:

> [e]mployers should not be responsible for recordkeeping involving independent contractors, workers from temporary agencies, etc. A major reason for this would be the difficulties presented when trying to track such individuals for injuries/illnesses that have long periods of days away from work. In addition, it is often difficult to assign work relatedness for cases to a specific employer—an example would be upper extremity repetitive motion disorders for an individual from a temporary agency that works for several different employers in the course of a week or month. To avoid such problems, recordkeeping should be the responsibility of the individual's actual employer.

OSHA agrees with these commenters that recording work-related injuries and illnesses for temporary, leased employees will sometimes present these difficulties. However, the solution is not, as some commenters urge, to require the personnel leasing agency to assume responsibility for Part 1904 recording and reporting. The personnel leasing firm will not necessarily have better information than the host employer about the worker's exposures or accidents in previous assignments, previously recorded injuries or illnesses, or the aftermath of an injury or illness. And the personnel leasing firm will certainly have less knowledge of and control over the work environment that may have caused, contributed to, or significantly aggravated an injury or illness. As described above, the two employers have shared responsibilities and may share information when there is a need to do so.

If Part 1904 records are inaccurate due to lack of reasonably reliable data about leased employees, there are ways for OSHA to address the problem. First, the OSH Act does not impose absolutely strict liability on employers. The controlling employer must make reasonable efforts to acquire necessary information in order to satisfy Part 1904, but may be able to show that it is not feasible to comply with an OSHA recordkeeping requirement. If entries for temporary workers are deficient in some way, the employer can always defend against citation by showing that it made the efforts that a reasonable employer would have made under the particular circumstances to obtain more complete or accurate data.

A few commenters suggested that OSHA should link the recording requirement to the duration of time that the contract or temporary employee works at a specific location (see, *e.g.*, Exs. 15: 185, 259, 341, 364). The National Wholesale Druggists Association (NWDA) believed that:

> [t]here should be a length-of-employment delineation to determine whether a temporary or contract employee illness or injury should be included in the OSHA log. OSHA should set a length of time that the contract or temporary employee must work in a location before requirements for OSHA log reporting are triggered. By setting a length of employment standard, OSHA will not only eliminate the possibility of duplicative reporting of injuries and illnesses but will also eliminate the reporting of those short-term temporary employee assignments that may be covered by the temporary agency (Ex. 15: 185).

The Society of the Plastics Industry (SPI) recommended that the controlling firm should only keep records for permanently leased workers, stating ''[f]or temporary employees, the employer who pays an employee (with the presumption that this is for whom they work) should be required to keep the records. For permanently assigned, leased employees, SPI agrees that such cases should be recorded by the leasing employer'' (Ex. 15: 364). The Iowa Health Care Association asked whether a temporary nurse's aide who works in a facility for seven days to cover a vacationing permanent employee would be considered to be under the day-to-day supervision of the host facility (Ex. 15: 259).

OSHA has decided not to base recording obligations on the temporary employee's length of employment. Recording the injuries and illnesses of some temporary employees and not others would not improve the value or accuracy of the statistics, and would make the system even more inconsistent and complex. In OSHA's view, the duration of the relationship is much less important than the element of control. In the example of the temporary nurse's aide, for OSHA recordkeeping purposes the worker would be considered an employee of the facility for the days he or she works under the day-to-day supervision of the host facility.

Several commenters questioned whether or not temporary workers would be included in the total number of employees of that employer (see, *e.g.*, Exs. 15: 67, 356, 375, 437). The number of employees is used in two separate areas of the recordkeeping system. The number of employees is used to determine the exemption for smaller employers, and is entered on the annual summary of occupational injuries and illnesses. The Small Business Administration expressed concern over whether counting these workers as employees would affect the exemption for smaller employers, stating ''[t]he definition of ''employee'' goes beyond the statutory intent * * * Small businesses would not only have new obligations for coverage, but this methodology for counting employees would impact the opportunity for an exemption under this standard'' (Exs. 15: 67, 437). The American Petroleum Institute (API) was concerned about how the employee count affects the way that the host employer completes the annual summary, particularly the entries for hours worked by all employees and the average number of employees:

> [u]sing the OSHA-specified approach for determining the number of employees and hours worked, particularly for temporary employees and/or smaller establishments, is not often feasible. Assumption (1) [that the employer already has this data] is not true for temporary employees. Their hours worked are maintained by their contract employers. Host employers have dollar costs paid to each contractor employer. Therefore, getting employee counts and hours worked for temporaries requires making assumptions and estimating (Ex. 15: 375).

Because OSHA is using the common law concepts to determine which workers are to be included in the records, a worker who is covered in

terms of recording an injury or illness is also covered for counting purposes and for the annual summary. If a given worker is an employee under the common law test, he or she is an employee for all OSHA recordkeeping purposes. Therefore, an employer must consider all of its employees when determining its eligibility for the small employer exemption, and must provide reasonable estimates for hours worked and average employment on the annual summary. OSHA has included instructions on the back of the annual summary to help with these calculations.

The Texas Chemical Council argued that supervising employers should not have to record injuries or illnesses of agency-supplied workers unless the supervising employer has authority to hold these workers accountable for safety performance (Ex. 15: 159). According to this commenter, most temporary agencies limit the contracting employer to following the agencies' policies for corrective action for unacceptable performance. OSHA would simply point out that this is a matter within the contract arrangements between the two employers, and that OSHA intervention in this area is not necessary or appropriate. In any event, we believe that this should not determine who records occupational injuries and illnesses.

The Phibro-Tech company asked ''[i]f the facility is now responsible for tracking these injuries on their Form 300, will this affect the Worker's Compensation liability?'' (Ex. 15: 35). Tracking injuries and illnesses for OSHA purposes does not affect an employer's workers' compensation liability. An employer's liability for workers' compensation is a separate matter that is covered by state law. Employers who maintain workers' compensation coverage will be responsible for injuries and illnesses regardless of which employer records them for OSHA purposes.

Bell Atlantic Network Services asked ''[a]re contract employee OSHA recordable injury/illness incidents to be recorded on the same OSHA 300 log as employer's full-time employees? Are they to be identified as ''Contract/ Temporary'' employees on the OSHA 300 Log, i.e., under the column E—Job Title?'' (Ex. 15: 218). OSHA's view is that a given establishment should have one OSHA Log and only one Log. Injuries and illnesses for all the employees at the establishment are entered into that record to create a single summary at the end of the year. OSHA does not require temporary workers or any other types of workers to be identified with special titles in the job title column, but also does not prohibit the practice. This column is used to list the occupation of the injured or ill worker, such as laborer, machine operator, or nursing aide. However, OSHA does encourage employers to analyze their injury and illness data to improve safety and health at the establishment. In some cases, identifying temporary or contract workers may help an employer to manage safety and health more effectively. Thus an employer may supplement the OSHA Log to identify temporary or contract workers, although the rule does not require it.

OSHA received two suggestions that would provide an OSHA inspector with injury and illness data for temporary workers without putting their injuries on the host employer's OSHA 300 Log. The National Grain and Feed Association, Grain Elevator and Processing Society, and National Oilseed Processors Association jointly recommended:

> [e]mployers with employees who work under contract at a site other than the employer's should be required to provide a copy of the appropriate first report of injury or OSHA 301 to the site controlling employer. The site controlling employer can then maintain a file of Form 301's to facilitate OSHA's evaluation of workplace hazards (Ex. 15: 119).

The Douglas Battery Manufacturing (Ex. 15: 82) company suggested the following alternative:

> [a]n option that would allow an employer of temporary workers to determine the incident rate of the temporaries, would be to require the temporary agency/ contractor to forward a copy of its OSHA log for workers at a particular facility, to that facility by February of the next calendar year. The names and other personal identifiers of the temporary/contract workers could be removed prior to submittal but the data would be available on site for agency inspection purposes.

OSHA believes that neither of these alternatives would be an acceptable substitute for completing the 300 Log and 301 form for injured workers. The information would not be entered into the annual summary, so the establishment's statistics would not be complete. While these options would create a method (although a cumbersome method) for providing the information to a government inspector, the data would not be collected for statistical purposes.

Some commenters asked OSHA about how they should deal with a variety of other types of workers. The American Ambulance Association suggested that OSHA ''[s]pecifically exclude from the definition of employee, students who are unpaid by the company/institution which is providing a clinical or practice setting'' (Ex. 15: 226). The Maine Department of Labor (Ex. 15: 41) asked the following question:

> [q]uestions about how to report people such as Interns, Aspire (welfare) program participants, prison release workers and volunteers are now being asked. A clear definition needs to be established to account for all kinds of employees. Our Public Sector law requires us to count all people who are permitted to work. Maybe you don't want that inclusive a definition, but it is something to consider. We had to come up with a specific definition of volunteers to exclude sporadic volunteers (essentially those not working at a specific place at a specific time on a regular basis). With some workplaces utilizing volunteers and with welfare reform changes expected, you may want to prepare for these questions now.

These workers should be evaluated just as any other worker. If a student or intern is working as an unpaid volunteer, he or she would not be an employee under the OSH Act and an injury or illness of that employee would not be entered into the Part 1904 records. If the worker is receiving compensation for services, and meets the common law test discussed earlier, then there is an employer-employee relationship for the purposes of OSHA recordkeeping. The employer in that relationship must evaluate any injury or illness at the establishment and enter it into the records if it meets the recording criteria.

Section 1904.32 Annual Summary

At the end of each calendar year, section 1904.32 of the final rule requires each covered employer to review his or her OSHA 300 Log for completeness and accuracy and to prepare an Annual Summary of the OSHA 300 Log using the form OSHA 300–A, Summary of Work-Related Injuries and Illnesses, or an equivalent form. The summary must be certified for accuracy and completeness and be posted in the workplace by February 1 of the year following the year covered by the summary. The summary must remain posted until April 30 of the year in which it was posted.

Preparing the Annual Summary requires four steps: reviewing the OSHA 300 Log, computing and entering the summary information on the Form 300–A, certification, and posting. First, the employer must review the Log as extensively as necessary to make sure it is accurate and complete. Second, the employer must total the columns on the Log; transfer them to the summary form; and enter the calendar year covered, the name of the employer, the name and

address of the establishment, the average number of employees on the establishment's payroll for the calendar year, and the total hours worked by the covered employees. If there were no recordable cases at the establishment for the year covered, the summary must nevertheless be completed by entering zeros in the total for each column of the OSHA 300 Log. If a form other than the OSHA 300–A is used, as permitted by paragraph 1904.29(b)(4), the alternate form must contain the same information as the OSHA 300–A form and include identical statements concerning employee access to the Log and Summary and employer penalties for falsifying the document as are found on the OSHA 300–A form.

Third, the employer must certify to the accuracy and completeness of the Log and Summary, using a two-step process. The person or persons who supervise the preparation and maintenance of the Log and Summary (usually the person who keeps the OSHA records) must sign the certification statement on the form, based on their direct knowledge of the data on which it was based. Then, to ensure greater awareness and accountability of the recordkeeping process, a company executive, who may be an owner, a corporate officer, the highest ranking official working at the establishment, or that person's immediate supervisor, must also sign the form to certify to its accuracy and completeness. Certification of the summary attests that the individual making the certification has a reasonable belief, derived from his or her knowledge of the process by which the information in the Log was reported and recorded, that the Log and summary are ''true'' and ''complete.''

Fourth, the Summary must be posted no later than February 1 of the year following the year covered in the Summary and remain posted until April 30 of that year in a conspicuous place where notices are customarily posted. The employer must ensure that the Summary is not defaced or altered during the 3 month posting period.

Changes from the former rule. Although the final rule's requirements for preparing the Annual Summary are generally similar to those of the former rule, the final rule incorporates four important changes that OSHA believes will strengthen the recordkeeping process by ensuring greater completeness and accuracy of the Log and Summary, providing employers and employees with better information to understand and evaluate the injury and illness data on the Annual Summary, and facilitating greater employer and employee awareness of the recordkeeping process.

1. Company Executive Certification of the Annual Summary. The final rule carries forward the proposed rule's requirement for certification by a higher ranking company official, with minor revision. OSHA concludes that the company executive certification process will ensure greater completeness and accuracy of the Summary by raising accountability for OSHA recordkeeping to a higher managerial level than existed under the former rule. OSHA believes that senior management accountability is essential if the Log and Annual Summary are to be accurate and complete. The integrity of the OSHA recordkeeping system, which is relied on by the BLS for national injury and illness statistics, by OSHA and employers to understand hazards in the workplaces, by employees to assist in the identification and control of the hazards identified, and by safety and health professionals everywhere to analyze trends, identify emerging hazards, and develop solutions, is essential to these objectives. Because OSHA cannot oversee the preparation of the Log and Summary at each establishment and cannot audit more than a small sample of all covered employers' records, this goal is accomplished by requiring employers or company executives to certify the accuracy and completeness of the Log and Summary.

The company executive certification requirement imposes different obligations depending on the structure of the company. If the company is a sole proprietorship or partnership, the certification may be made by the owner. If the company is a corporation, the certification may be made by a corporate officer. For any management structure, the certification may be made by the highest ranking company official working at the establishment covered by the Log (for example, the plant manager or site supervisor), or the latter official's supervisor (for example, a corporate or regional director who works at a different establishment, such as company headquarters).

The company executive certification is intended to ensure that a high ranking company official with responsibility for the recordkeeping activity and the authority to ensure that the recordkeeping function is performed appropriately has examined the records and has a reasonable belief, based on his or her knowledge of that process, that the records are accurate and complete.

The final rule does not specify how employers are to evaluate their recordkeeping systems to ensure their accuracy and completeness or what steps an employer must follow to certify the accuracy and completeness of the Log and Summary with confidence. However, to be able to certify that one has a reasonable belief that the records are complete and accurate would suggest, at a minimum, that the certifier is familiar with OSHA's recordkeeping requirements, and the company's recordkeeping practices and policies, has read the Log and Summary, and has obtained assurance from the staff responsible for maintaining the records (if the certifier does not personally keep the records) that all of OSHA's requirements have been met and all practices and policies followed. In most if not all cases, the certifier will be familiar with the details of some of the injuries and illnesses that have occurred at the establishment and will therefore be able to spot check the OSHA 300 Log to see if those cases have been entered correctly. In many cases, especially in small to medium establishments, the certifier will be aware of all of the injuries and illnesses that have been reported at the establishment and will thus be able to inspect the forms to make sure all of the cases that should have been entered have in fact been recorded.

The certification required by the final rule may be made by signing and dating the certification section of the OSHA 300–A form, which replaces the summary portion of the former OSHA 200 form, or by signing and dating a separate certification statement and appending it to the OSHA Form 300–A. A separate certification statement must contain the identical penalty warnings and employee access information as found on the OSHA Form 300–A. A separate statement may be needed when the certifier works at another location and the certification is mailed or faxed to the location where the Summary is posted.

The certification requirement modifies the certification provision of the former rule (former paragraph 1904.5(c)), which required a certification of the Annual Summary by the employer or an officer or employee who supervised the preparation of the Log and Summary. The former rule required that individual to sign and date the year-end summary on the OSHA Form 200 and to certify that the summary was true and complete. Alternatively, the recordkeeper could, under the former rule, sign a separate certification statement rather than signing the OSHA form.

Both the former rule (paragraph 1904.9 (a) and (b)) and the proposed rule (paragraph 1904.16(a) and (b))

contained penalty provisions for the falsification of OSHA records or for the failure to record recordable cases; these provisions do not appear in the final rule. OSHA believes, based on the record and the Agency's own recordkeeping and audit experience, that this deletion will not affect the accuracy or completeness of the records, employers' recording obligations, or OSHA's enforcement powers. The criminal penalties referred to in paragraph 1904.9(a) of the former rule are authorized by section 17(g) of the OSH Act and do not need to be repeated in the final rule to be enforced. Similarly, the administrative citations and penalties referred to in paragraph 1904.9(b) of the former rule are authorized by sections 9 and 17 of the OSH Act. The warning statement on the final OSHA 300–A form or its equivalent should be sufficient to remind those who certify the forms of their legal obligations under the Act.

OSHA has revised the final rule's certification requirement in response to questions about its usefulness raised in the preamble to the proposal (61 FR 4047). In particular, the proposal noted that the person responsible for preparing the Log and Summary might, in some cases, have an incentive not to report injuries and illnesses, which would, of course, impair the accuracy of the Log. OSHA stated that ''some employers mistakenly believe that recording a case implies fault on the part of the employer'' and thus has the potential to adversely affect their ability to defend workers' compensation claims or lawsuits. Some employers also have established ''accountability systems'' that are based on the number of OSHA recordables, *i.e.,* that evaluate the safety performance of managers by the number of injuries and illnesses reported by workers in the departments or organizational units under their control. OSHA noted that individuals whose performance, promotions, compensation, and/or bonuses depend on the achievement of reduced injury and illness rates ''may be discouraged from fully and accurately recording injuries and illnesses (61 FR 4047) * * *'' Managers and supervisors being evaluated by the numbers'' also may have an incentive to avoid recording as many cases as possible.

OSHA proposed to change the former rule's certification requirements. In the proposed rule, OSHA proposed to require that a responsible company official certify to the accuracy and completeness of the Log and Summary. According to the proposal, that person would sign the summary to certify that ''he or she has examined the OSHA Injury and Illness Log and Summary and that the entries on the form and the year-end summary are true, accurate, and complete'' (61 FR 4060). ''Responsible company official'' was defined in the proposal as ''an owner of the company, the highest ranking company official working at the establishment, or the immediate supervisor of the highest ranking company official working at the establishment'' (61 FR 4059). By requiring a high level individual to sign each establishment Log certification, the proposal sought to create an incentive for that official to take steps to ensure the accuracy and completeness of the information on the log or face penalties for failing to do so.

Several commenters (see, *e.g.*, Exs. 15: 50, 105, 415) confirmed that an underreporting incentive did exist under the former rule's certification system. For example, the International Chemical Workers' Union (Ex. 15: 415) and Mr. George Cook (Ex. 15: 50) noted the potential for this problem to arise in their comments to the record. Harsco Corporation (Ex. 15: 105) pointed out that a contractor's accident rate will affect its ability to bid for jobs, and there is thus an incentive to keep rates low by not recording all injuries and illnesses.

There were many responses to the proposed change in the certification requirement. In general, a broad cross-section of commenters (see, *e.g.*, Exs. 15: 70, 127, 136, 137, 141, 153, 163, 170, 224, 266, 278, 324, 371, 407, 418, 429) gave unqualified support to the proposal's certification by a ''responsible corporate official.'' Typical of these comments was the New Jersey Department of Labor's statement that the proposed change would result in heightened awareness of health and safety problems by management, enhanced efforts to reduce workplace injuries and illnesses, and more accurate reporting (Ex. 15: 70). The AFL–CIO noted that requiring top corporate officials to be responsible ''represents a fundamental change in the importance of data gathering in the workplace'' (Ex. 15: 418).

A number of commenters expressed reservations about the definition of ''responsible corporate official'' and the extent of the responsibility and/or legal liability such certification might impose on certifying officials. Some commenters argued that it was unreasonable for a high corporate official, who might not be familiar with the recordkeeping function and its legal requirements, to certify to the accuracy and completeness of the Log and Summary. These commenters argued that it would be more appropriate for a high level management official, industrial hygienist, or director of health and safety to certify the Log and Summary because these individuals are already responsible for ensuring the accuracy and completeness of the Log, especially in multi-establishment businesses where recordkeeping is centralized (see, *e.g.*, Exs. 21; 25; 27; 33; 15: 44, 48, 65, 122, 132, 133, 147, 154, 161, 169, 174, 176, 193, 194, 199, 203, 231, 242, 263, 269, 270, 272, 273, 283, 284, 289, 290, 292, 295, 297, 299, 301, 304, 305, 317, 325, 329, 332, 341, 345, 346, 348, 364, 368, 377, 385, 386, 387, 403, 405, 410, 412, 413, 420, 425, 442). Two commenters suggested that, if a high level official were to be responsible for the certification, he or she should only be required to certify that the ''[c]ompany has * * * taken reasonable steps to ensure the accuracy of the logs'' (Exs. 15: 200, 442). Several representatives from the construction industry (see, *e.g.*, Exs. 15: 126, 342, 355) urged OSHA to make sure that any certification provision reflect the operation of multi-employer construction sites. These commenters recommended that the certifying official either be the senior official on-site or that person's immediate superior.

Other employer representatives believed that the broad nature of the proposed certification could make the certification vulnerable to legal liability (see, *e.g.*, Exs. 20; 33; 15: 122, 133, 147, 149, 176, 193, 199, 201, 205, 220, 231, 236, 272, 273, 284, 290, 292, 297, 301, 304, 313, 318, 320, 335, 345, 346, 352, 353, 368, 373, 375, 389, 396, 424, 425, 427, 428, 430). The National Association of Manufacturers (Ex. 15: 305), in a statement that is representative of the views of these commenters, said that:

> [t]he language of the certification is totally impractical and unreasonable in that it is written as a certification of absolute completeness and accuracy. This creates such an unreasonably high standard that no one should legitimately be asked or required to sign it. As a general rule, we believe an individual would be expected to have significantly better knowledge of the information on his/her personal income tax return than on the OSHA Form 300; yet even the certification on the personal income tax return includes the language ''to the best of my knowledge and belief.'' This clause must be added to the certifying language.

Numerous commenters favored a dual level of accountability, with a first level certification by the ''responsible company official,'' as defined in the proposal, and a second level certification required by a high level corporate official with safety and health responsibilities (see, *e.g.*, Exs. 20, 15: 65, 89, 182, 369, 380, 409, 415). These

participants recommended that OSHA require a more senior official, at a corporate level beyond the establishment keeping the records, additionally certify that the company had made a good faith effort to ensure accurate and complete records for all of the employer's establishments. The American Automobile Manufacturers Association (AAMA) stated that it:

> [a]grees that a corporate official responsible for health and safety and the highest ranking company official at an establishment should certify that a good faith effort for proper recordkeeping has taken place, and the individual responsible for day-to-day OSHA recordkeeping should certify the accuracy and completeness of the log (Ex. 15–409).

OSHA has not adopted a dual certification requirement because one certification should be enough to make sure that the records are accurate. In addition, a dual certification requirement would increase the complexity and burdens of the final rule, without significantly adding incentives for employers to keep better records.

Some commenters wished OSHA to maintain the former rule's approach to certification. These participants were generally skeptical of senior management certification, characterizing it as impractical, onerous, burdensome, unrealistic, intrusive, and infringing on the prerogative of management to designate the appropriate person(s) to certify the Log (see, *e.g.*, Exs. 15: 9, 15, 39, 45, 60, 89, 96, 132, 149, 156, 183, 184, 185, 195, 200, 201, 203, 204, 213, 218, 225, 239, 259, 260, 262, 265, 271, 272, 303, 304, 313, 317, 318, 320, 332, 335, 338, 344, 352, 353, 360, 373, 378, 389, 390, 392, 401, 406, 414, 423, 424, 427, 428, 430, 431). According to the Battery Council International, ''[t]he threat of civil and criminal liability provides more than enough incentive to ensure the accuracy of the recordkeeping Log and Summary'' (Ex. 15: 161). Mallinckrodt Chemical, Inc., and the Interconnecting and Packaging Electronic Circuits Corporation echoed this belief (Exs. 15: 69, 172). The Vulcan Chemical Company went so far as to recommend that OSHA delete certification requirements completely and rely only on the proposed penalty provisions (Ex. 15: 171).

Most commenters opposing high-level management certification argued that management-designated, well-qualified, lower level administrative personnel perform the recordkeeping function and can therefore best certify to the accuracy of the OSHA 300 Log (see, *e.g.*, Exs. 15: 69, 220, 225, 227, 281, 297, 305, 313, 352, 353). According to the American Textile Manufacturers Institute (Ex. 15: 156), ''[a] corporate official (*i.e.,* safety director, human resources director, Chief Executive Officer) should never be required to certify the accuracy of the logs. Commenters also stated that placing the responsibility on senior management would increase the economic and paperwork burden of the rule because these individuals would need additional training and would conduct audits, particularly at businesses with many work locations (see, *e.g.*, Exs. 15 : 213, 259, 375, 395). A few commenters stated that none of OSHA's proposed approaches, including the Log and Summary certification, would significantly decrease the financial incentives employers have for underreporting (see, *e.g.*, Exs. 15: 39, 199, 406). The Ogletree, Deakins, Nash, Smoak & Stewart Coalition (ODNSSC) said that ''[i]n the final analysis, the one measure that will have the greatest effect in fostering the maintenance of accurate logs is finally within the grasp of all interested parties: the promulgation of a final rule * * * that is well conceived, makes intuitive and analytical sense, and as such is largely accepted within the regulated community'' (Ex. 15: 406).

Although OSHA believes that the final rule has many features that will enhance the accuracy and completeness of reporting, the Agency has included a company executive level of certification in the final rule. OSHA believes that company executive certification will raise employer awareness of the importance of the OSHA records, improve their accuracy and completeness (and thus utility), and decrease any underreporting incentive.

The final rule therefore requires a higher level company official to certify to their accuracy and completeness. Thus the final rule reflects OSHA's agreement with those commenters who stated that the Log and Summary must be actively overseen by higher level management and that certification by such an official would make management's responsibility for the accuracy and completeness of the system clear (see, *e.g.*, Exs. 20; 15: 31, 65, 70, 89, 127, 136, 137, 141, 153, 163, 170, 182, 224, 266, 278, 324, 369, 371, 380, 396, 407, 409, 415, 418, 429). As the Union Carbide Company stated, having a higher authority sign a qualified certification of the summary ''[w]ould encourage activities, such as training and periodic reviews/audits of the logs, to improve the accuracy and completeness of the data'' (Ex. 15: 396). In the words of one safety consultant, ''[u]ntil there is a Corporate Commitment the information will be suspect'' (Ex. 15: 31).

OSHA has slightly modified the proposed definition of responsible company official in the text of the final rule. In the final rule, the person who must perform the certification must be a company executive. OSHA does not believe that an industrial hygienist or a safety officer is likely to have sufficient authority to ensure the integrity of a company's recordkeeping process. Therefore, the final rule requires that the certification be provided by an owner of a sole proprietorship or partnership, an officer of the corporation, the highest-ranking official at the establishment, or that person's supervisor. OSHA believes that this definition takes into account and addresses the concerns of the comments received from construction employers (see, *e.g.*, Exs. 15: 105, 126.342, 355).

OSHA is also aware that senior management officials cannot be expected to have hands-on experience in the details of the logs and summaries and therefore that their certification attests to the overall integrity of the recordkeeping process. In response to numerous comments that certification by the responsible company official be qualified by the addition to the certification of a clause such as ''to the best of my knowledge and belief'' (see, *e.g.*, Exs. 20, 15: 122, 193, 199, 205, 220, 272, 273, 290, 305, 320, 335, 375, 396, 424, 425, 427, 428, 430), OSHA has added that the certification required by the final rule must be based on the official's ''reasonable belief'' that the Log and Summary are accurate and complete. Certification thus means that the certifying official has a general understanding of the OSHA recordkeeping requirements, is familiar with the company's recordkeeping process, and knows that the company has effective recordkeeping procedures and uses those procedures to produce accurate and complete records. The precise meaning of ''reasonable belief'' will be determined on a case-by-case basis because circumstances vary from establishment to establishment and decisions about the recordability of individual cases may differ, depending upon case-specific details.

2. Number of employees and hours worked. Injury and illness records provide a valuable tool for OSHA, employers, and employees to determine where and why injuries and illnesses occur, and they are crucial in the development of prevention strategies. The final rule requires employers to include in the Annual Summary (the OSHA Form 300–A) the annual average number of employees covered by the

Log and the total hours worked by all covered employees. In the proposal (61 FR 4037), OSHA stated that this information would facilitate hazard analysis and incidence rate calculations for each covered establishment. A number of commenters supported the proposed approach and felt that it would not be a burden on employers, as long as OSHA granted some flexibility to employers who did not have sophisticated recordkeeping systems (see, *e.g.*, Exs. 15: 48, 61, 70, 78, 153, 163, 181, 262, 310, 350, 369, 429). For example, the Safety Services Administration of the City of Mesa, Arizona, a small employer, stated:

> [f]or most employers, the average number of employees is readily available; the work hour totals may, or may not be so easily obtained, depending upon the book keeping methodology. For salaried employees, where detailed hourly records are not maintained, the 2,000 hr/yr would be used in any case. In our case, both employee numbers and total hours worked is available and presents no problem (Ex. 15: 48).

Other commenters stated that the total number of hours worked was readily available through payroll records and that calculating it would present only a minimal burden, but were opposed to the required inclusion of the annual average number of employees because this number is highly variable, difficult to assess where employment is seasonal and subject to high turnover, and not important to incidence calculations (see, *e.g.*, Exs. 15: 123, 145, 170, 225, 359, 375).

Other commenters opposed including in the summary the average number of employees and the total number of hours worked because they believed the costs of compiling this information would outweigh its benefits, which they believed to be minimal (see, *e.g.*, Exs. 15: 9, 44, 184, 195, 205, 214, 247, 272, 303, 308, 313, 335, 341, 352, 353, 412, 423, 431), especially in industries, like health care, with high turnover rates (Ex. 15: 341). One company estimated its cost of collecting data on total hours worked to be $200,000 to $300,000 and to take four to six months (Ex. 15: 423). Sprint Corporation proposed that ''[i]ncidence rates continue to be calculated on an exception basis by the compliance officer at the time of the inspection. Larger employers, like Sprint, maintain such incidence rates by department or business unit and not by physical location as broken out on the OSHA log'' (Ex. 15: 133).

Some commenters recommended alternatives, including permitting employers to estimate the total number of hours worked, possibly by using the ANSI Z16.4 standard of 173.33 hours per month per employee, to minimize the burden (see, *e.g.*, Exs. 15: 272, 303, 335, 359) or excluding establishments with fewer than 100 employees from the requirement altogether (Ex. 15: 375).

OSHA's view is that the value of the total hours worked and average number of employees information requires its inclusion in the Summary, and the final rule reflects this determination. Having this information will enable employers and employees to calculate injury and illness incidence rates, which are widely regarded as the best statistical measure for the purpose of comparing an establishment's injury and illness experience with national statistics, the records of other establishment, or trends over several years. Having the data available on the Form 300–A will also make it easier for the employer to respond to government requests for the data, which occurs when the BLS and OSHA collect the data by mail, and when an OSHA or State inspector visits the facility. In particular, it will be easier for the employer to provide the OSHA inspector with the hours worked and employment data for past years.

OSHA does not believe that this requirement creates the time and cost burden some commenters to the record suggested, because the information is readily available in payroll or other records required to be kept for other purposes, such as income tax, unemployment, and workers' compensation insurance records. For the approximately 10% of covered employers who participate in the BLS's Annual Survey of Occupational Injuries and Illnesses, there will be no additional burden because this information must already be provided to the BLS. Moreover, the rule does not require employers to use any particular method of calculating the totals, thus providing employers who do not maintain certain records—for example the total hours worked by salaried employees—or employers without sophisticated computer systems, the flexibility to obtain the information in any reasonable manner that meets the objectives of the rule. Employers who do not have the ability to generate precise numbers can use various estimation methods. For example, employers typically must estimate hours worked for workers who are paid on a commission or salary basis. Additionally, the instructions for the OSHA 300–A Summary form include a worksheet to help the employer calculate the total numbers of hours worked and the average number of.

3. Extended posting period. The final rule's requirement increasing the summary Form 300–A posting period from one month to three months is intended to raise employee awareness of the recordkeeping process (especially that of new employees hired during the posting period) by providing greater access to the previous year's summary without having to request it from management. The additional two months of posting will triple the time employees have to observe the data without imposing additional burdens on the employer. The importance of employee awareness of and participation in the recordkeeping process is discussed in the preamble to sections 1904.35 and 1904.36.

The requirement to post the Summary on February 1 is unchanged from the posting date required by the former rule. As OSHA stated in the proposal (61 FR 4037) ''one month (January) is a reasonable time period for completing the summary section of the form.'' Only three commenters disagreed (see, *e.g.*, Exs. 15: 347, 402, 409); two of these commenters suggested that 60 days were required to do so (Exs. 15: 347, 409). OSHA believes that, since the required process is simple and straightforward, 30 days will be sufficient. Delaying the posting any further would mean that employers would not have access to the Summary for a longer period, thus diminishing the timeliness of the posted information.

OSHA's proposal would have required employers to post the summary for one year, based on the Agency's preliminary conclusion that continuous posting presented no additional burden for employers and would be beneficial to employees (61 FR 4037–4038). The one-year posting period was unconditionally supported by a number of commenters (see, *e.g.*, Exs. 15: 70, 153, 154, 199, 277) and was supported by others on the condition that no updating of the posted summary be required (see, *e.g.*, Exs. 15: 262, 288, 435). The AAMA and the Ford Motor Co. supported a ten-month posting period (from March 1 to December 31) (Exs. 15: 347, 409).

A number of commenters stated that a one-year posting period was too long and would not be justified by the minimal benefits to be achieved by such year-long posting. Some of these participants contended that the Annual Summary does not continue to provide useful, accurate information after its initial posting and will not enhance employee awareness because, although posting of a new summary is noticed when it is done, it becomes ''wallpaper'' shortly thereafter, especially if it is on a cluttered bulletin board (see, *e.g.*, Exs. 33; 15: 9, 23, 39, 40, 45, 60, 66, 98, 107, 119, 121, 122, 176, 203, 204, 231, 232,

273, 281, 289, 301, 317, 322, 329, 335, 341, 344, 347, 348, 356, 358, 381, 389, 399, 405, 409, 414, 428, 430, 431, 434, 441). For example, the Witco Corporation predicted that the 12-month posting requirement ''[w]ill result in no one noticing the old Log's removal and the posting of a new one'' (Ex. 15: 107). One commenter even suggested that continuous posting ''[u]ndermines the Agency's intent in bringing the information to employees'' attention'' (Ex. 15: 428).

Other commenters argued that year-long posting was excessive because it created too great a burden on employers. They stated that extended posting would require employers to make periodic inspections to ensure that the summary had not been taken down, covered, or defaced (see, *e.g.*, Exs. 37, 15: 57, 80, 97, 151, 152, 179, 180, 272, 303, 335, 346, 381, 410, 431), and that this additional administrative burden, especially to employers with large establishments that now voluntarily post Logs in multiple locations, could be significant (see, *e.g.*, Exs. 15: 97, 184, 239, 272, 283, 297, 303, 304, 305, 348, 395, 396, 410, 424, 430). One suggestion made by commenters to minimize this burden was to post the Summary for one month at the establishment and then at a central location for the remaining eleven months (see, *e.g.*, Exs. 15: 151, 152, 179, 180) or to permit electronic posting (Ex. 15: 184). Other employers opposed the extended posting period on the grounds that a one-month period posting was sufficient to achieve OSHA's objectives (see, *e.g.*, Exs. 15: 9, 15, 39, 45, 49, 57, 69, 74, 80, 89, 97, 98, 116, 119, 133, 163, 182, 184, 195, 203, 287, 289, 335, 356, 396, 424, 427, 428, 441, 443), especially since employees have access to the summary at any time during the retention period (see, *e.g.*, Exs. 15: 9, 15, 69, 80, 98, 119, 136, 137, 141, 161, 200, 204, 224, 225, 266, 272, 278, 303, 312, 317, 324, 348, 374, 395, 405, 406, 410, 412, 431). Still other commenters thought the one-year period was too long but supported a two or even three-month posting period as adding little, if any, additional burden (see, *e.g.*, Exs. 37, 15: 78, 89, 199, 235, 256, 277).

After a review of all the comments received and its own extensive experience with the recordkeeping system and its implementation in a variety of workplaces, OSHA has decided to adopt a 3-month posting period. The additional posting period will provide employees with additional opportunity to review the summary information, raise employee awareness of the records and their right to access them, and generally improve employee participation in the recordkeeping system without creating a ''wallpaper'' posting of untimely data. In addition, OSHA has concluded that any additional burden on employers will be minimal at best and, in most cases, insignificant. All the final rule requires the employer to do is to leave the posting on the bulletin board instead of removing it at the end of the one-month period. In fact, many employers preferred to leave the posting on the bulletin board for longer than the required one-month period in the past, simply to provide workers with the opportunity to view the Annual Summary and increase their awareness of the recordkeeping system in general and the previous year's injury and illness data in particular. OSHA agrees that the 3-month posting period required by the final rule will have these benefits which, in the Agency's view, greatly outweigh any minimal burden that may be associated with such posting. The final rule thus requires that the Summary be posted from February 1 until April 30, a period of three months; OSHA believes that the 30 days in January will be ample, as it has been in the past, for preparing the current year's Summary preparatory to posting.

4. Review of the records. The provisions of the final rule requiring the employer to review the Log entries before totaling them for the Annual Summary are intended as an additional quality control measure that will improve the accuracy of the information in the Annual Summary, which is posted to provide information to employees and is also used as a data source by OSHA and the BLS. Depending on the size of the establishment and the number of injuries and illnesses on the OSHA 300 Log, the employer may wish to cross-check with any other relevant records to make sure that all the recordable injuries and illnesses have been included on the Summary. These records may include workers' compensation injury reports, medical records, company accident reports, and/or time and attendance records.

OSHA did not propose that any auditing or review provisions be included in the final rule. However, several commenters suggested that OSHA include requirements that would require employers to audit the OSHA 300 Log information (see, *e.g.*, Exs. 35; 36; 15: 31, 310, 418, 438). For example, the United Auto Workers (Ex. 15: 438) stated:

> [t]he most important change OSHA could make in recordkeeping rules would be to require employers to conduct an independent audit of the completeness of the record. The purpose of the audit would be to determine that no case went unrecorded, and that no disabling injury or illness was mislabeled as non lost workday. Such requirements were not in the proposal, but are desperately needed.

Linda Ballas (Ex. 15: 31), a safety consultant who performs audits of OSHA injury and illness records for employers, added [u]ntil there is Corporate Commitment the information will be suspect. * * * Audits are necessary.'' In fact, the Laborers' Health & Safety Fund of North America (Ex. 15: 310) recommended biennial third-party audits.

In the final rule, OSHA has not adopted regulatory language that requires formal audits of the OSHA Part 1904 records. However, the final rule does require employers to review the OSHA records as extensively as necessary to ensure their accuracy. The Agency believes that including audit provisions is not necessary because the high-level certification requirement will ensure that recordkeeping receives the appropriate level of management attention.

Some companies, especially larger ones, may choose to conduct audits, however, to ensure that the records are accurate and complete; many companies commented that they already perform records audits as part of their company's safety and health program. For example, the Ford Motor Company (Ex. 15: 347), Dow Chemical Company (Ex. 15: 335), and Brown & Root (Ex. 15: 423) reported that they audit their injury and illness records on a regular basis. Also, three commenters to the record were safety and health consultants who provide injury and illness auditing services to employers, in addition to other safety and health services (Exs. 15: 31, 345, 406). In the past, OSHA has entered into a number of corporate-wide settlement agreements with individual companies that included third-party audits of the employers' injury and illness records (*e.g.*, Ford, General Motors, Union Carbide). OSHA expects that many of these companies will continue to audit their injury and illness records and their recordkeeping procedures, and to take any other quality control measures they believe to be necessary to ensure the quality of the records. However, OSHA has not required records audits in the final rule because the Agency believes that the combination of final rule requirements providing for employee participation (§ 1904.35), protecting employees against discrimination for reporting work-related injuries and illnesses to their employer (section

1904.36), requiring review by employers of the records at the end of the year, and mandating two level certification of the records will provide the quality control mechanisms needed to improve the quality of the OSHA records.

Deletions from the former rule. Except for the foregoing changes discussed above, the final rule is generally similar to the former rule in its requirements for preparing, certifying and posting of the year-end Summary. However, some provisions of the former rule related to the Summary have not been included in the final rule. For example, the former rule required employers with employees who did not report to or work at a single establishment, or who did not report to a fixed establishment on a regular basis, to hand-deliver or mail a copy of the Summary to those employees. OSHA proposed to maintain this requirement, which was supported by one commenter (Ex. 15: 298) but opposed by many others because of the administrative cost of preparing such mailings, especially in high turnover industries like construction (see, *e.g.*, Exs. 15: 116, 132, 199, 200, 201, 312, 322, 329, 335, 342, 344, 355, 375, 395, 430, 440, 441). These commenters pointed out that employees who do not report to a single establishment still have the right to view the summary at a central location and to obtain copies of it.

In the final rule, OSHA has decided not to include the proposed requirement for individual mailings as unnecessary because final paragraph 1904.30(b)(3) requires that every employee be linked, for recordkeeping purposes, to at least one establishment keeping a Log and Summary that will be prepared and posted. In other words, every employee covered by the rule will have his or her injuries or illnesses recorded on a particular establishment's Log, even if that employee does not routinely report to that establishment or is temporarily working there. Thus every employee will have 3-month access to the Log and Summary at the posted location or may obtain a copy the next business day under paragraph 1904.35(b)(2)(iii), making the need for hand-delivery or mailing unnecessary.

Under the former rule, multi-establishment employers who closed an establishment during the year were not obligated to post an Annual Summary for that establishment. OSHA believes that this requirement is also unnecessary because it is obvious in such cases that there is no physical location at which to post the Summary. Closing an establishment does not, however, relieve an employer of the obligation to prepare and certify the Summary for whatever portion of the calendar year the establishment was operating, retain the Summary, and make the Summary accessible to employees and government officials.

Other comments. Some commenters availed themselves of the opportunity to comment on portions of the recordkeeping rule that OSHA did not propose to change. Some of these comments addressed the issue of whether to post a year-end Summary at all. Posting the Summary was almost unanimously supported, but a few commenters opposed posting on the grounds that posting had ''[a] de minimus effect on employee safety and accident prevention'' (Ex. 15: 46), was not an accurate measure of current safety and health conditions (see, *e.g.*, Exs. 15: 95, 126), or was unnecessary and burdensome for their industry (*e.g,* the maritime industry (Ex. 15: 95), construction industry (Ex. 15: 126), and retail store industry (Ex. 15: 367)). Although opposed to the posting of a year-end summary, one company urged OSHA to require that year-end summaries be submitted to OSHA (Ex. 15: 63).

Alternatives to posting were suggested by some commenters. One advocated annual informational meetings with employees instead (Ex. 15: 126), while others supported mailing the summary to each employee and providing the summary to new employees at orientation (Ex. 15: 154) or by e-mail (Ex. 15: 156). Three employers recommended excluding small establishments (fewer than 20, 50 or 100 employees) from posting if all column totals on the Log were zero (see, *e.g.*, Exs. 15: 304, 358, 375).

OSHA believes, based on the record evidence and its own extensive recordkeeping experience, that posting the Summary is important to safety and health for all the reasons described above. Some of the suggested alternatives may be useful, and OSHA encourages employers to use any practices that they believe will enhance their own and employee awareness of safety and health issues, provided that they also comply fully with the final rule's posting requirements.

Another issue raised by commenters was whether multi-establishment employers should be required to post their summaries in each establishment, as required by the former rule. Employers generally supported posting at each establishment, although one commenter opposed posting at each establishment in multi-establishment companies as overly burdensome and without benefit (Ex. 15: 356). One construction employer argued that construction companies should be allowed to post their summaries at a centralized location and only be required to do so at the establishment if it was a major construction site in operation for at least one year (Ex. 15: 116).

OSHA believes that permitting centralized posting only would substantially interfere with ready employee access to the Log, especially for employers operating many different sites. The record does not suggest that retaining the requirement for posting summaries at each establishment will be burdensome to employers and the final rule accordingly requires that multi-establishment employers post a Summary in each establishment relating that establishment's injury and illness experience for the preceding year.

Section 1904.33 Retention and Updating

Section 1904.33 of the final rule deals with the retention and updating of the OSHA Part 1904 records after they have been created and summarized. The final rule requires the employer to save the OSHA 300 Log, the Annual Summary, and the OSHA 301 Incident Report forms for five years following the end of the calendar year covered by the records. The final rule also requires the employer to update the entries on the OSHA 300 Log to include newly discovered cases and show changes that have occurred to previously recorded cases. The provisions in section 1904.33 state that the employer is not required to update the 300A Annual Summary or the 301 Incident Reports, although the employer is permitted to update these forms if he or she wishes to do so.

As this section makes clear, the final rule requires employers to retain their OSHA 300 and 301 records for five years following the end of the year to which the records apply. Additionally, employers must update their OSHA 300 Logs under two circumstances. First, if the employer discovers a recordable injury or illness that has not previously been recorded, the case must be entered on the forms. Second, if a previously recorded injury or illness turns out, based on later information, not to have been recorded properly, the employer must modify the previous entry. For example, if the description or outcome of a case changes (a case requiring medical treatment becomes worse and the employee must take days off work to recuperate), the employer must remove or line out the original entry and enter the new information. The employer also has a duty to enter the date of an employee's return to work or the date of an injured worker's death on the Form 301; OSHA considers the

entering of this information an integral part of the recordkeeping for such cases. The Annual Summary and the Form 301 need not be updated, unless the employer wishes to do so. The requirements in this section 1904.33 do not affect or supersede any longer retention periods specified in other OSHA standards and regulations, *e.g.*, in OSHA health standards such as Cadmium, Benzene, or Lead (29 CFR 1910.1027, 1910.1028, and 1910.1025, respectively).

The proposed rule (61 FR 4030, at 4061) would have reduced the retention and updating periods for these records to three years. The language of the proposal was as follows:

(a) Retention. OSHA Forms 300 and 301 or equivalents, year-end summaries, and injury and illness records for ''subcontractor employees'' as required under Sec. 1904.17 of this Part shall be retained for 3 years following the end of the year to which they relate.

(b) Updating. During the retention period, employers must revise the OSHA Form 300 or equivalent to include newly discovered recordable injuries or illnesses. Employers must revise the OSHA Form 300 to reflect changes which occur in previously recorded injuries and illnesses. If the description or outcome of a case changes, remove the original entry and enter the new information to reflect the more severe consequence. Employers must revise the year-end summary at least quarterly if such changes have occurred.

Note to Sec. 1904.9: Employers are not required to update OSHA Form 301 to reflect changes in previously recorded cases.

A number of commenters supported the proposed reduction in the retention period from five years to three years on the ground that it would reduce administrative burdens and costs without having any demonstrable effect on safety and health (see, *e.g.*, Exs. 22, 33, 37, 15: 9, 39, 61, 69, 82, 89, 95, 107, 121, 133, 136, 137, 141, 154, 173, 179, 181, 184, 201, 204, 213, 224, 225, 239, 242, 263, 266, 269, 270, 272, 278, 283, 288, 304, 307, 321, 322, 332, 334, 341, 347, 348, 368, 375, 377, 384, 387, 390, 392, 395, 396, 397, 409, 413, 424, 425, 427, 443). According to the American Iron and Steel Institute (AISI), whose views were typical of those of this group of commenters, a three-year retention period:

[s]hould reduce employers' administrative costs without sacrificing any accuracy in the records of serious illnesses and injuries. Additional cost savings could be accomplished by limiting the time period during which an employer must update its injury and illness records to one year. Such a change would allow employers to close the books sooner on the health and safety data for a particular year, without resulting in any loss of accuracy. In AISI's experience, it is extremely rare that any new information on an illness or injury surfaces more than a few months after an injury is recorded, while the administrative cost of having to update a log and summary is significant for the rare cases that yield information after one year (Ex. 15: 395).

Several commenters, however, opposed the three-year retention period and favored the former rule's five-year retention period (see, *e.g.*, Exs. 20, 24, 15: 153, 350, 359, 379, 407, 415, 429). For example, the American Industrial Hygiene Association (AIHA) opposed the shorter retention period, stating:

[A]IHA opposes OSHA's proposed change of OSHA recordkeeping record retention from 5 to 3 years. There is little work in record retention, and much information lost if they are discarded. We recommend maintaining the 5 year retention for OSHA Logs and supporting 301 forms (Ex. 15: 153.)

According to NIOSH, which favored the longer retention period, retaining records for five years:

[a]llows the aggregation of data over time that is important for evaluating distributions of illnesses and injuries in small establishments with few employees in each department/job title. Also, the longer retention period is important for the observation of trends over time in the recognition of new problems and the evaluation of the effectiveness of intervention in large companies. In addition, the longer retention period makes possible the assessment of trends over time or to determine if a current cluster of cases is unusual for that industry. Reducing the retention period would thus have a detrimental effect on these types of analysis, which are frequently used by NIOSH in field studies (Ex. 15: 407).

The American Industrial Hygiene Association recommended a longer retention period (up to 30 years) for the OSHA 301 form to accommodate occupational diseases with long latency periods (Ex. 15: 153).

In this final rule, OSHA has decided to retain the five-year retention requirement for OSHA injury and illness records because the longer time period will enable employers, employees, and researchers to obtain sufficient data to discover patterns and trends of illnesses and injuries and, in many cases, to demonstrate the statistical significance of such data.

In addition, OSHA has concluded that the five-year retention period will add little additional cost or administrative burden, since relatively few cases will surface more than three years after the injury and illness occurred, and the vast majority of cases are resolved in a short time and do not require updating. In addition, OSHA believes that other provisions of the final rule (*e.g.*, computerization of records, centralized recordkeeping, and the capping of day counts) will significantly reduce the recordkeeping costs and administrative burden associated with the tracking of long-term cases.

The comments on the proposed rule's updating requirements for individual entries on the OSHA Form 300 reflected a considerable amount of confusion about the proposed rule's requirements for updating. Because the proposed rule did not state how frequently the form was to be updated, some employers interpreted the proposed rule as permitting quarterly updates (proposed by OSHA for year-end summaries only) during the retention period (see, *e.g.*, Exs. 15: 9, 61, 89, 170, 181, 288, 389). Some participants argued for even less frequent updating (see, *e.g.*, Exs. 15: 151, 152, 179, 180, 317, 348). Several employers recognized that the Log is an ongoing document and that information must be updated on a regular basis, preferably at the same frequency as required for initial recording (see, *e.g.* Exs. 15: 65, 201, 313, 346, 352, 353, 430). The final rule requires Log updates to be made on a continuing basis, *i.e.,* as new information is discovered. For example, if a new case is discovered during the retention period, it must be recorded within 7 calendar days of discovery, the same interval required for the recording of any new case. If new information about an existing case is discovered, it should be entered within 7 days of receiving the new information. OSHA has also decided to require updating over the entire five-year retention period. OSHA believes that maintaining consistency in the length of the retention and updating periods will simplify the recordkeeping process without imposing additional burdens on employers, because most updating of the records occurs during the first year following an injury or illness.

The comments OSHA received on the proposed quarterly updating of year-end summaries were mixed. Some thought that such updating would provide timely and accurate information to employees at little cost (see, *e.g.* Exs. 15: 9, 89, 170, 260, 262, 265, 401), while others saw the requirement as burdensome and costly and without commensurate value (see, *e.g.* Exs. 15: 78, 225, 289, 337, 406, 412). Typical of those commenters who viewed such a requirement as burdensome was the American Automobile Manufacturing Association (AAMA), which stated ''[u]pdating prior year totals on the annual summary(s) once posted, is of little value. The increase in total numbers is generally so modest as to not affect the overall magnitude of problems within an establishment'' (Ex. 15: 409).

Some commenters recommended that the summaries be updated less frequently, such as semi-annually (see, *e.g.*, Exs. 37, 15: 163). The National Safety Council (Ex. 15: 359) recommended quarterly updates the first year and annual updates thereafter. Others interpreted the proposed rule as requiring quarterly updates and re-certification and re-posting of the year-end summaries after the posting period had ended; these commenters opposed such a requirement as being overly burdensome (see, *e.g.*, Exs. 15: 181, 199, 201, 225, 272, 288, 303, 308, 351). Lucent Technologies (Ex. 15: 272), one of these commenters, urged OSHA to add the following qualifier to any requirement for the updating of the annual summary: ''[t]he quarterly update of the summary is for tracking purposes only and will not require re-certification or posting.''

After reviewing these comments and the evidence in the record, OSHA has decided not to require the updating of annual summaries. Eliminating this requirement from the final rule will minimize employers' administrative burdens and costs, avoid duplication, and avoid the complications associated with the certification of updated summaries, the replacement of posted summaries, and the transmission of summaries to remote sites. The Agency concludes that updating the OSHA Form 300 or its equivalent for a period of five years will provide a sufficient amount of accurate information for recordkeeping purposes. OSHA is persuaded that updating the year-end summary would provide little benefit as long as the information from which the summaries are derived (the OSHA Form 300) is updated for a full five-year period.

Very few comments were received on OSHA's proposed position not to require the updating of the 301 form. All of the comments received supported OSHA's proposed approach (see, *e.g.*, Exs. 15: 260, 262, 265, 401). OSHA does not believe that updating the OSHA Form 301 will enhance the information available to employers, employees, and others sufficiently to warrant including such a requirement in the final rule. However, the final rule makes it clear that employers may, if they choose, update either the Summary or the Form 301.

Section 1904.34 Change in Business Ownership

Section 1904.34 of the final rule addresses the situation that arises when a particular employer ceases operations at an establishment during a calendar year, and the establishment is then operated by a new employer for the remainder of the year. The phrase ''change of ownership,'' for the purposes of this section, is relevant only to the transfer of the responsibility to make and retain OSHA-required injury and illness records. In other words, if one employer, as defined by the OSH Act, transfers ownership of an establishment to a different employer, the new entity becomes responsible for retaining the previous employer's past OSHA-required records and for creating all new records required by this rule.

The final rule requires the previous owner to transfer these records to the new owner, and it limits the recording and recordkeeping responsibilities of the previous employer only to the period of the prior owner. Specifically, section 1904.34 provides that if the business changes ownership, each employer is responsible for recording and reporting work-related injuries and illnesses only for that period of the year during which each employer owned the establishment. The selling employer is required to transfer his or her Part 1904 records to the new owner, and the new owner must save all records of the establishment kept by the prior owner. However, the new owner is not required to update or correct the records of the prior owner, even if new information about old cases becomes available.

The former OSHA injury and illness recording and reporting rule also required both the selling and buying employers to record and report data for the portion of the year for which they owned the establishment. Although the former rule required the purchasing employer to preserve the records of the prior employer, it did not require the prior employer to transfer the OSHA injury and illness records to the new employer. Section 1904.11 of the former rule stated:

> Where an establishment has changed ownership, the employer shall be responsible for maintaining records and filing reports only for that period of the year during which he owned such establishment. However, in the case of any change in ownership, the employer shall preserve those records, if any, of the prior ownership which are required to be kept under this part. These records shall be retained at each establishment to which they relate, for the period, or remainder thereof, required under § 1904.6.

The section of OSHA's proposed rule addressing ''change of ownership'' mirrored the former rule with only slight language changes, as follows:

> Where an establishment has changed ownership, each employer shall be responsible for recording and reporting occupational injuries and illnesses only for that period of the year during which he or she owned such establishment, but the new owner shall retain all records of the establishment kept by the prior owner, as required by § 1904.9(a) of this Part.

Some commenters felt that this proposed section suggested that new owners could be held responsible for obtaining OSHA injury and illness records, but that the former owners were not required to provide them (see, *e.g.*, Exs. 15: 119 298, 323, 356, 397, 323). This interpretation, which would clearly place the new owner in an untenable position, was not accurate. Consequently, to avoid confusion in the future, the final rule requires former owners to transfer their Part 1904 records to the new owner. This requirement ensures that the continuity of the records is maintained when a business changes hands.

Sections 1904.35 Employee Involvement, and 1904.36, Prohibition Against Discrimination

One of the goals of the final rule is to enhance employee involvement in the recordkeeping process. OSHA believes that employee involvement is essential to the success of all aspects of an employer's safety and health program. This is especially true in the area of recordkeeping, because free and frank reporting by employees is the cornerstone of the system. If employees fail to report their injuries and illnesses, the ''picture'' of the workplace that the employer's OSHA forms 300 and 301 reveal will be inaccurate and misleading. This means, in turn, that employers and employees will not have the information they need to improve safety and health in the workplace.

Section 1904.35 of the final rule therefore establishes an affirmative requirement for employers to involve their employees and employee representatives in the recordkeeping process. The employer must inform each employee of how to report an injury or illness, and must provide limited access to the injury and illness records for employees and their representatives. Section 1904.36 of the final rule makes clear that § 11(c) of the Act prohibits employers from discriminating against employees for reporting work-related injuries and illnesses. Section 1904.36 does not create a new obligation on employers. Instead, it clarifies that the OSH Act's anti-discrimination protection applies to employees who seek to participate in the recordkeeping process.[3]

[3] The relevant language of Section 11(c) that ''No person shall discharge or in any manner discriminate against any employee * * * because of the exercise by such employee on behalf of himself or others of any rights afforded by this Act.''

Under the employee involvement provisions of the final rule, employers are required to let employees know how and when to report work-related injuries and illnesses. This means that the employer must establish a procedure for the reporting of work-related injuries and illnesses and train its employees to use that procedure. The rule does not specify how the employer must accomplish these objectives. The size of the workforce, employees' language proficiency and literacy levels, the workplace culture, and other factors will determine what will be effective for any particular workplace.

Employee involvement also requires that employees and their representatives have access to the establishment's injury and illness records. Employee involvement is further enhanced by other parts of the final rule, such as the extended posting period provided in section 1904.32 and the access statements on the new 300 and 301 forms.

These requirements are a direct outgrowth of the issues framed by OSHA in the 1996 proposal. In that **Federal Register** notice, OSHA proposed an employee access provision, § 1904.11(b), and discussed the issue at length in the preamble (61 FR 4038, 4047, and 4048). OSHA did not propose a specific provision for employee involvement in the reporting process, but raised the issue for discussion in the preamble (61 FR 4047–48) (*see* Issue 7. Improving employee involvement). The proposed rule did contain a reference to section 11(c) of the OSH Act and its applicability to retaliatory discrimination by employers against employees who report injuries or illnesses (61 FR 4062).

Specifically, OSHA noted in the NPRM that the Keystone Dialogue report (Ex. 5) advocated greater employee awareness and involvement in the recordkeeping process to improve the process and enhance safety and health efforts in general. There was agreement among members of the Dialogue group that, for a number of reasons, among them lack of knowledge, fear of reprisal, and apathy, ''employees often do not seek access to injury/illness logs (to a sufficient extent) * * * [and] that overall workplace safety and health would benefit if the information in the logs were more widely known. * * *'' In this regard, the group made several recommendations to modify the recordkeeping process and to involve employees in accident prevention efforts:

- OSHA should require employers to notify employees individually of log entries for each recordable case and their right to access the records, either by providing them with a copy of the 101 form or the log, by having the employee initial or otherwise acknowledge the log entry, or by other means negotiated with a designated employee representative;
- Employers should inform employees of an affirmative duty to bring cases to the employer's attention;
- OSHA should add statements to the OSHA recordkeeping forms 101 and 200 that inform employees of their right to access the 200 form;
- OSHA should extend the posting period for the 200 form from one month to 12 months;
- Employers should share data with employees and members of safety committees;
- Employers should include more employees in accident investigations and analyses; and
- Detailed survey data systems should be developed so those employees could assist employers in evaluating accident and exposure risks associated with their work processes.

OSHA also noted that the General Accounting Office (GAO) report (Ex. 3) identified employee lack of knowledge and understanding of the recordkeeping system as one cause of the underreporting of occupational injuries and illnesses. Based on these and other reports and OSHA's compliance experience, OSHA requested comment in the proposal on (1) whether employers should notify employees that their injuries or illnesses have been entered into the records, (2) if so, how employers could meet such a requirement and the degree of flexibility OSHA should give employers, (3) any other ideas for improving employee involvement in the recordkeeping system, and (4) the costs and benefits of alternate proposals.

These issues drew considerable comment during the rulemaking. With few exceptions (see, *e.g.*, Exs. 15: 13, 78, 201, 389, 406), commenters generally supported increasing employee awareness and involvement in the recordkeeping process in some form (see, *e.g.*, Exs. 15: 26, 85, 87, 154, 170, 199, 234, 310, 341, 357, 378, 414, 415, 418, 426). For example, some commenters supported increasing employee awareness by requiring year-round posting of the OSHA 300 Log (see, *e.g.*, Exs. 15: 154, 170, 199, 415, 426), adding an employee accessibility statement to the OSHA 300 Log (Ex. 15: 418) , and requiring employee training on recordkeeping issues and procedures (Ex. 15: 418). A number of commenters also discussed their own efforts to involve employees in various recordkeeping activities, such as in filling out accident forms (see, *e.g.*, Exs. 15: 23, 87, 225), assisting in accident investigations (see, *e.g.*, Exs. 15: 170, 357, 425), and reviewing accident data (see, *e.g.*, Exs. 15: 260, 262, 265, 310, 357, 401, 414).

However, most employers, including many who supported various methods to increase employee awareness and involvement in the process, opposed a provision requiring employers to notify individual employees that their injuries have been recorded on the Log because, in their views, such a requirement would not be likely to achieve OSHA's stated objective and would be too burdensome and costly for employers (see, *e.g.*, Exs. 15: 9, 49, 60, 76, 82, 85, 95, 109, 123, 145, 154, 170, 172, 199, 204, 218, 225, 262, 281, 283, 288, 324, 341, 357, 374, 393, 406, 426). Representative of these comments were those of AT&T and Lucent Technologies, which pointed out that workers are currently required to be notified about the status of job-related incidents by workers' compensation regulations and company benefit programs and that separate notification of an OSHA 300 Log entry would therefore be confusing and redundant (Exs. 15: 272 and 15: 303).

On the other hand, individual notification of employees was supported by commenters from the unions and professional organizations, as well as by some employers (see, *e.g.*, Exs. 15: 156, 181, 233, 247, 310, 350, 369, 414). For example, the American Association of Occupational Health Nurses (Ex. 15: 181) supported notification ''[a]s a means of improving employee cooperation and helping employees recognize their role in working safely and promoting a safe workplace.'' Those supporting notification suggested that reasonable means of providing such notification would be direct mail, including a notice in a pay envelope, or e-mailing a notice and/or the OSHA 301 form to affected employees (see, *e.g.*, Exs. 15: 310, 350).

The National Safety Council's comment (Ex. 15: 359) typifies the views of these commenters:

> [w]e believe that employee involvement in occupational safety and health issues is highly desirable and that notification is one aspect of employee involvement. * * * If OSHA were to require notification, then OSHA should require each employer to create and comply with its own written notification policy—perhaps subject to some limitation such as notification within 7–14 days of entry on the Log. The OSHA compliance officer can verify compliance with the company's policy on a test basis during an inspection.

Other commenters (see, *e.g.*, Exs. 15: 234, 283, 348, 426) agreed that the final rule should not specify how employee notification should be accomplished. For example, E. I. du Pont de Nemours Corporation (Ex. 15: 348) stated:

[l]egislating how people communicate is confining. Many companies do a fine job of notifying employees about injuries, investigation findings, hazard reduction, and ways to contribute to a safer workplace. Mandating a particular method would be counterproductive to those organizations already doing a good job. * * * We suggest that unless full implications of involving employees in the process are clearly understood (and are not prohibited by any other federal agency) no guideline should be written—but perhaps suggestions of ways successful companies have worked with their employees to improve safety performance could be provided and would be useful.

One participant suggested a policy of having the injured employee view the Log to verify its accuracy, noting that ''[t]his procedure * * * does not appear to place additional costs or undue burden on the employer'' (Ex. 15: 163). Another recommended a ''face-to-face advisory'' after an investigation of the accident had been completed (Ex. 15: 414). The American Textile Manufacturers Institute (Ex. 15: 156) suggested more proactive approaches:

[o]ther methods for improving employee involvement in the injury and illness recordkeeping system include giving employees accident causation and prevention information from the records. In addition, information about departments, accident types, injury types, hazards and contributing factors, etc., could and should be shared for the benefit of employer and employees.

The AFL–CIO, United Auto Workers (UAW), Services Employees International Union (SEIU), and MassCOSH addressed the reporting disincentive that occurs when employees are threatened, disciplined, or discriminated against for reporting injuries or illnesses (Exs. 58X, 15: 79, 418, 438). MassCOSH recounted how health care workers were disciplined for reporting multiple needle stick injuries, and the United Auto Workers noted that some injury victims were subject to drug testing (Ex. 15: 438). The unions recommended that discriminatory treatment of employees who report injuries should be presumed to be a violation of section 11(c), the anti-discrimination provision of the OSH Act (see, *e.g.*, Exs. 48, 58X, 15: 379, 418, 438). Specifically, the UAW (Ex. 15: 438) recommended that the following regulatory text be added to the final rule:

[r]eporting * * * an injury or illness to management is an activity in support of the purposes of the Act. Since an injury report may trigger an employer's responsibility to abate a hazard, such report is an exercise of an employee's right under the Act and therefore protected activity under Section 11(c) of the Act. Adverse action by an employer following such a report shall be presumed to be discrimination. Examples of adverse action are verbal warnings, disparate treatment, additional training provided only to injury victims, disciplinary action of any kind, or drug testing. Suffering an injury or illness by itself shall not be considered probable cause to trigger a drug test. An employer may rebut the presumption of discrimination by showing substantial evidence that injured employees receive consistent treatment to those who have not suffered injuries. Granting of prizes or compensation to employees or groups of employees who do not report injuries is discrimination against those employees who do report injuries. Therefore, such programs are violations of Section 11(c) of the Act.

The AFL–CIO (Ex. 15: 4218) supported this language and, along with the Union of Needletrades, Industrial and Textile Employees (UNITE) (Ex. 15: 380), also recommended that the rule include a prohibition against retaliation or discrimination that would be enforced in the same manner as other violations of the recordkeeping rule (Ex. 15: 418). The AFL–CIO (Ex. 15: 418) also requested that OSHA include in the final rule:

[a]n affirmative obligation on employers to inform employees of their right to report injuries or illnesses without fear of reprisal and to gain access to the Log 300 and to the Form 301 with certain limitations. At a minimum, the Log 300 should contain a statement, which informs employees of their rights and protections afforded under the rule. We recommend the following language be added to the log: 'Employees have a right to report work-related injuries and illnesses to their employer and to gain access to the Log 300 and Form 301.'

OSHA has concluded that the rulemaking record overwhelmingly demonstrates that employee awareness and involvement is a crucial part of an effective recordkeeping program, as well as an overall safety and health program. There was little disagreement over this point among participants in the rulemaking, whether they represented management, labor, government or professional associations (see, *e.g.*, Exs. 15: 26, 85, 87, 154, 170, 199, 234, 310, 341, 357, 378, 414, 415, 426). There was also no disagreement with the unions' contention that employees should not be retaliated against for reporting work-related injuries and illnesses and for exercising their right of access to the Log and Incident Report forms. The prominent employee involvement issues in the rulemaking were thus not whether employee involvement should be strengthened but to what extent and in what ways employees should be brought into the process.

In response to this support in the record, OSHA has strengthened the final rule to promote better injury and illness information by increasing employees' knowledge of their employers' recordkeeping program and by removing barriers that may exist to the reporting of work-related injuries and illnesses. To achieve this goal, the final rule establishes a simple two-part process for each employer who is required to keep records, as follows:

—Set up a way for employees to report work-related injuries and illnesses promptly; and
—Inform each employee of how to report work-related injuries and illnesses.

OSHA agrees with commenters that employees must know and understand that they have an affirmative obligation to report injuries and illnesses. Additionally, OSHA believes that many employers already take these actions as a common sense approach to discovering workplace problems, and that the rule will thus, to a large extent, be codifying current industry practice, rather than breaking new ground.

OSHA is convinced that a performance requirement, rather than specific requirements, will achieve this objective effectively, while still giving employers the flexibility they need to tailor their programs to the needs of their workplaces (see, *e.g.*, Exs. 15: 234, 283, 348, 359, 426). The Agency finds that employee awareness and participation in the recordkeeping process is best achieved by such provisions of the final rule as the requirement to extend the posting period for the OSHA 300 summary, the addition of accessibility statements on the OSHA Summary, and requirements designed to facilitate employee access to records.

Many of the specific suggestions made by commenters have not been adopted in the final rule in favor of the more performance-based approach to employee involvement supported by so many commenters. For example, OSHA has decided not to require employers to devise a method of notifying individual employees when a case involving them has been entered on the OSHA 300 Log. An employee notification requirement would be very burdensome and costly, and the potential advantages of an employee notification system have not been shown in the record for this rule. Thus, OSHA is not sure that employee notification would improve the quality of the records enough to justify the

added burdens. Additionally, employees and their representatives have a right to access the records under the final rule, if they wish to review the employer's recording of a given occupational injury or illness case. OSHA believes that the improved recordkeeping that will result from the changes being made to the final rule, the enhanced employee involvement reflected in many of the rule's provisions, and the prohibition against discrimination will all work in concert to achieve the goal envisioned by those commenters who urged OSHA to require employee notification: more and better reporting and recording.

Several of the other suggestions made by participants—such as including employees in accident investigations and involving employees in program evaluation—are beyond the scope of the Part 1904 regulation, which simply requires employers to record and report occupational deaths, injuries and illnesses. OSHA encourages employers and employees to work together to determine how best to communicate the information that workers need in the context of each specific workplace. Moreover, OSHA encourages employers to involve their workers in activities such as accident investigations and the analysis of accident, injury and illness data, as suggested by some commenters, but believes that requiring these activities is beyond the scope of this rule.

OSHA has also included in the final rule, in section 1904.36, a statement that section 11(c) of the OSH Act protects workers from employer retaliation for filing a complaint, reporting an injury or illness, seeking access to records to which they are entitled, or otherwise exercising their rights under the rule. This section of the rule does not impose any new obligations on employers or create new rights for employees that did not previously exist. In view of the evidence that retaliation against employees for reporting injuries is not uncommon and may be ''growing'' (see, *e.g.*, Ex. 58X, p. 214), this section is intended to serve the informational needs of employees who might not otherwise be aware of their rights and to remind employers of their obligation not to discriminate. OSHA concurs with the International Chemical Workers Union, which, while discussing the issue of whether personal identifiers should be used on the Log, stated (Ex. 15: 415), ''We have never heard of [personal identifiers] being an issue for our members, except when management used the reports as an excuse to discipline 'unsafe' workers. The addition of language notifying workers of their rights to 11(c) protection * * * should help alleviate any such concerns.''

Employee access to OSHA injury and illness records

The Part 1904 final rule continues OSHA's long-standing policy of allowing employees and their representatives access to the occupational injury and illness information kept by their employers, with some limitations. However, the final rule includes several changes to improve employees' access to the information, while at the same time implementing several measures to protect the privacy interests of injured and ill employees. Section 1904.35 requires an employer covered by the Part 1904 regulation to provide limited access to the OSHA recordkeeping forms to current and former employees, as well as to two types of employee representatives. The first is a personal representative of an employee or former employee, who is a person that the employee or former employee designates, in writing, as his or her personal representative, or is the legal representative of a deceased or legally incapacitated employee or former employee. The second is an authorized employee representative, which is defined as an authorized collective bargaining agent of one or more employees working at the employer's establishment.

Section 1904.35 accords employees and their representatives three separate access rights. First, it gives any employee, former employee, personal representative, or authorized employee representative the right to a copy of the current OSHA 300 Log, and to any stored OSHA 300 Log(s), for any establishment in which the employee or former employee has worked. The employer must provide one free copy of the OSHA 300 Log(s) by the end of the next business day. The employee, former employee, personal representative or authorized employee representative is not entitled to see, or to obtain a copy of, the confidential list of names and case numbers for privacy cases. Second, any employee, former employee, or personal representative is entitled to one free copy of the OSHA 301 Incident Report describing an injury or illness to that employee by the end of the next business day. Finally, an authorized employee representative is entitled to copies of the right-hand portion of all OSHA 301 forms for the establishment(s) where the agent represents one or more employees under a collective bargaining agreement. The right-hand portion of the 301 form contains the heading ''Tell us about the case,'' and elicits information about how the injury occurred, including the employee's actions just prior to the incident, the materials and tools involved, and how the incident occurred, but does not contain the employee's name. No information other than that on the right-hand portion of the form may be disclosed to an authorized employee representative. The employer must provide the authorized employee representative with one free copy of all the 301 forms for the establishment within 7 calendar days.

Employee privacy is protected in the final rule in paragraphs 1904.29(b)(7) to (10). Paragraph 1904.29(b)(7) requires the employer to enter the words ''privacy case'' on the OSHA 300 Log, in lieu of the employee's name, for recordable privacy concern cases involving the following types of injuries and illnesses: (i) an injury from a needle or sharp object contaminated by another person's blood or other potentially infectious material; (ii) an injury or illness to an intimate body part or to the reproductive system; (iii) an injury or illness resulting from a sexual assault; (iv) a mental illness; (v) an illness involving HIV, hepatitis; or tuberculosis, or (vi) any other illness, if the employee independently and voluntarily requests that his or her name not be entered on the log. Musculoskeletal disorders (MSDs) are not considered privacy concern cases, and thus employers are required to enter the names of employees experiencing these disorders on the log. The employer must keep a separate, confidential list of the case numbers and employee names for privacy cases.

The employer may take additional action in privacy concern cases if warranted. Paragraph 1904.29(b)(9) allows the employer to use discretion in describing the nature of the injury or illness in a privacy concern case, if the employer has a reasonable basis to believe that the injured or ill employee may be identified from the records even though the employee's name has been removed. Only the six types of injuries and illnesses listed in Paragraph 1904.29(b)(7) may be considered privacy concern cases, and thus the additional protection offered by paragraph 1904.29(b)(9) applies only to such cases.

Paragraph 1904.29(b)(10) protects employee privacy if the employer decides voluntarily to disclose the OSHA 300 and 301 forms to persons other than those who have a mandatory right of access under the final rule. The paragraph requires the employer to remove or hide employees' names or

other personally identifying information before disclosing the forms to persons other than government representatives, employees, former employees or authorized representatives, as required by paragraphs 1904.40 and 1904.35, except in three cases. The employer may disclose the forms, complete with personally identifying information, (2) only: (i) to an auditor or consultant hired by the employer to evaluate the safety and health program; (ii) to the extent necessary for processing a claim for workers' compensation or other insurance benefits; or (iii) to a public health authority or law enforcement agency for uses and disclosures for which consent, an authorization, or opportunity to agree or object is not required under section 164.512 of the final rule on Standards for Privacy of Individually Identifiable Health Information, 45 CFR 164.512.

The former rule. The access provisions of the former recordkeeping regulation required employers to provide government representatives, as well as employees, former employees, and their representatives, with access to the OSHA Logs and year-end summaries, including the names of all injured and ill employees. The former regulation permitted only government representatives to have access to the supplemental incident reports (the former Form 101). *Id.* Employees, former employees and their representatives had no right to inspect and copy the incident reports, although employers were permitted to disclose these forms if doing so was included in the terms of a collective bargaining agreement. *Id.*

The proposed rule. The proposed rule would have required employers to provide government representatives, and employees, former employees, and their representatives, with access to the unredacted OSHA Logs and summaries (61 FR 4061). The proposal would have expanded the scope of the former rule's access provisions by requiring employers to make available the incident reports (former OSHA Form 101, renumbered Form 301 in the final rule) to employees, former employees, and their designated representatives. *Id.* At the same time, OSHA did not intend to provide access to the general public. The proposed standard stated: ''OSHA asks for input on possible methodologies for providing easy access to workers while restricting access to the general public'' (61 FR 4048).

The access provisions of the proposed rule attracted considerable comment. Many industry representatives argued that disclosure of information contained in the injury and illness records to employees, former employees and their representatives would violate an injured or ill employee's right, under the Constitution and several statutes, to privacy. On the other hand, a number of commenters emphasized the importance of the information contained in the records to employees and unions in their voluntary efforts to uncover and eliminate workplace safety and health hazards. The following paragraphs discuss privacy and access issues, and their relationship to the recordkeeping rule.

The Privacy Interest of the Injured or Ill Employee

Whether, and to what extent, the U.S. Constitution grants individuals a right of privacy in personal information has not been firmly established. In *Whalen* v. *Roe,* 429 U.S. 589 (1977), the Supreme Court considered whether a New York law creating a central computer record of the names and addresses of persons taking certain dangerous but lawful drugs violated the constitutional privacy interest of those taking the drugs. The Court rejected the claim, primarily because the state statute required that government employees with access keep the information confidential and there was no basis to assume that the requirement would be violated. 429 U.S. at 601, 605–606. Although the decision does not say whether the Constitution affords protection against disclosure of personal information, some language suggests that it does, at least in some circumstances. The Court stated:

> The cases sometimes characterized as protecting ''privacy'' have in fact involved at least two different kinds of interests. One is the individual interest in avoiding disclosure of personal matters, and another is the interest in independence in making certain kinds of decisions. 429 U.S. at 598, 599.
>
> Recognizing that in some circumstances th[e] duty [to avoid unwarranted disclosure of personal matters] arguably has its roots in the Constitution, nevertheless New York's statutory scheme, and its implementing administrative procedures, evidence a proper concern with, and protection of, the individual's interest in privacy. 429 U.S. at 605

A subsequent case, *Nixon* v. *Administrator of General Services,* 433 U.S. 425 (1977), lends further support to the existence of a constitutional right of privacy in personal information. At issue in *Nixon* was a statute that required the former president to turn over both public and private papers to an archivist who would review them and return any personal materials. The Court appeared to acknowledge that Nixon had a Constitutionally protected privacy right in personal information. 433 U.S. at 457. It upheld the statute because of the strong public interest in preserving the documents and because the statute's procedural safeguards made it unlikely that truly private materials would be disclosed to the public.

A number of federal circuit courts of appeals, building on *Whalen* and *Nixon,* have held that individuals possess a qualified constitutional right to confidentiality of personal information, including medical information. See, *e.g.*, *Paul* v. *Verniero,* 170 F.3d 396, 402 (3d Cir. 1999); *Norman-Bloodsay* v. *Lawrence Berkeley Laboratory,* 135 F.3d 1260, 1269 (9th Cir. 1998); *F.E.R.* v. *Valdez,* 58 F.3d 1530, 1535 (10th Cir. 1995); *John Doe* v. *City of New York,* 15 F.3d 264, 267 (2d Cir. 1994); *Fadjo* v. *Coon,* 633 F.2d 1172, 1175 (5th Cir. 1981). See also *Anderson* v. *Romero,* 72 F.3d 518, 522 (7th Cir. 1995) (noting holdings of federal circuits, including seventh circuit, recognizing qualified constitutional right to confidentiality in medical records, but finding it ''not clearly established'' that prison inmate enjoyed such right in 1992).

Of the remaining circuits that have addressed the issue, only the Sixth has squarely rejected a general constitutional right to nondisclosure of personal information. *E.g., J.P.* v. *DeSanti,* 653 F.2d 1080, 1089 (6th Cir. 1981). Two circuits have expressed skepticism as to the existence of such a right. See *American Federation of Government Employees, AFL–CIO* v. *Department of Housing and Urban Development,* 118 F.3d 786, 788 (D.C. Cir. 1987) (expressing ''grave doubt'' whether the Constitution protects against disclosure of personal information); *Borucki* v. *Ryan,* 827 F.2d 836, 845–846 (1st Cir. 1987) (noting lack of concrete guidance by Supreme Court and disagreement among circuits on constitutional right of confidentiality). See also *Ferguson* v. *City of Charleston, S.C.,* 186 F.3d 469, 483 (4th Cir.1999) (declining to decide whether individuals possess a general constitutional right to privacy, noting circuit conflict).

Where the right to privacy is recognized, protection extends to information that the individual would reasonably expect to remain confidential. *Fraternal Order of Police Lodge No. 5* v. *City of Philadelphia,* 812 F.2d 105, 112 (3d Cir. 1987); *Mangels* v. *Pena,* 789 F.2d 836, 839 (10th Cir. 1986). ''The more intimate or personal the information, the more justified is the expectation that it will not be subject to public scrutiny.'' *Fraternal Order of Police,* 812 F.2d at 105. Thus, information about the state of a person's health, including his or her medical

treatment, prescription drug use, HIV status and related matters, is entitled to privacy protection. See *Paul* v. *Verniero,* 170 F.3d at 401–402 (collecting cases). See also *Doe* v. *City of New York,* 15 F.3d at 267 (''[T]here are few matters that are quite so personal as the status of one's health, and few matters the dissemination of which one would prefer to maintain greater control over.'')

The right to privacy is not limited only to medical records. Other types of records containing medical information are also covered. See, *e.g.*, *Whalen,* (computer tapes containing prescription drug information); *Fraternal Order of Police,* 812 F.2d at 112 (police questionnaire eliciting information about employee's physical and mental condition); *Doe* v. *SEPTA,* 72 F.3d 1133 (3d Cir. 1995) (utilization report listing prescription drugs dispensed to employees under employer health plan). Moreover, personal financial data and other types of private information may be subject to privacy protection in certain cases. See *Nixon* v. *Administrator of General Services,* 433 U.S. 425, 455 (1977) (personal matters, including personal finances, reflected in presidential papers); *Paul* v. *Verniero,* 170 F.3d at 404 (home address of sex offender subject to disclosure under ''Megan's Law''); *Fadjo* v. *Coon,* 633 F.2d at 1175 (private details contained in subpoenaed testimony).

A finding that information is entitled to privacy protection is only the first step in determining whether a disclosure requirement is valid. A balancing test must be applied, which weighs the individual's interest in confidentiality against the public interest in disclosure. *Fraternal Order of Police,* 812 F.2d at 113. In evaluating the government's interest, at least two factors must be considered; the purpose to be served by disclosure of personal information to individuals authorized by law to receive it, and the adverse effect of unauthorized public disclosure of such information. *Id.* at 117, 118. *Accord, Barry* v. *City of New York,* 712 F.2d 1554, 1561–5162 (2d Cir. 1983). Thus, the fact that disclosure of highly personal information to parties who have need for it serves an important public interest is not sufficient justification for a disclosure requirement in the absence of adequate safeguards against broader public access. *Fraternal Order of Police,* 812 F.2d at 118 (''It would be incompatible with the concept of privacy to permit protected information and material to be publicly disclosed. The fact that protected information must be disclosed to a party who has need for it * * * does not strip the information of its protection against disclosure to those who have no similar need.'')

Balancing the Interests of Privacy and Access

OSHA historically has recognized that the Log and Incident Report (Forms 300 and 301, respectively) may contain information of a sufficiently intimate and personal nature that a reasonable person would wish it to remain confidential. In its 1978 records access regulation (29 CFR 1910.1020), OSHA addressed the privacy implications of its decision to grant employee access to the Log. The agency noted that while Log entries are intended to be brief, they may contain medical information, including diagnoses of specific illnesses, and that disclosure to other employees, former employees or their representatives raised a sensitive privacy issue. 43 FR 31327 (1978). However, OSHA concluded that disclosure of the Log to current and former employees and their representatives benefits these employees generally by increasing their awareness and understanding of the health and safety hazards to which they are, or have been, exposed. OSHA found that this knowledge ''will help employees to protect themselves from future occurrences,'' and that ''[i]n such cases, the right of privacy must be tempered by the obvious exigencies of informing employees about the effects of workplace hazards.'' *Id.* at 31327, 31328.

The proposed rule would have expanded the right of access of employees, former employees, and their designated representatives beyond the Log to include the Incident Report (Form 301) (61 FR 4061). OSHA discussed the potentially conflicting interests involved, and explained its preliminary balancing of these interests, as follows:

> OSHA's historical practice of allowing employee access to all of the information on the log permits employees and their designated representatives to be totally informed about the employer's recordkeeping practices, and the occupational injuries and illnesses recorded in the workplace. However, this total accessibility may infringe on an individual employee's privacy interest. At the same time, the need to access individual's Incident Records to adequately evaluate the safety and health environment of the establishment has been expressed.
>
> These two interests—the privacy interests of the individual employee versus the interest in access to health and safety information concerning one's own workplace—are potentially at odds with one another. For injury and illness recordkeeping purposes, OSHA has taken the position that an employee's interest in access to health and safety information on the OSHA forms concerning one's own workplace carries greater weight than an individual's right to privacy. More complete access to the detailed injury and illness records has the potential for increasing employee involvement in workplace safety and health programs and therefore has the potential for improving working conditions. Analysis of injury and illness data provides a wealth of information for injury and illness prevention programs. Analysis by workers, in addition to analyses by the employer, lead to the potential of developing methods to diminish workplace hazards through additional or different perspectives (61 FR 4048).

The proposal asked for comment on alternatives that would preserve broad access rights while protecting fundamental privacy interests, including requiring omission of personal identifying information for certain specific injury and illness cases recorded on the Log, and restricting non-government access to the Incident Reports to that portion of the Form 301 that does not contain personal information. *Ibid.*

OSHA continues to believe that granting employees a broad right of access to injury and illness records serves important public interests. There is persuasive evidence that access by employees and their representatives to the Log and the Incident Report serves as a useful check on the accuracy of the employer's recordkeeping and promotes greater employee involvement in prevention programs that contribute to safer, more healthful workplaces. For example, the Building and Construction Trades Department, AFL–CIO stated that:

> In the main, the name of the employee is critically important to understanding and verifying recordable cases. It is often necessary to speak with the employee to explore the conditions that lead to the injury or illness, and this is impossible without employee names. In addition, employees and unions play an important role in assuring the proper administration of the recordkeeping rule, and they cannot audit an employer's recordkeeping performance without having access to employee names, which are necessary to verify that all properly recordable cases are actually on the log, and to verify that recorded cases are properly classified. (Ex. 15: 394, p. 35)

Similarly, the American Federation of State, County and Municipal Employees, AFL–CIO stated that ''[w]hen employees and their representatives have complete access to the detailed injury and illness records, employee involvement in workplace safety and health programs increases. Worker representatives use the data on the forms to assist in the identification of specific hazards, as well as other

factors affecting workplace safety'' (Ex.15: 362, p. 7).

The United Auto Workers (Ex. 15: 438) argued that the OSHA 301 incident reports are as valuable as the log is in aiding voluntary enforcement efforts. The UAW stated:

> The OSHA 101 (proposed 301) form is an available data source on circumstances of an injury or illness. The collected data contains information for prevention, and also indicates the effectiveness of management's health and safety program. The information on the OSHA [301] relevant to hazard identification and control should be made available to employee representatives on the same basis as they are made available to OSHA compliance officers. Personal data on treatment details, physician's name, personal information on employee can be recorded on the ''other'' side of the form and blanked out.

The Laborers' Health and Safety Fund (Ex. 15: 310) also emphasized the practical value of the information contained in the Form 301:

> We wholeheartedly support the specific language in the proposed rule allowing designated representatives access to the OSHA 300 and 301 forms. In a project we administered to determine the major causes of serious injuries and illnesses in road construction under a Federal Highway Administration grant, several employers would not allow access to even information from the injured person's 101 workers compensation equivalent form, because the form contained other information such as the employee's age and salary. The event information contained in the 301 form is critical in determining the hazards and possible preventive measures.

Other commenters also supported the proposal's approach of broadening employee access to records (see, *e.g.* Exs. 24; 36; 15: 350, 380, 418).

Recognition of the important purpose served by granting access to injury and illness records does not end the analysis. The public interest that is served when information contained in the records is used to promote safety and health must be balanced against the possible harm that would result from the misuse of private information. There are two ways in which harm could occur. First, the information could be used for unauthorized purposes, such as to harass or embarrass employees. Second, employees and their representatives with access to records could, deliberately or inadvertently, disclose private information to others who have no need for it.

Several commenters indicated concern about the unauthorized disclosure of private material contained in the injury and illness records. The joint comments filed by the National Broiler Council and the National Turkey Council express the view shared by many employers:

> There is universal support among employees and employers for the communication of information about workplace illnesses and injuries. It also seems apparent that there is universal opposition to the communication of personal information about individuals involved in those incidents. There are many circumstances in the workplace where employees have no desire for fellow employees to know the extent, description, or type of injury or illness they have incurred. The reasons for an employee's concern about his or her personal privacy may vary but almost always find their foundation in very strong and personal emotions. One example that clearly illustrates this point would be the employee who has experienced an exposure incident under the bloodborne pathogens standard. Most people would not want it to be known that they may have been exposed to HIV, let alone if they tested positive for HIV. * * * In addition to the concerns about how this information could be used by other individuals, employers also have very serious concerns about the misuse of this information by individuals or organizations for purposes in no way related to the issue of workplace health and safety (Ex. 15: 193, pp. 4–5).

A number of commenters argued that granting access to the Log and Incident Report to employees, former employees and their representatives will deter employees from reporting their injuries and illnesses, especially in cases involving exposure to bloodborne pathogens and injuries and illnesses involving reproductive organs (see, *e.g.*, Exs. 15–185, 15–193, 15–238, 15–239, 15–305). A representative of the Middlesex Convalescent Center wrote:

> [R]equiring employers to disclose personal identifiers (which include name and occupation) will result in *fewer* people reporting injuries and illnesses because employees will feel shame or embarrassment for being involved in an accident. * * * Additionally, employees who do not want co-workers to know their physical handicaps and other personal business will choose not to report accidents, including those in which the employee is not at fault (Ex. 15: 23 (emphasis in original)).

There exist at present no mechanisms to protect against unwarranted disclosure of private information contained in OSHA records. While Agency policy is that employees and their representatives with access to records should treat the information contained therein as confidential except as necessary to further the purposes of the Act, the Secretary lacks statutory authority to enforce such a policy against employees and representatives (*e.g.* 29 U.S.C. §§ 658, 659) (Act's enforcement mechanisms directed solely at employers). Nor are there present here other types of safeguards that have been held to be adequate to protect against misuse of private material. See *Whalen,* 589 U.S. at 605 (''The right to collect and use [private] data for public purposes is typically accompanied by a concomitant statutory or regulatory duty to avoid unwarranted disclosures.'') See also *Fraternal Order of Police,* 812 F.2d at 118 (appropriate safeguards could include statutory sanctions for unauthorized disclosures, security provisions to prevent mishandling of files, coupled with express regulatory prohibition on disclosure, or procedures such as storage of private material in locked cabinets with automatic removal and destruction within six months); *In re Search Warrant (Sealed),* 810 F.2d 67, 72 (3d Cir. 1987) (district court order that medical records and related information be kept confidential except as disclosure was reasonably required in connection with criminal investigation).

The degree of harm that could result from unauthorized use or disclosure of information on the Log and Incident Report varies depending upon the nature and sensitivity of the injury or illness involved. An employee might reasonably have little to fear from disclosure of a garden-variety injury or illness of the kind that one might sustain in everyday life. Cf. *Wilson* v. *Pennsylvania State Police Department,* 1999 WL 179692 (E.D.Pa) (vision-related information not as intimate as other types of medical information, and less likely to result in harm if disclosed to the public). However, there is a much greater risk that social stigma, harassment and discrimination could result from public knowledge that one has, or may have, AIDS, has been the victim of a sexual assault, or has suffered an injury to a reproductive organ or other intimate body part. See, *e.g. Doe* v. *SEPTA,* 712 F.2d at 1140 (AIDS); *New Jersey Bell Telephone Co.* v. *NLRB,* 720 F.2d 789, 790 (3d Cir. 1983) (reasons given by employees for absence or tardiness included colitis, insertion of urethral tubes, vaginal infections, scalded rectal areas, and heart problems).

OSHA has concluded that the disclosure of occupational injury and illness records to employees and their representatives serves important public policy interests. These interests support a requirement for access by employees and their representatives to personally identifiable information for all but a limited number of cases recorded on the Log, and to all information on the right-hand side of the Form 301. However, OSHA also concludes that prior Agency access policies may not have given

adequate consideration to the harm which could result from disclosure of intimate medical information. In the absence of effective safeguards against unwarranted use or disclosure of private information in the injury and illness records, confidentiality must be preserved for particularly sensitive cases. These ''privacy concern cases'' listed in paragraph 1904.29 (b)(7) of the final rule involve diseases, such as AIDS and hepatitis, other illnesses if the employee voluntarily requests confidentiality, as well as certain types of injuries, the disclosure of which could be particularly damaging or embarrassing to the affected employee. MSDs are not included in privacy concern cases because OSHA's ergonomics rule independently provides for access by employees and their representatives to the names of workers who report work-related MSDs. (See 29 CFR 1910.900(v)(1) and (2.)

The record supports this approach. For example, API recommended that OSHA protect employee confidentiality for cases involving HIV, fertility problems, bloodborne pathogens, seroconversions, and impotence (Ex. 15: 375). OSHA agrees that employee confidentiality should be protected in these and similar cases. Therefore, the final rule requires that the employer withhold the employee's name from the OSHA 300 Log for each ''privacy concern case,'' and maintain a separate confidential list of employee names and case numbers. In all other respects, the final rule ensures full access to the OSHA Log by employees, former employees, personal representatives and authorized employee representatives.

Protections Against Broad Public Access

In the proposal, OHSA noted that the access requirements were intended as a tool for employees and their representatives to affect safety and health conditions at the workplace, not as a mechanism for broad public disclosure of injury and illness information. (61 FR 4048.) A number of commenters suggested that OSHA should include specific language in the final rule protecting employee confidentiality whenever injury and illness data are disclosed for other than safety or health purposes, or to persons other than those who have a legitimate need to know. Dow argued that:

> OSHA should allow an employer to develop a system that will protect personal identifiers and other non-safety or health related information. Further, such information should only be available for the specific use by an OSHA inspector who is reviewing an employer's logs during an inspection, medical personnel, the employer's incident investigation designated officials, and the individual's supervisor. Outside of these individuals, access should be granted only after written authorization from the injured or ill employee has been obtained. This approach would allow those individuals who have a legitimate ''need to know'' limited access to the information (Ex.. 15: 335).

Other commenters suggested requiring that employee names be shielded if the forms are disclosed to third parties (see, *e.g.*, Exs. 15: 374, 375).

OSHA agrees that confidentiality of injury and illness records should be maintained except for those persons with a legitimate need to know the information. This is a logical extension of the agency's position that a balancing test is appropriate in determining the scope of access to be granted employees and their representatives. Under this test, ''the fact that protected information must be disclosed to a party who has need for it* * * does not strip the information of its protection against disclosure to those who have no similar need.'' *Fraternal Order of Police,* 812 F2d at 118.

OSHA has determined that employees, former employees and authorized employee representatives have a need for the information that justifies their access to records, including employee names, for all except privacy concern cases. While the possibility exists that employees and their representatives with access to the records could disclose the information to the general public, OSHA does not believe that this risk is sufficient to justify restrictions on the use of the records by persons granted access under sections 1904.40 and 1904.35. As discussed in the following section, strong policy and legal considerations militate against placing restrictions on employees' and employee representatives' use of the injury and illness information.

There is also a concern that employers may voluntarily grant access to OSHA records to persons outside their organization, who do not need the information for safety and health purposes. To protect employee confidentiality in these circumstances, paragraph 1904.29(b)(10) requires employers generally to remove or shield employee names and other personally identifying information when they disclose the OSHA forms to persons other than government representatives, employees, former employees or authorized employee representatives. Employers remain free to disclose unredacted records for purposes of evaluating a safety and health program or safety and health conditions at the workplace, processing a claim for workers' compensation or insurance benefits, or carrying out the public health or law enforcement functions described in section 164.512 of the final rule on Standards for Privacy of Individually Identifiable Health Information.

OSHA believes that this provision protects employee privacy to a reasonable degree consistent with the legitimate business needs of employers and sound public policy considerations. The record does not demonstrate that routine access by the general public to personally identifiable injury and illness data is necessary or useful. Indeed, several prominent industry representatives stated that the OSHA log should not be made available to the general public. See Ex. 335 (Dow); Ex. 15–375 (API). Furthermore, employers are always free to seek authorization from employees to disclose their names in particular cases. Thus, employers retain a degree of flexibility to tailor their voluntary disclosure policies to meet exigent circumstances.

Misuse of the Records by Employees and Their Representatives

Several commenters were concerned about inappropriate uses of the records once they are released to employees (see, *e.g.*, Exs. 15: 9, 39, 102, 185, 193, 201, 304, 305, 317, 321, 330, 341, 346, 359, 363, 375, 389, 397, 412, 413, 423, 424, 431). The American Petroleum Institute stated: ''API has concerns about potentials for uncontrolled and unscrupulous use of these data for purposes unrelated to safety and health—uses such as for plaintiff-lawyer ''fishing expeditions'', in union organizing attempts, to create adverse publicity as contracts expire, or to foster other special interests'' (Ex. 15: 375). Several commenters stated that information requests could be used as a harassment by unions (see, *e.g.*, Exs. 15: 9, 201, 317, 423, 424), and the Caterpillar Corporation (Ex. 15: 201) related its labor management difficulties during a recent strike (Ex. 15: 201). The American Crystal Sugar Company (Ex. 15 363) expressed concern that ''there have been instances where an employee is paid a finder's fee to identify possible cases for personal injury lawyers.'' A few commenters suggested methods to solve these potential misuse problems, including a requirement for all information requests to be made in writing (see, *e.g.*, Exs. 15: 163, 235, 281, 397). Two commenters suggested requirements for the employee or employee representative to sign a pledge not to misuse the information (Exs. 15: 359, 389). For example, the Waste

Management, Inc. Company suggested that ''OSHA should require the individual(s) obtaining a copy of the log or record to certify that the information will be maintained in confidence and will not be released to a third party under any circumstances under penalty of law. OSHA shall also promulgate severe penalties for violation'' (Ex. 15: 389).

While there may be instances where employees share the data with third parties who normally would not be allowed to access the data directly, the final rule contains no enforceable restrictions on use by employees or their representatives. Employees and their representatives might reasonably fear that they could be found personally liable for violations of such restrictions. This would have a chilling effect on employees' willingness to use the records for safety and health purposes, since few employees would voluntarily risk such liability. Moreover, despite the concerns of commenters about abuse problems, OSHA has not noted any significant problems of this type in the past. This suggests that, if such problems exist, they are infrequent. In addition, as noted in the privacy discussion above, a prohibition on the use of the data by employees or their representatives is beyond the scope of OSHA's enforcement authority. For these reasons, the employer may not require an employee, former employee or designated employee representative to agree to limit the use of the records as a condition for viewing or obtaining copies of records.

OSHA has added a statement to the Log and Incident Report forms indicating that these records contain information related to employee health and must be used in a manner that protects the confidentiality of employees to the extent possible while the information is used for occupational safety and health purposes. This statement is intended to inform employees and their representatives of the potentially sensitive nature of the information in the OSHA records and to encourage them to maintain employee confidentiality if compatible with the safety and health uses of the information. Encouraging parties with access to the forms to keep the information confidential where possible is reasonable and should not discourage the use of the information for safety and health purposes. OSHA stresses, however, that the statement does not reflect a regulatory requirement limiting the use of records by those with access under sections 1904.35 and 1904.40.

The Records Access Requirement and the ADA

Several commenters alleged that a requirement that individually identifiable injury and illness records be disclosed to employees and union representatives would conflict with the confidentiality provisions of the Americans With Disabilities Act, 42 U.S.C. §§ 12112 (d)(3)(B), (d)(4)(C) (1994 ed. and Supp. III) (ADA) (see, *e.g.*, Exs. 15: 64, 290, 304, 315, 397).

Section 12112(d)(3)(B) of the ADA permits an employer to require a job applicant to submit to a medical examination after an offer of employment has been made but before commencement of employment duties, provided that medical information obtained from the examination is kept in a confidential medical file and not disclosed except as necessary to inform supervisors, first aid and safety personnel, and government officials investigating compliance with the ADA. Section 12112(d)(4)(C) requires that the same confidentiality protection be accorded health information obtained from a voluntary medical examination that is part of an employee health program.

By its terms, the ADA requires confidentiality for information obtained from medical examinations given to prospective employees, and from medical examinations given as part of a voluntary employee health program. The OSHA injury and illness records are not derived from pre-employment or voluntary health programs. The information in the OSHA injury and illness records is similar to that found in workers' compensation forms, and may be obtained by employers by the same process used to record needed information for workers' compensation and insurance purposes. The Equal Employment Opportunity Commission (EEOC) recognizes a partial exception to the ADA's strict confidentiality requirements for medical information regarding an employee's occupational injury or workers' compensation claim. See *EEOC Enforcement Guidance: Workers' Compensation and the ADA*, 5 (September 3, 1996). Therefore, it is not clear that the ADA applies to the OSHA injury and illness records.

Even assuming that the OSHA injury and illness records fall within the literal scope of the ADA's confidentiality provisions, it does not follow that a conflict arises. The ADA states that ''nothing in this Act shall be construed to invalidate or limit the remedies, rights, and procedures of any Federal law. * * *'' 29 U.S.C. 12201(b). In enacting the ADA, Congress was aware that other federal standards imposed requirements for testing an employee's health, and for disseminating information about an employee's medical condition or history, determined to be necessary to preserve the health and safety of employees and the public. See H.R. Rep. No. 101–485 pt. 2, 101st Cong., 2d Sess. 74–75 (1990), *reprinted in* 1990 U.S.C.C.A.N. 356, 357 (noting, *e.g.* medical surveillance requirements of standards promulgated under OSH Act and Federal Mine Safety and Health Act, and stating ''[t]he Committee does not intend for [the ADA] to override any medical standard or requirement established by Federal * * * law * * * that is job-related and consistent with business necessity''). See also 29 CFR part 1630 App. p. 356. The ADA recognizes the primacy of federal safety and health regulations; therefore such regulations, including mandatory OSHA recordkeeping requirements, pose no conflict with the ADA. Cf. *Albertsons, Inc.* v. *Kirkingburg,* 527 U.S. 555, (1999) (''When Congress enacted the ADA, it recognized that federal safety and health rules would limit application of the ADA as a matter of law.'')

The EEOC, the agency responsible for administering the ADA, has recognized both in the implementing regulations at 29 CFR part 1630, and in interpretive guidelines, that the ADA yields to the requirements of other federal safety and health standards. The implementing regulation codified at 29 CFR 1630.15(e) explicitly states that an employer's compliance with another federal law or regulation may be a defense to a charge of violating the the ADA:

> (e) Conflict with other Federal laws. It may be a defense to a charge of discrimination under this part that a challenged action is required or necessitated by another Federal law or regulation, or that another Federal law or regulation prohibits an action (including the provision of a particular reasonable accommodation) that would otherwise be required by this part.

Interpretive guidance provided by the EEOC further underscores this point. The 1992 Technical Assistance Manual on Title I of the ADA states as follows:

> *4.6 Health and Safety Requirements of Other Federal or State Laws*
>
> The ADA recognizes employers' obligations to comply with requirements of other laws that establish health and safety standards. However, the [ADA] gives greater weight to Federal than to state or local law.
>
> 1. Federal Laws and Regulations
>
> The ADA does not override health and safety requirements established under other Federal laws. If a standard is required by another Federal law, an employer must

comply with it and does not have to show that the standard is job related and consistent with business necessity (emphasis added).

U.S. Equal Employment Opportunity Commission, *A Technical Assistance Manual on the Employment Provisions (Title I) of the Americans With Disabilities Act,* IV–16 (1992) (Technical Assistance Manual). The Technical Assistance Manual also states that, while medical-related information about employees must generally be kept confidential, an exception applies where ''[o]ther Federal laws and regulations * * * require disclosure of relevant medical information.'' Assistance Manual at VI–12. See also Assistance Manual at VI–14–15 (actions taken by employers to comply with requirements imposed under the OSH Act are job related and consistent with business necessity). For these reasons, OSHA does not believe that the mandatory employee access provisions of the final recordkeeping rule conflict with the provisions of the ADA.

Times Allowed To Provide Records

In its proposal, OSHA would have required the employer to allow the employee to view the 300 Log and the Form 301 records by the end of the next business day and provide copies within seven calendar days. An employer would have been required to provide access to the 301 forms for all injuries and illnesses ''in a reasonable time'' (61 FR 4061). Several commenters agreed with OSHA's proposed times for providing copies of the records to employees and their representatives (see, *e.g.*, Exs. 15: 213, 277, 359). For example, Consolidated Edison (Ex. 15: 213) stated that ''[t]he time limits in the proposal are acceptable but [Con Ed] recommends that a time limit of seven days be included at [proposed] paragraph 1904.11(b)(5) [which addressed the copying of 301 forms] rather than the vague ''reasonable time'' included in the text.''

A number of commenters disagreed with OSHA's proposed times for providing copies of the records (see, *e.g.*, Exs. 15: 195, 201, 213, 218, 226, 235, 326, 347, 369, 370, 389, 409, 423, 425, 440). These commenters suggested a variety of times, including four hours (Ex. 15: 369), 24 hours (Ex. 15: 425), two workdays (Ex. 15: 226), five working days (Ex. 15: 235), within seven calendar days or one week (Ex. 15: 195, 370), 15 days to match the requirements of the OSHA medical records access rule (Ex. 15: 218, 347, 409, 423), and 21 days (Ex. 15: 389). The International Brotherhood of Teamsters (Ex. 15: 369) suggested that ''[e]mployees and their designated representatives be provided with the same access rule as proposed for governmental officials, RE: obtain copies of logs four hours after the request.''

The Tennessee Valley Authority (TVA) argued that ''[a]ll requests for records should be made in writing and the information provided to the authorized requester within five working days. This provides the documentation for who received the information and reduces the burden on the employer'' (Ex. 15: 235). Bell Atlantic Network Services, Inc. (Ex. 15: 218) recommended that ''OSHA should simplify the very confusing and differing ''access'' and ''copies'' schedule to an uniform 15 working days as is the requirement in 29 CFR 1910.20, Access to Employee Exposure and Medical Records.''

In addition, the Caterpillar Company (Ex. 15: 201) recommended that the final rule should not establish time frames at all, stating that ''The time limit of providing access by the close of business on the next scheduled workday is unnecessarily restrictive. Noncompliance situations could be generated by simple work schedule conflicts or other minor difficulties. The access period should be stated as a reasonable time period allowing employees and employers adequate flexibility.''

Under the final rule, an employer must provide a copy of the 300 Log to an employee, former employee, personal representative or authorized employee representative on the business day following the day on which an oral or written request for records is received. Likewise, when an employee, former employee or personal representative asks for copies of the 301 form for an injury or illness to that employee, the employer must provide a copy by the end of the next business day. OSHA finds that these are appropriate time frames for supplying a copy of the existing forms, which in the case of the Form 301 is a single page. The average 300 Log is also only one page, although employers who have a larger number of occupational injuries and illnesses will have more than one page.

The final rule allows the employer seven business days to provide copies of the OSHA 301 forms for all occupational injuries and illnesses that occur at the establishment. Several commenters stated that there is additional burden for these large requests (see, *e.g.*, Exs. 15: 172, 260, 262, 265, 294, 297, 401). For example, the Boeing Corporation stated that ''[s]ince Boeing is a large employer with several thousand employees at several sites, (up to 30,000 at one site), the administrative burden could be immense, particularly, if large numbers of records are requested by several employees. For example, if 100 employees requested ten thousand 301 forms, one million records would have to be available. This requirement is simply not administratively realistic.'' OSHA agrees that, because these records may involve more copying, the employer needs more time to produce copies of the 301 forms. In addition, as stated in the final rule, the employer may not provide the authorized employee representative with the information on the left side of the 301 form, so the employer needs additional time to redact this information. Because the final rule only provides a right of access to an authorized employee representative (authorized collective bargaining agent), the number of requests should not exceed the number of unions representing employees at the establishment. Thus, the multiple request problem envisioned by Boeing should not surface. In addition, OSHA expects that, in large plants such as the one described by Boeing, the authorized employee representatives will ask for the data on a periodic basis, either monthly or quarterly, so the data requested at one time will be limited. In addition, the employer must provide only one free copy. If additional copies are requested, the employer may charge for the copies.

Charging Employees for Copies of the OSHA Records

The proposal also required the employer to provide copies without cost, or provide access to copying facilities without charge, or allow the employee or representative to take the records off site to make copies (61 FR 4061). Linda Ballas (Ex. 15: 31) commented that the copies should be provided at no cost to the employee. Several commenters stated that employees who access the records should pay for them (see, *e.g.*, Exs. 15: 151, 152, 179, 180, 201, 226, 317, 397, 424). Atlantic Marine, Inc. stated: ''Providing copies of records without cost to individuals may produce an undue administrative and financial burden for some employers. Although there is merit to providing information access to employees, the charging of a fee not to exceed the actual cost for duplicating the documents may deter unnecessary or frivolous requests'' (Ex. 15: 151). The United Parcel Service Company (Ex. 15: 424) stated that:

[i]f expanded access to safety and health records is afforded, certainly such access should not be at the employer's cost. This is an unfair burden on the employer, and will

encourage improper, harassing requests. These risks are not alleviated by the alternative of permitting the employer to give its records to the requesting party to copy, Proposed § 1904.11(b)(3)(iii), 61 Fed. Reg. at 4061, since employers often will be reluctant to entrust their only original copies to a current or former employee. (Ex. 15: 424)

In the final rule, OSHA has implemented the proposed provision requiring employers to provide copies free of charge to employees who ask for the records. The costs of providing copies is a minimal expense, and employees are more likely to access the data if it is without cost. In addition, allowing the employer to charge for copies of the OSHA records would only serve to delay production of the records. Providing free copies for employees thus helps meet one of the major goals of this rulemaking; to improve employee involvement. However, OSHA agrees that there are some circumstances where employers should have the option of charging for records. After receiving an initial, free copy of requested records, an employee, former employee, or designated representative may be charged a reasonable search and copying fee for duplicate copies of the records. However, no fee may be charged for an update of a previously requested record.

Section 1904.37 State Recordkeeping Regulations

Section 1904.37 addresses the consistency of the recordkeeping and reporting requirements between Federal OSHA and those States where occupational safety and health enforcement is provided by an OSHA-approved State Plan. Currently, in 21 States and 2 territories, the State government has been granted authority to operate a State OSHA Plan covering both the private and public (State and local government) sectors under section 18 of the OSH Act (see the State Plan section of this preamble for a listing of these States). Two additional States currently operate programs limited in scope to State and local government employees only. State Plans, once approved, operate under authority of State law and provide programs of standards, regulations and enforcement which must be ''at least as effective'' as the Federal program. (State Plans must extend their coverage to State and local government employees, workers not otherwise covered by Federal OSHA regulations.) Section 1904.37 of the final rule describes what State Plan recordkeeping requirements must be identical to the Federal requirements, which State regulations may be different, and provides cross references to the State Plan regulations codified in Section 1902.3(k), 1952.4, and 1956.10(i). The provisions of Subpart A of 29 CFR part 1952 specify the regulatory discretion of the State Plans in general, and section 1952.4 spells out the regulatory discretion of the State Plans specifically for the recordkeeping regulation.

In the final rule, OSHA has rewritten the text of the corresponding proposed section and moved it into Subpart D of the final rule. Under Section 18 of the OSH Act, a State Plan must require employers in the State to make reports to the Secretary in the same manner and to the same extent as if the Plan were not in effect. Final section 1904.37 makes clear that States with approved State Plans must promulgate new regulations that are substantially identical to the final Federal rule. State Plans must have recording and reporting regulations that impose identical requirements for the recordability of occupational injuries and illnesses and the manner in which they are entered. These requirements must be the same for employers in all the States, whether under Federal or State Plan jurisdiction, and for State and local government employers covered only through State Plans, to ensure that the occupational injury and illness data for the entire nation are uniform and consistent so that statistics that allow comparisons between the States and between employers located in different States are created.

For all of the other requirements of the Part 1904 regulations, the regulations adopted by the State Plans may be more stringent than or supplemental to the Federal regulations, pursuant to paragraph 1952.4(b). This means that the States' recording and reporting regulations could differ in several ways from their Federal Part 1904 counterparts. For example, a State Plan could require employers to keep records for the State, even though those employers are within an industry exempted by the Federal rule. A State Plan could also require employers to keep additional supplementary injury and illness information, require employers to report fatality and multiple hospitalization incidents within a shorter timeframe than Federal OSHA does, require other types of incidents to be reported as they occur, or impose other requirements. While a State Plan must assure that all employee participation and access rights are assured, the State may provide broader access to records by employees and their representatives. However, because of the unique nature of the national recordkeeping program, States must secure Federal OSHA approval for these enhancements.

The final rule eliminates paragraph (b) of section 1904.14 of the proposed rule. Proposed paragraph (b) stated that records maintained under State Plan rules would be considered to be in compliance with the Federal rule. OSHA has eliminated paragraph (b) as unnecessary because it is redundant to state that the records kept under State law will be acceptable; since State regulations must be identical to, or more stringent than the Federal regulations, compliance by private sector employers with approved State laws would by definition constitute compliance with the Federal regulations. Paragraph (c), which deals with public sector recording and reporting requirements in both comprehensive State Plans (those covering both the private and public sector employees) and those which are limited to the public sector (State and local government), has been reworded and moved to 1904.37(b)(3).

Because Federal OSHA does not provide coverage to State and local government employees, the State-Plan States may grant State recordkeeping variances to the State and local governments under their jurisdiction. However, the State must obtain concurrence from Federal OSHA prior to issuing any such variances. In addition, the State-Plan States may not grant variances to any other employers and must recognize all 1904 variances granted by Federal OSHA. These steps are necessary to ensure that the injury and illness data requirements are consistent from State to State.

Rulemaking comments on this issue were unanimous in supporting identical State and Federal regulations for recordkeeping. Multi-State employers and their representatives, such as US West, Lucent Technologies, AT&T, and the National Association of Manufacturers, thought that identical State regulations would simplify and reduce their recordkeeping burdens (see, *e.g.*, Exs. 15: 194, 272, 303, 305, 346, 348, 358, 375).

OSHA understands the advantages to multi-State businesses of following identical OSHA rules in both Federal and State Plan jurisdictions, but also recognizes the value of allowing the States to have different rules to meet the needs of each State, as well as the States' right to impose different rules as long as the State rule is at least as effective as the Federal rule. Accordingly, the Part 1904 rules impose identical requirements where they are needed to create consistent injury and illness statistics for the nation and allows the States to impose

supplemental or more stringent requirements where doing so will not interfere with the maintenance of comprehensive and uniform national statistics on workplace fatalities, injuries and illnesses.

Section 1904.38 Variances From the Recordkeeping Rule

Section 1904.38 of the final rule explains the procedures employers must follow in those rare instances where they request that OSHA grant them a variance or exception to the recordkeeping rules in Part 1904. The rule contains these procedures to allow an employer who wishes to maintain records in a manner that is different from the approach required by the rules in Part 1904 to petition the Assistant Secretary. Section 1904.8 allows the employer to apply to the Assistant Secretary for OSHA and request a Part 1904 variance if he or she can show that the alternative recordkeeping system: (1) Collects the same information as this Part requires; (2) Meets the purposes of the Act; and (3) Does not interfere with the administration of the Act.

The variance petition must include several items, namely the employer's name and address; a list of the State(s) where the variance would be used; the addresses of the business establishments involved; a description of why the employer is seeking a variance; a description of the different recordkeeping procedures the employer is proposing to use; a description of how the employer's proposed procedures will collect the same information as would be collected by the Part 1904 requirements and achieve the purpose of the Act; and a statement that the employer has informed its employees of the petition by giving them or their authorized representative a copy of the petition and by posting a statement summarizing the petition in the same way notices are posted under paragraph 1903.2(a).

The final rule the describes how the Assistant Secretary will handle the variance petition by taking the following steps:

—The Assistant Secretary will offer employees and their authorized representatives an opportunity to comment on the variance petition. The employees and their authorized representatives will be allowed to submit written data, views, and arguments about the petition.

—The Assistant Secretary may allow the public to comment on the variance petition by publishing the petition in the **Federal Register**. If the petition is published, the notice will establish a public comment period and may include a schedule for a public meeting on the petition.

—After reviewing the variance petition and any comments from employees and the public, the Assistant Secretary will decide whether or not the proposed recordkeeping procedures will meet the purposes of the Act, will not otherwise interfere with the Act, and will provide the same information as the Part 1904 regulations provide. If the procedures meet these criteria, the Assistant Secretary may grant the variance subject to such conditions as he or she finds appropriate.

—If the Assistant Secretary grants the variance petition, OSHA will publish a notice in the **Federal Register** to announce the variance. The notice will include the practices the variance allows, any conditions that apply, and the reasons for allowing the variance.

The final rule makes clear that the employer may not use the proposed recordkeeping procedures while the Assistant Secretary is processing the variance petition and must wait until the variance is approved. The rule also provides that, if the Assistant Secretary denies the petition, the employer will receive notice of the denial within a reasonable time and establishes that a variance petition has no effect on the citation and penalty for a citation that has been previously issued by OSHA and that the Assistant Secretary may elect not to review a variance petition if it includes an element which has been cited and the citation is still under review by a court, an Administrative Law Judge (ALJ), or the OSH Review Commission.

The final rule also states that the Assistant Secretary may revoke a variance at a later date if the Assistant Secretary has good cause to do so, and that the procedures for revoking a variance will follow the same process as OSHA uses for reviewing variance petitions. Except in cases of willfulness or where necessary for public safety, the Assistant Secretary will: Notify the employer in writing of the facts or conduct that may warrant revocation of a variance and provide the employer, employees, and authorized employee representatives with an opportunity to participate in the revocation procedures.

The final rule differs somewhat from the variance section of the former rule. The text of the previous rule gave the Bureau of Labor Statistics authority to grant, deny, and revoke recordkeeping variances and exceptions. Under the former rule, applicants were required to petition the Regional Commissioner of the Department of Labor's Bureau of Labor Statistics (BLS) for the region where the establishment was located. Petitions that stretched beyond the regional boundary were referred to the BLS Assistant Commissioner. These responsibilities were transferred to OSHA in 1990 (Memorandum of Understanding between OSHA and BLS, 7/11/90) (Ex. 6), but the variance section of the rule itself was not amended at that time. This section of the final rule codifies the shift in responsibilities from the BLS to OSHA with regard to variances.

Like the former variance section of the rule, the final rule does not specifically note that the states operating OSHA-approved state plans are not permitted to grant recordkeeping variances. Paragraph (b) of former section 1952.4, OSHA's rule governing the operation of the State plans, prohibited the states from granting variances, and paragraph (c) of that rule required the State plans to recognize any Federal recordkeeping variances. The same procedures continue to apply to variances under section 1904.37 and section 1952.4 of this final rule. OSHA has not included the provisions from these two sections in the variance sections of this recordkeeping rule, because doing so would be repetitive.

The final rule adds several provisions to those of the former rule. They include (1) the identification of petitioning employers' pending citations in State plan states, (2) the discretion given to OSHA not to consider a petition if a citation on the same subject matter is pending, (3) the clarification that OSHA may provide additional notice via the **Federal Register** and opportunity for comment, (4) the clarification that variances have only prospective effect, (5) the opportunity of employees and their representatives to participate in revocation procedures, and (6) the voiding of all previous variances and exceptions.

Variance procedures were not discussed in the *Recordkeeping Guidelines* (Ex. 2), nor have there been any letters of interpretations or OSHRC or court decisions on recordkeeping variances. As noted in the proposal, at 61 FR 4039, only one recordkeeping variance has ever been granted by OSHA. This variance was granted to AT&T and subsequently expanded to its Bell subsidiaries to enable them to centralize records maintenance for workers in the field.

The final rule does not adopt the approach to variances proposed by OSHA in 1996 (see section 1904.15 of the proposal). OSHA proposed to eliminate the variance and exception procedure from the recordkeeping rules

altogether and instead to require all variances and exceptions to the recordkeeping rule to be processed under OSHA's general variance regulations, which are codified at 29 CFR Part 1905. As stated in the proposal, OSHA believed that this change would streamline the final recordkeeping rule and eliminate duplicate procedures for obtaining variances. OSHA also proposed to amend paragraph 1952.4(c) to make clear that employers were required to obtain all recordkeeping variances or exceptions from OSHA instead of from the BLS.

OSHA received very few comments on the proposed changes to the variance procedures. Some commenters approved the proposed approach but did not comment on its merits (see, *e.g.*, Exs. 15: 133, 136, 137, 141, 224, 266, 278). The International Dairy Foods Association (IDFA) supported the change if ''it is indeed * * * a duplicative section'' and ''no significant change will occur by deleting the provision'' (Ex. 15: 203). Another commenter stated that ''no employer should be exempt from record keeping and I cannot imagine what kind of variance for record keeping exceptions could exist. I am requesting that this proposal be removed from the standard'' (Ex. 15: 62). The Air Transport Association urged ''OSHA * * * [to] permit [airline] companies to keep records according to location or division * * * and without the need to seek and acquire variances, so long as records can be retrieved in a reasonable time for OSHA oversight purposes'' (Ex. 15: 378).

OSHA has decided, after further consideration, to continue to include a specific recordkeeping variance section in the final rule, and not to require employers who wish a recordkeeping variance or exception to follow the more rigorous procedures in 29 CFR part 1905. The procedures in Part 1905, which were developed for rules issued under sections 6 and 16 of the OSH Act, may not be appropriate for rules issued under section 8 of the Act, such as this recordkeeping rule.

The final rule thus retains a section on variance procedures for the recordkeeping rule. OSHA believes that few variances or exceptions will be granted under the variance procedures of the final rule because other provisions of the final rule already reflect many of the alternative recordkeeping procedures that employers have asked to use over the years, such as electronic storage and transmission of data, centralized record maintenance, and the use of alternative recordkeeping forms. Because these changes have been made to other sections of the final rule, there should be little demand for variances or exceptions. As OSHA noted in the proposal (61 FR 4039) in relation to the AT&T variance, ''[t]he centralization of records provision contained in this proposal [and subsequently adopted in the final rule] will eliminate the continued need for this variance.'' Similarly, the changes in paragraphs 1904.3(e) and (f) of the final rule that permit substitute forms and computerization of recordkeeping by employers, combined with the changes in paragraph 1904.30(c) that allow for recordkeeping at a central location will accommodate the Air Transport Association's request that OSHA ''permit airline companies to keep records according to location or division * * * without the need to seek and acquire variances'' (Ex. 15: 378). Under the final rule, companies are still required to summarize their injury and illness records for individual establishments, but may also produce records for separate administrative units if they wish to do so. Centralized and computerized recordkeeping systems make this a relatively simple task when compared to paper-driven and decentralized systems.

The final changes to the variance section of the former rule are minor. The primary change is to make clear that OSHA, rather than the BLS, has the responsibility for granting recordkeeping variances or exceptions. The other changes reflected in the final rule follow from the proposed rule and are intended to add several provisions from OSHA's general variance procedures in Part 1905. For example, paragraph (e) of section 1904.38 of the final rule is a modification of § 1905.11(b)(8), and paragraph (i) of this section of the final rule derives from section 1905.5. The objective of this paragraph is to give OSHA discretionary authority to decline to act on a petition where the petitioner has a pending citation. OSHA concludes that it would not be appropriate to consider granting a recordkeeping variance to an employer who has a pending recordkeeping violation before OSHRC or a State agency.

Paragraph (i) of the final rule supports paragraph (c)(7) from this same section because it provides a mechanism for giving OSHA notice of a citation pending before a state agency. Paragraph (i) also clarifies that variances only apply to future events, not to past practices. Paragraph (j) of section 1904.38 of the final rule nullifies all prior variances and exceptions. OSHA believes that it is important to begin with a ''clean slate'' when the final recordkeeping rule goes into effect. Employers with existing variances can re-petition the agency if the final rule does not address their needs. Another addition to the final rule makes explicit that OSHA can provide additional public notice via the **Federal Register** and may offer additional opportunity for public comment. A final addition recognizes and makes clear that employees can participate in variance revocation proceedings.

Subpart E. Reporting Fatality, Injury and Illness Information to the Government

Subpart E of this final rule consolidates those sections of the rule that require employers to give recordkeeping information to the government. In the proposed rule, these sections were not grouped together. OSHA believes that grouping these sections into one Subpart improves the overall organization of the rule and will make it easier for employers to find the information when needed. The four sections of this subpart of the final rule are:

(a) Section 1904.39, which requires employers to report fatality and multiple hospitalization incidents to OSHA.

(b) Section 1904.40, which requires an employer to provide his or her occupational illness and injury records to a government inspector during the course of a safety and health inspection.

(c) Section 1904.41, which requires employers to send their occupational illness and injury records to OSHA when the Agency sends a written request asking for specific types of information.

(d) Section 1904.42, which requires employers to send their occupational illness and injury records to the Bureau of Labor Statistics (BLS) when the BLS sends a survey form asking for information from these records.

Each of these sections, and the record evidence pertaining to them, is discussed below.

Section 1904.39 Reporting Fatality or Multiple Hospitalization Incidents to OSHA

Paragraph (a) of section 1904.39 of the final rule requires an employer to report work-related events or exposures involving fatalities or the in-patient hospitalization of three or more employees to OSHA. The final rule requires the employer, within 8 hours after the death of any employee from a work-related incident or the in-patient hospitalization of three or more

employees as a result of a work-related incident, to orally report the fatality/multiple hospitalization by telephone or in person to the Area Office of the Occupational Safety and Health Administration (OSHA), or to OSHA via the OSHA toll-free central telephone number, 1–800–321–6742.

The final rule makes clear in paragraph 1904.39(b)(1) that an employer may not report the incident by leaving a message on OSHA's answering machine, faxing the Area Office, or sending an e-mail, but may report the fatality or multiple hospitalization incident using the OSHA 800 number. The employer is required by paragraph 1904.39(b)(2) to report several items of information for each fatality or multiple hospitalization incident: the establishment name, the location of the incident, the time of the incident, the number of fatalities or hospitalized employees, the names of any injured employees, the employer's contact person and his or her phone number, and a brief description of the incident.

As stipulated in paragraph 1904.39(b)(3), the final rule does not require an employer to call OSHA to report a fatality or multiple hospitalization incident if it involves a motor vehicle accident that occurs on a public street or highway and does not occur in a construction work zone. Employers are also not required to report a commercial airplane, train, subway or bus accident (paragraph 1904.39(b)(4)). However, these injuries must still be recorded on the employer's OSHA 300 and 301 forms, if the employer is required to keep such forms. Because employers are often unsure about whether they must report a fatality caused by a heart attack at work, the final rule stipulates, at paragraph 1904.39(b)(5), that such heart attacks must be reported, and states that the local OSHA Area Office director will decide whether to investigate the incident, depending on the circumstances of the heart attack.

Paragraph 1904.39(b)(6) of the final rule clarifies that the employer is not required to report a fatality or hospitalization that occurs more than thirty (30) days after an incident, and paragraph 1904.39(b)(7) states that, if the employer does not learn about a reportable incident when it occurs, the employer must make the report within 8 hours of the time the incident is reported to the employer or to any of the employer's agents or employees.

Section 1904.39 of the final rule includes several changes from the proposed rule and section 1904.17 of the former rule. First, OSHA has rewritten the requirements of the former rule using the same plain-language question-and-answer format that is used throughout the rest of the rule. Second, this section clarifies that the report an employer makes to OSHA on a workplace fatality or multiple hospitalization incident must be an oral report. As the regulatory text makes clear, the employer must make such reports to OSHA by telephone (either to the nearest Area Office or to the toll-free 800 number) or in person. Third, the employer may not merely leave a message at the OSHA Area Office; instead, the employer must actually speak to an OSHA representative. Fourth, this section of the rule lists OSHA's 800 number for the convenience of employers and to allow flexibility in the event that the employer has difficulty reaching the OSHA Area Office. Fifth, this section eliminates the former requirement that employers report fatalities or multiple hospitalizations that result from an accident on a commercial or public transportation system, such as an airplane accident or one that occurs in a motor vehicle accident on a public highway or street (except for those occurring in a construction work zone, which must still be reported).

OSHA's proposal would have made three changes to the former rule: (1) it would have clarified the need for employers to make oral reports, (2) it would have included OSHA's 800 number in the text of the regulation, and (3) it would have required a site-controlling employer at a major construction site to report a multiple hospitalization incident if the injured workers were working at that site under the control of that employer.

A number of commenters supported all three of these proposed changes (see, *e.g.*, Exs. 15: 133, 136, 137, 141, 204, 224, 266, 278, 369, 378, 429). However, many commenters discussed the changes OSHA proposed, raised additional issues not raised in the proposal, and made various suggestions for the final rule. Comments are discussed below for each of the proposed changes.

Making oral reports of fatalities or multiple hospitalization incidents and the OSHA 800 number. The former rule required an employer to ''orally report'' fatality or multiple hospitalization incidents to OSHA by telephone or in person, although the rule did not specify that messages left on the Area Office answering machine or sent by e-mail would not suffice. Since the purpose of this notification is to alert OSHA to the occurrence of an accident that may warrant immediate investigation, such notification must be made orally to a ''live'' person. The changes made to the final rule are consistent with those proposed, except that the proposal would have required employers to report to the Area Office either by telephone or in person during normal business hours and to limit use of the toll-free 800 number to non-business hours.

A few commenters suggested ways for OSHA to make the 800 number more available to employers and to ensure that reports are made orally (see, *e.g.*, Exs. 15: 9, 154, 203, 229, 238, 239, 389). For example, the National Pest Control Association suggested that:

> [t]he agency print OSHA's emergency toll free number on the OSHA 300 and 301 forms and explain that employers are to call the number in the case of a fatality or multiple hospitalization during non-business hours. We would also urge OSHA to define ''non-business'' hours both in the regulatory text and on the forms (Ex. 15: 229).

Waste Management, Inc. (WMI) (Ex. 15: 389) recommended full reliance on the 800 number, proposing that:

> [t]he 800 number be used at all times. A recent event entailing an attempt to report to the local area office illustrates the difficulty in complying with this proposal. The caller was away from the office out-of-town and attempted to rely on information obtained from the local telephone information service. No local OSHA telephone number was identified as the local emergency number. The city had multiple area offices and telephone numbers without adequate identification at the telephone company information desk. The local number which was finally identified as the local OSHA emergency number could not be accessed from outside the calling area even if the caller was willing to pay the charges. After numerous calls and involvement of several levels of telephone management, the normal business day was completed and so the 800 number in Washington was called. The use of a single, nationwide 800 number has worked for EPA and other agencies. WMI believes it would simplify reporting requirements and ensure more timely reporting.

Houston Lighting and Power (Ex. 15: 239) suggested that OSHA allow employers to report either to the local OSHA Office or to the 800 number:

> [r]eporting of an incident either to the nearest Area Office or through the use of the 1–800 number should be available alternatives to the reporting requirement. The proposal limits when the 1–800 number may be used. In many cases the person reporting the incident may not be at the incident site. It is much more efficient to use a number that does not change from location to location than to attempt to identify each area office.

Tri/Mark Corporation (Ex. 15: 238) asked about reporting using fax or e-mail: ''If a live person is available to answer the 800 number, there is no

problem with this item. Could a fax or e-mail message be an appropriate notification tool?''

It is essential for OSHA to speak promptly to any employer whose employee(s) have experienced a fatality or multiple hospitalization incident to determine whether the Agency needs to begin an investigation. Therefore, the final rule does not permit employers merely to leave a message on an answering machine, send a fax, or transmit an e-mail message. None of these options allows an Agency representative to interact with the employer to clarify the particulars of the catastrophic incident. Additionally, if the Area Office were closed for the weekend, a holiday, or for some other reason, OSHA might not learn of the incident for several days if electronic or facsimile transmission were permitted. Paragraph 1904.39(b)(1) of the final rule makes this clear.

As noted, OSHA allows the employer to report a fatality or multiple hospitalization incident by speaking to an OSHA representative at the local Area Office either on the phone or in person, or by using the 800 number. This policy gives the employer flexibility to report using whatever mechanism is most convenient. The employer may use whatever method he or she chooses, at any time, as long as he or she is able to speak in person to an OSHA representative or the 800 number operator. Therefore, there is no need to define business hours or otherwise add additional information about when to use the 800 number; it is always an acceptable option for complying with this reporting requirement.

This final rule also includes the 800 number in the text of the regulation. OSHA has decided to include the number in the regulatory text at this time to provide an easy reference for employers. OSHA will also continue to include the 800 number in any interpretive materials, guidelines or outreach materials that it publishes to help employers comply with the reporting requirement.

Reporting by a site-controlling employer at a major construction site. The proposed rule would have required a ''site controlling employer or designee'' to report a case to OSHA ''if no more than two employees of a single employer were hospitalized but, collectively, three or more workers were hospitalized as in-patients.'' This provision was designed to capture those cases where three or more employees of different employers were injured and hospitalized in a single incident. Because a site-controlling employer was defined in the proposed rule as a construction firm with control of a project valued at $1,000,000 or more, the proposed rule would have applied only to those employers. Under the former rule, employers only needed to report if three of their own employees were hospitalized.

A number of commenters opposed the proposed change (see, *e.g.*, Exs. 25, 15: 9, 126, 199, 289, 305, 312, 335, 346, 356, 389, 406, 420). Several commenters argued that the provision would be unworkable because individual employers often do not know about the post-accident condition of the injured employees of other employers (see, *e.g.*, Exs. 15: 126, 346). Other commenters objected to placing the burden of such reporting on the general contractor on a construction site rather than on the individual employers of the affected employees (see, *e.g.*, Exs. 15: 312, 356). Still other commenters noted that, since the term ''site-controlling employer'' is defined by OSHA as an employer in the construction industry, this provision would have no apparent application in multi-employer settings outside the construction industry (see, *e.g.*, Exs. 15: 199, 335, 346).

After considering the issue further, OSHA agrees that it would be impractical to impose on one employer a duty to report cases of multiple hospitalizations of employees who work for other employers. Although such a reporting requirement would provide OSHA with information that the Agency could use to inspect some incidents that it might otherwise not know about, OSHA believes that the fatality and catastrophe provisions of the final rule will capture most such incidents. Accordingly, OSHA has not included this proposed provision in the final rule.

Eight hours to report. A number of commenters asked OSHA to extend the 8-hour period allowed for employers to report a fatality or a multiple hospitalization incident to OSHA. Most of the commenters who believe that this interval is too short recommended a 24- or 48-hour reporting time (see, *e.g.*, Exs. 33, 15: 35, 37, 176, 203, 218, 229, 231, 273, 301, 335, 341, 423, 425). For example, the International Dairy Foods Association (IDFA) (Ex. 15: 203) recommended that ''the reporting period be extended from 8 hours to 24 hours after the event. We feel this is appropriate because the resultant devastation in this type of situation would clearly overshadow the need to inform OSHA of an event that, with all due respect, could not be remedied by reporting it within 8 hours or less.'' The American Health Care Association (AHCA) (Ex. 15: 341) stated:

> [r]eporting workplace fatalities or multiple employee hospitalization within 8 hours is unrealistic and unreasonable because the employer's first concern should be to the employee(s) injured or killed, his/her family or damage to the building when others may be in imminent danger (*e.g.*, a fire in a health care facility may require evacuating and finding alternative placement for frail, elderly residents). AHCA recommends that OSHA revise the regulation by extending the time period for reporting fatalities or hospitalization of 3 or more employees to ''within 48 hours.''

After considering these comments, and reviewing the comments received during the comment period for the April 1, 1994 rulemaking on this issue (59 FR 15594–15600), OSHA has decided to continue the 8-hour requirement. The 1994 rulemaking noted the support of many commenters for the 8-hour rule, as well as support for 4-hours, 24 hours, and 48 hours. As OSHA discussed in the April 1, 1994 rulemaking, prompt reporting enables OSHA to inspect the site of the incident and interview personnel while their recollections are immediate, fresh and untainted by other events, thus providing more timely and accurate information about the possible causes of the incident. The 8-hour reporting time also makes it more likely that the incident site will be undisturbed, affording the investigating compliance officer a better view of the worksite as it appeared at the time of the incident. Further, from its enforcement experience, OSHA is not aware that employers have had difficulty complying with the 8-hour reporting requirement.

Motor vehicle and public transportation accidents. Several commenters recommended that OSHA not require employers to report to OSHA fatalities and multiple hospitalization catastrophes caused by public transportation accidents and motor vehicle accidents (see, *e.g.*, Exs. 33, 15: 176, 199, 231, 272, 273, 301, 303, 375). The comments of NYNEX (Ex. 15: 199) are typical:

> [t]he primary purpose of this section is to provide OSHA with timely information necessary to make a determination whether or not to investigate the scene of an incident. To NYNEX's knowledge, OSHA has not investigated public transportation accidents or motor vehicle accidents occurring on public streets or highways. In order to reduce unnecessary costs for both employers and OSHA, NYNEX recommends that fatalities and multiple hospitalizations resulting from these types of accidents be exempt from the reporting requirement.

OSHA agrees with these commenters that there is no need for an employer to report a fatality or multiple hospitalization incident when OSHA is

clearly not going to make an investigation. When a worker is killed or injured in a motor vehicle accident on a public highway or street, OSHA is only likely to investigate the incident if it occurred in a highway construction zone. Likewise, when a worker is killed or injured in an airplane crash, a train wreck, or a subway accident, OSHA does not investigate, and there is thus no need for the employer to report the incident to OSHA. The text of paragraphs 1904.39(b)(3) and (4) of the final rule clarifies that an employer is not required to report these incidents to OSHA. These incidents are normally investigated by other agencies, including local transit authorities, local or State police, State transportation officials, and the U.S. Department of Transportation.

However, although there is no need to *report* these incidents to OSHA under the 8-hour reporting requirement, any fatalities and hospitalizations caused by motor vehicle accidents, as well as commercial or public transportation accidents, are *recordable* if they meet OSHA's recordability criteria. These cases should be captured by the Nation's occupational fatality and injury statistics and be included on the employer's injury and illness forms. The statistics need to be complete, so that OSHA, BLS, and the public can see where and how employees are being made ill, injured and killed. Accordingly, the final rule includes a sentence clarifying that employers are still required to record work-related fatalities and injuries that occur as a result of public transportation accidents and injuries.

Although commenters are correct that OSHA only rarely investigates motor vehicle accidents, the Agency does investigate motor vehicle accidents that occur at street or highway construction sites. Such accidents are of concern to the Agency, and OSHA seeks to learn new ways to prevent these accidents and protect employees who are exposed to them. For example, OSHA is currently participating in a Local Emphasis Program in the State of New Jersey that is designed to protect highway construction workers who are exposed to traffic hazards while performing construction work. Therefore, the final rule provides provisions that require an employer to report a fatality or multiple hospitalization incident that occurs in a construction zone on a public highway or street.

Other issues related to the reporting of fatalities and multiple hospitalization incidents. Commenters also raised several issues not addressed in the proposed rule. The National Pest Control Association (NPCA) (Ex. 15: 229) asked OSHA to allow for a longer reporting time in those rare cases where the owner of a small business was himself or herself incapacitated in the accident, suggesting that:

> [l]anguage be included in the rule revisions to provide for additional time to report fatalities and multiple hospitalizations if the employer is hospitalized or otherwise incapacitated. * * * Typically, pest control companies are very small operations. Many employ five or less employees. Often times the business owner is out in the field as much as the employees. So, let's say an employer is hospitalized during a work-related incident that also claimed the life of an employee, who happened to be the lone employee. Can the employer really be expected to report the fatality within eight hours? In most instances the eight hour requirement is rather reasonable, however, in this circumstance it is not. NPCA asks that the agency consider adding language allowing small employers who are hospitalized additional time to report a multiple hospitalization or fatality.

OSHA has decided that there is no need to include language to address this very rare occurrence. If such an unfortunate event were to occur, OSHA would certainly allow a certain amount of leeway for the employer or a representative to report the case. The OSHA inspector can, for good cause, provide the employer with reasonable relief from citation and penalty for failing to report the incident within 8 hours, especially if the employer reports it as soon as possible.

Bell Atlantic (Ex. 15: 218) and the Dow Chemical Company (Ex. 15: 335) recommended that OSHA include additional provisions for employees who are admitted to the hospital for observation only. Bell Atlantic's comments were: ''Bell Atlantic also recommends that the hospitalization requirement [for reporting multiple hospitalizations] be limited to those workers that are hospitalized overnight for treatment. The current proposal does not address hospitalization for observation, only that they are non-recordable.''

OSHA disagrees with these comments, as it did when similar comments were submitted to the record in the 1994 rulemaking on this provision [59 FR 15596–15597]. If three or more workers are hospitalized overnight, whether for treatment or observation, the accident is clearly of a catastrophic nature, and OSHA needs to learn about it promptly. Additionally, the inpatient distinction provides an easy-to-understand trigger for reporting. In many instances, a patient who is admitted for observation as an inpatient later receives treatment after the true nature and extent of the injury becomes known. At the time of the incident, when reporting is most useful, the employer is unlikely to know the details about the treatment that the worker is receiving (*e.g.*, observation only or medical treatment). However, the employer will probably know that the employee has been admitted to the hospital as an inpatient.

The United Parcel Service (UPS) (Ex. 15: 424) suggested that the 8-hour time period for reporting apply only when a higher ranking official of the company learns of the fatality or catastrophe, stating:

> [U]PS supports this proposal, with one modification: the provision that the eight-hour limit begins to run on notice to an employee or agent is over broad. It may happen that workers who learn of the death or hospitalization of a co-worker do not notify the employer in sufficient time to enable the manager in charge of contacting OSHA to meet the deadline. The better rule, therefore, is to require OSHA modification within eight hours of the incident's being reported to a supervisor, manager, or company official. This allowance is particularly necessary for incidents occurring away from the work site.

The issue of who within the company must learn of the incident before the reporting deadline was also discussed in the 1994 rulemaking [59 FR 15597]. As in the former rule, the final rule requires reporting within 8 hours of the time any agent or employee of the employer becomes aware of the incident. It is the employer's responsibility to ensure that appropriate instructions and procedures are in place so that corporate officers, managers, supervisors, medical/health personnel, safety officers, receptionists, switchboard personnel, and other employees or agents of the company who learn of employee deaths or multiple hospitalizations know that the company must make a timely report to OSHA.

Section 1904.40 Providing Records to Government Representatives

Under the final rule, employers must provide a complete copy of any records required by Part 1904 to an authorized government representative, including the Form 300 (Log), the Form 300A(Summary), the confidential listing of privacy concern cases along with the names of the injured or ill privacy case workers, and the Form 301 (Incident Report), when the representative asks for the records during a workplace safety and health inspection. This requirement is unchanged from the corresponding requirement in OSHA's former recordkeeping rule. However, the

former rule combined the requirements governing both government inspectors' and employers' rights of access to the records into a single section, section 1904.7 ''Access to Records.'' The final rule separates the two. It places the requirements governing access to the records by government inspectors in Subpart E, along with other provisions requiring employers to submit their occupational injury and illness records to the government or to provide government personnel access to them. Provisions for employee access to records are now in section 1904.35, Employee Involvement, in Subpart D of this final rule.

The final regulatory text of paragraph (a) of section 1904.40 requires an employer to provide an authorized government representative with records kept under Part 1904 within four business hours. As stated in paragraph 1904.40(b)(1), the authorized government representatives who have a right to obtain the Part 1904 records are a representative of the Secretary of Labor conducting an inspection or investigation under the Act, a representative of the Secretary of Health and Human Services (including the National Institute for Occupational Safety and Health (NIOSH) conducting an investigation under Section 20(b) of the Act, or a representative of a State agency responsible for administering a State plan approved under section 18 of the Act. The government's right to ask for such records is limited by the jurisdiction of that Agency. For example, a representative of an OSHA approved State plan could only ask for the records when visiting an establishment within that state.

The final rule allows the employer to take into account difficulties that may be encountered if the records are kept at a location in a different time zone from the establishment where the government representative has asked for the records. If the employer maintains the records at a location in a different time zone, OSHA will use the business hours of the establishment at which the records are located when calculating the deadline, as permitted by paragraph 1904.40(b)(2).

The former rule. Paragraph 1904.7(a) of the former OSHA recordkeeping rule required employers to provide authorized government representatives with access to the complete Form 200, without the removal of any information (unredacted). That paragraph read as follows:

> Each employer shall provide, upon request, records provided for in §§ 1904.2, 1904.4, and 1904.5, for inspection and copying by any representative of the Secretary of Labor for the purpose of carrying out the provisions of the Act, and by representatives of the Secretary of Health, Education, and Welfare during any investigation under section 20(b) of the Act, or by any representative of a State accorded jurisdiction for occupational safety and health inspections or for statistical compilation under sections 18 and 24 of the Act.

The proposal. The proposed regulation was consistent with OSHA's former recordkeeping regulation in that it continued to require employers to provide government representatives with access to the entire OSHA injury and illness Log and Summary (Forms 300 and 300A) and OSHA Incident Record (Form 301). Proposed paragraph 1904.11(a), ''Access to Records,'' read as follows:

> *Government Representatives.* Each employer shall provide, upon a request made in person or in writing, copies of the OSHA Forms 300 and 301 or equivalents, and year-end summaries for their own employees, and injury and illness records for ''subcontractor employees'' as required under this Part to any authorized representative of the Secretary of Labor or Secretary of Health and Human Services or to any authorized representative of a State accorded jurisdiction for occupational safety and health for the purposes of carrying out the Act.
>
> (1) When the request is made in person, the information must be provided in hard copy (paper printout) within 4 hours. If the information is being transmitted to the establishment from some other location, using telefax or other electronic transmission, the employer may provide a copy to the government representative present at the establishment or to the government representative's office.
>
> (2) When the request is made in writing, the information must be provided within 21 days of receipt of the written request, unless the Secretary requests otherwise.

The proposal thus would have continued to combine the records access provisions for government personnel with the access provisions for employees, former employees and employee representatives. The proposed rule would have modified the former rule in several ways, however (61 FR 4038). First, it would have required the employer to provide copies of the forms, while the former rule simply required the employer to provide records for inspection and copying. Second, the proposal would have required the employer to produce the records within 4 hours, while the former rule did not specify any time period. Third, the proposed rule would have allowed an employer either to provide the records at the inspection location, or to fax the records to the government inspector's home office. This would allow employers to keep their records at a centralized location as long as the government inspector could obtain the information promptly. Fourth, the proposed rule would have required the employer to send Part 1904 information to OSHA within 21 days of the date on which a written request was received from the Agency. This time limit for mailed survey forms was established in section 1904.17 of the former rule and is carried forward in this final rule at section 1904.40.

The proposal also requested comment on situations where the 4-hour requirement might be infeasible and posed several questions for the public to consider:

> OSHA solicits input on these time limitations. Are they reasonable? Should they be shortened or extended? Should the requirement be restricted to business hours, and if so, to the business hours of the establishment to which the records pertain or the establishment where the records are maintained?

Many commenters agreed with OSHA that government representatives should have access to the records themselves (see, *e.g.*, Exs. 15: 78, 163, 218, 359, 369, 405). For example, Alliant Techsystems remarked ''[c]opies of this data should be given to OSHA personnel'' (Ex. 15: 78). A number of commenters agreed that OSHA personnel should have access to the OSHA 301 records, even though they did not think that employees and their representatives should have access to the Form 301 (see, *e.g.*, Exs. 33, 15: 1, 39, 76, 82, 83, 159, 183, 185, 193, 226, 330, 335, 338, 359, 373, 383, 385, 389, 399, 409, 423). For example, the American Meat Institute (AMI) (Ex. 15: 330) ''[b]elieves that it is imperative that personal identifiers be explicitly excluded from information that would be readily available to anyone, with the single exception of an interested government regulator.'' The Texas Chemical Council (Ex. 15: 159) argued: ''[L]ogs with employees'' names should only be accessed by selected individuals (i.e., OSHA inspectors, medical personnel, etc.). Posting or viewing of OSHA 300 log or 301 reports without names should be the avenue for employees to access information.''

Other commenters disagreed with one or more of the proposed access provisions (see, *e.g.*, Exs. 25, 27, 15: 13, 22, 39, 60, 82, 100, 102, 105, 111, 117, 119, 124, 139, 142, 154, 170, 174, 181, 182, 183, 193, 215, 239, 258, 277, 294, 297, 305, 313, 315, 317, 318, 346, 347, 352, 353, 359, 375, 378, 390, 392. 393, 395, 397, 399, 409, 425, 430, 440.) These commenters raised a wide range of issues. These included the right of OSHA inspectors to access the records; employers' Fourth Amendment rights; the way the government handles

information in its possession; employee privacy concerns; and the proposed requirement to produce the records within 4 hours. On the right of OSHA inspectors to access the records, for example, the Douglas Battery Manufacturing Company (Ex. 15: 82) stated:

> [n]one of these records should be * * * used to conduct an OSHA compliance inspection. Such action would be in direct conflict with the purpose of the OSHA log which is to track injury and illness trends so corrective action can be taken by the employer.

OSHA does not agree with this view, because government inspectors conducting workplace safety and health inspections need these records to carry out the purposes of the Act, i.e., to identify hazards that may harm the employees working there. The Part 1904 records provide information about how workers are injured or made ill at work and help guide the inspector to the hazards in the workplace that are causing injury and illness. Although these records may not cover all hazards that exist in a particular workplace, they help the inspector to identify hazards more completely during an inspection.

Fourth amendment issues. A number of commenters argued that the regulatory requirement to provide records to a government inspector violated Fourth Amendment guarantees against unreasonable searches and the right to demand a warrant or subpoena before the government can search a citizen's property (see, *e.g.*, Exs. 25, 27, 15: 124, 139, 154, 174, 193, 215, 258, 305, 315, 318, 346, 375, 390, 392 395, 397). For example, the Workplace Safety and Health Council (Ex. 15: 313) stated:

> [t]his provision would require employers to give OSHA a copy of a Form 300 and 301. This proposal flies in the face of court decisions holding that employers may not be penalized for declining to provide current Form 101 upon request and that, to gain access to them, OSHA must proceed by subpoena or inspection warrant. Secretary v. Taft Broadcasting Co., 849 F.2d 990 (6th Cir. 1988); *Brock* v. *Emerson Electric Co.,* 834 F.2d 994 (11th Cir. 1987). These decisions are based on an employer's constitutional rights and they are not subject to change by OSHA regulation.

These commenters appear to be arguing that including a subpoena or warrant enforcement mechanism in the text of the rule is necessary to adequately protect their Fourth Amendment right to privacy. This is not the case, however. The Fourth Amendment protects against ''unreasonable'' intrusions by the government into private places and things. Reporting rules that do not depend on subpoena or warrant powers are not ''unreasonable'' per se. *See e.g., California Bankers Ass'n* v. *Shultz,* 416 U.S. 21, 67 (1974) (upholding reporting regulation issued under the Bank Secrecy Act of 1970 that did not provide for subpoenas or warrants where the ''information was sufficiently described and limited in nature and sufficiently related to a tenable Congressional determination'' that the information would have a high degree of usefulness in criminal, tax, or regulatory investigations or proceedings).

In any event, the text of the rule is silent as to the enforcement mechanism OSHA will use in what OSHA hopes will be the rare case in which an employer does not provide a copy of the records on request. OSHA may proceed by applying for a warrant, or by administrative subpoena, or by citation where doing so is consistent with the Fourth Amendment. OSHA notes that employers have a Fourth Amendment right to require a warrant before an OSHA representative may physically enter a business establishment for an inspection.

The totality of circumstances surrounding a warrantless or ''subpoena-less'' administrative investigation or investigation program determines its reasonableness. For example, in *McLaughlin* v. *A.B. Chance,* 842 F.2d at 727 (4th Cir. 1988), the Fourth Circuit upheld a records access citation against an employer who refused an OSHA inspector access to its OSHA Logs and forms on the ground that it had a right to insist on a warrant or subpoena; the Court held that the inspector had such a right because a summary of the information was posted annually on the employee bulletin board and the inspector was lawfully on the premises to investigate a safety complaint. In *New York* v. *Burger,* 482 U.S. 691, 702–703 (1987), the Supreme Court noted that agencies may gather information without a warrant, subpoena, or consent if the information would serve a substantial governmental interest, a warrantless (or subpoena-less) inspection is necessary to further the regulatory scheme, and the agency acts pursuant to an inspection program that is limited in time, place, and scope. The *Burger* court upheld a warrantless inspection of records during an administrative inspection of business premises. See also *Kings Island* (noting that under *Burger* a warrantless or subpoena-less inspection of records might be reasonable, but concluding that the facts of the case did not satisfy *Burger* analysis); *Emerson Electric* (noting that under *California Bankers* an agency may gain access to information without a subpoena or warrant but concluding that the facts of that case were not comparable to those reviewed in *California Bankers*).

Given that some warrantless and subpoena-less searches during an OSHA inspection may be reasonable while others may not, depending on the circumstances of the individual inspection, OSHA has decided not to include a subpoena or warrant enforcement mechanism in the text of the rule. However, OSHA will continue to enforce the rule within the parameters of applicable court decisions.

Privacy of medical records. A number of commenters questioned the right of the government to access information in the records because of privacy concerns about medical records (see, *e.g.*, Exs. 27, 15: 13, 22, 39, 60, 82, 117, 119, 142, 183, 359, 378, 392, 399.) The National Association of Manufacturers (NAM) (Ex. 15: 142) stated that ''[t]he privacy interference as proposed that opens up medical records to most anyone is inconceivable, and should be eliminated.'' The National Oilseed Processors Association (Ex. 15: 119) recommended:

> [t]he issue of privacy is an important one that should be handled carefully and with sensitivity to individual rights. We believe that the release of medical records of a specific employee should only be done after the employee whose records may be released has provided written permission to the employer to do so.

This section of the final rule does not give unfettered access to the records by the public, but simply allows a government inspector to use the records during the course of a safety and health inspection. As discussed above in the section covering access to the records for employees, former employees, and employee representatives (Section 1904.35), OSHA does not consider the Forms 300 and 301 to be medical records, for the following reasons. First, they do not have to be completed by a physician or other licensed health care professional. Second, they do not contain the detailed diagnostic and treatment information usually found in medical records. Finally, the injuries and illnesses found in the records are usually widely known among other employees at the workplace where the injured or ill worker works; in fact, these co-workers may even have witnessed the accident that gave rise to the injury or illness.

OSHA does not agree that its inspectors should be required to obtain permission from all injured or ill employees before accessing the full records. Gaining this permission would make it essentially impossible to obtain

full access to the records, which is needed to perform a meaningful workplace investigation. For example, an inspector would not be able to obtain the names of employees who were no longer working for the company to perform follow-up interviews about the specifics of their injuries and illnesses. The names of the injured or ill workers are needed to allow the government inspector to interview the injured and ill workers and determine the hazardous circumstances that led to their injury or illness. The government inspector may also need the employee's names to access personnel and medical records if needed (medical records can only be accessed after the inspector obtains a medical access order). Additionally, refusing the inspector access to the names of the injured and ill workers would effectively prohibit any audit of the Part 1904 records by the government, a practice necessary to verify the accuracy of employer recordkeeping in general and to identify problems that employers may be having in keeping records under OSHA's recordkeeping rules. Adopting the inefficient access method suggested by these commenters would also place a substantial administrative burden on the employer, the employees, and the government. Further, since OSHA inspectors do not allow others to see the medical records they have accessed, the privacy of employees is not compromised by CSHO access to the records.

Time for response to requests for records. Paragraphs 1904.40(a) and (b) of the final rule require records to be made available to a government inspector within 4 business hours of an oral request for the records, using the business hours of the establishment at which the records are located.

A number of commenters opposed the proposed 4-hour records production requirement as being unreasonable and burdensome (see, *e.g.*, Exs. 15: 89, 182, 185, 204, 213, 226, 260, 262, 265, 277, 294, 297, 317, 324, 348, 392, 401, 409, 425). Several of these commenters recommended longer intervals, ranging from 8 hours (see, *e.g.*, Exs. 15: 9, 133, 204, 271, 294, 343), the ''next business day,'' or 24 hours (see, *e.g.*, Exs. 15: 200, 225, 277, 394, 425), 72 hours (see, *e.g.*, Exs. 15: 65, 154), 6 days (Ex. 15: 226), and 21 days (Ex. 15: 317). On the other hand, some commenters were concerned that access not be unduly delayed (see, *e.g.*, Exs. 15: 350, 369, 418, 429). Two commenters (Exs. 15: 418, 429) recommended that the 4-hour requirement be reduced to two hours, except when the request would extend the reply period beyond regular business hours, when 4 hours would be acceptable.

OSHA has concluded that 4 hours is a reasonable and workable length of time for employers to respond to governmental requests for records. The 4-hour time period for providing records from a centralized source strikes a balance between the practical limitations inherent in record maintenance and the government official's need to obtain these records and use the information to conduct a workplace inspection.

Some commenters noted that temporary computer or fax failures could interfere with an employer's ability to comply with the 4-hour requirement (see, *e.g.*, Exs. 15: 203, 254, 423). One commenter felt that additional time should be given to employers if equipment failure prevented the retrieval of the records within four hours (Ex. 15: 423). The American Society of Safety Engineers (ASSE) questioned whether four hours is a reasonable time frame for employers who use independent third parties to maintain their records (Ex. 15: 182).

Several commenters raised concerns that other difficulties might make it difficult to produce the records in the allotted time. Some noted that the 4-hour time limit might not be adequate for large facilities with voluminous records (see, *e.g.*, Exs. 15: 181, 297, 425). For example, the American Automobile Manufacturers Association (AAMA) (Ex. 15: 409) stated:

> [m]any of our members' locations have only one medical person working, and to disrupt the normal medical care of injured or ill employees to produce records within a four hour period is not in the best interests of the health and safety of all concerned. Many additional factors must be taken into account in terms of the production of records such as locating the files, copying the files, having appropriate staffing to do the copying, and if the records are on a computer, the computer must not be on down time.

OSHA believes that it is essential for employers to have systems and procedures that can produce the records within the 4-hour time. However, the Agency realizes that there may be unusual or unique circumstances where the employer cannot comply. For example, if the records are kept by a health care professional and that person is providing emergency care to an injured worker, the employer may need to delay production of the records. In such a situation, the OSHA inspector may allow the employer additional time.

If a government representative requests records of an establishment, but those records are kept at another location, the 4-hour period can be measured in accordance with the normal business hours at the location where the records are being kept. Some commenters observed that personnel at the centralized location might not be available to respond to requests if the 4-hour period extended outside the regular business hours of that location (see, *e.g.*, Exs. 15: 105, 111, 159, 170, 225, 239, 272, 294, 303, 332, 336, 343, 356, 359, 389, 393, 430). This problem could arise under two different scenarios. First, if the centralized location were in a different time zone than the site whose records are requested, the business hours of the respective locations may differ by three or even more hours. Second, the business hours of a manufacturing plant or a construction site might differ from the business hours of the company's central offices, even if the operations are in the same time zone. Under the final rule, the employer has 4 regular business hours at the location at which the records are kept in which to comply with the request of a government representative.

OSHA has designed the final rule to give each employer considerable flexibility in maintaining records. It permits an employer to centralize its records, to use computer and facsimile technologies, and to hire a third party to keep its records. However, an employer who chooses these options must also ensure that they are sufficiently reliable to comply with this rule. In other words, the flexibility provided to employers for recordkeeping must not impede the Agency's ability to obtain and use the records.

Provide copies. Several commenters objected to the proposed requirement that employers provide copies of the records to government personnel without charging the government to do so (see, *e.g.*, Exs. 15: 69, 86, 100, 179, 347, 389, 397, 409). Most of these commenters cited the paperwork burden on employers as the primary reason for objecting. Several suggested that the employer be allowed to charge for copies, or that the government representative make their own copies (see, *e.g.*, Exs. 15: 179, 347, 389, 409). This view was expressed in a comment from the Ford Motor Company (Ex. 15: 347):

> [a]n undue burden may be placed on the establishment should a compliance officer ask for an inordinate amount of records or records which will not be utilized. Authorized government representatives should make their own copies and therefore will be diligent in asking only for those materials they will be utilizing.

OSHA's experience has been that the vast majority of employers willingly provide copies to government representatives during safety and health inspections. Making copies is a routine office function in almost every modern workplace. With the widespread availability of copying technology, most workplaces have copy machines on-site or readily available. The cost of providing copies is minimal, usually less than five cents per copy. In addition, the government representative needs to obtain copes of records promptly, so that he or she can analyze the data and identify workplace hazards. Therefore, in this final rule, OSHA requires the employer to provide copies of the records requested to authorized government representatives.

Other Section 1904.40 issues. Commenters raised additional issues about providing occupational illness and injury information to OSHA during an inspection. The American Ambulance Association (Ex. 15: 226) recommended that OSHA ''[p]lace greater emphasis on the fact that employers do not have to provide Forms 300 and 301 unless OSHA specifically asks for their submission.'' OSHA believes that the final rule is clear on this point, because it states that the employer must provide the records only when asked by an authorized government representative to do so.

Several commenters stated that all requests for occupational safety and health information should be made in writing (see, *e.g.*, Exs. 15: 69, 317, 397). OSHA believes that it is neither appropriate nor necessary to require a government representative to request the information in writing. Government officials who are conducting workplace inspections may ask for any number of materials or ask verbally for information about various matters during the course of an inspection. Putting these requests in writing would impede workplace inspections and delay efforts to address workplace hazards.

Section 1904.41 Annual OSHA Injury and Illness Survey of Ten or More Employers

Section 1904.41 of this final rule replaces section 1904.17, ''Annual OSHA Injury and Illness Survey of Ten or More Employers,'' of the former rule issued on February 11, 1997. The final rule does not change the contents or policies of the corresponding section of the former rule in any way. Instead, the final rule simply rephrases the language of the former rule in the plain language question-and-answer format used in the rest of this rule. The following table shows the text of Section 1904.17 of the former rule, followed by the text of Section 1904.41 of this final rule.

Former sections 1904.17	New section 1904.41
''Annual OSHA Injury and Illness Survey of Ten or More Employers''	''Annual OSHA Injury and Illness Survey of Ten or more Employers''
1904.17(a) Each employer shall, upon receipt of OSHA's Annual Survey Form, report to OSHA or OSHA's designee the number of workers it employed and number of hours worked by its employees for periods designated in the Survey Form and such information as OSHA may request from records required to be created and maintained pursuant to 29 CFR Part 1904.	1904.41(a) Basic Requirement. If you receive OSHA's annual survey from, you must fill it out and send it to OSHA or OSHA's designee, as stated on the survey form. You must report the following information for the year described on the form: (1) the number of workers you employed; (2) the number of hours worked by your employees; and (3) the requested information from the records that you keep under Part 1904.
No comparable provision	1904.41(b)(1) Does every employer have to send data to OSHA?
	No. Each year, OSHA sends injury and illness survey forms to employers in certain industries. In any year, some employers will receive an OSHA survey form and others will not. You do not have to send injury and illness data to OSHA unless you receive a survey form.
1904.17(b) Survey reports shall be transmitted to OSHA by mail or other remote transmission authorized by the Survey Form within the time period specified in the Survey Form, or 30 calendar days, whichever is longer..	1904.41(b)(2) How quickly do I need to respond to an OSHA survey form?
	You must send the survey reports to OSHA, or OSHA's designee, by mail or other means described in the survey form, within 30 calendar days, or by the date stated in the survey form, whichever is later.
1904.17(c) Employers exempted from keeping injury and illness records under §§ 1904.15 and 1904.16 shall maintain injury and illness records required by §§ 1904.2 and 1904.4, and make Survey Reports pursuant to this Section, upon being notified in writing by OSHA, in advance of the year for which injury and illness records will be required, that the employer has been selected to participate in an information collection.''.	1904.41(b)(3) Do I have to respond to an OSHA survey form if I am normally exempt from keeping OSHA injury and illness records?
	Yes. Even if you are exempt from keeping injury and illness records under § 1904.1 to § 1904.3, OSHA may inform you in writing that it will be collecting injury and illness information from you in the following year. If you receive such a survey form, you must keep the injury and illness records required by § 1904.5 to § 1904.15 and make survey reports for the year covered by the survey.
1904.17(d) Nothing in any State plan approved under Section 18 of the Act shall affect the duties of employers to comply with this section..	1904.41(b)(4) Do I have to answer the OSHA survey form if I am located in a State-Plan State?
	Yes. All employers who receive survey forms must respond to the survey, even those in State-Plan States
1904.17(e) Nothing in this section shall affect OSHA's exercise of its statutory authorities to investigate conditions related to occupational safety and health.	1904.41(b)(5) Does this section affect OSHA's authority to inspect my workplace?
	No. Nothing in this section affects OSHA's statutory authority to investigate conditions related to occupational safety and health.

Thus, section 1904.41 of the final rule merely restates, in a plain language question-and-answer format, the requirements of former rule section 1904.17, with one minor change. The final rule adds paragraph 1904.41(b)(1), which contains no requirements or prohibitions but simply informs the employer that there is no need to send in the Part 1904 injury and illness data until the government asks for it.

Section 1904.42 Requests From the Bureau of Labor Statistics for Data

Section 1904.42 of the final rule derives from the subpart of the former rule titled ''Statistical Reporting of Occupational Injuries and Illnesses.'' The former rule described the Bureau of Labor Statistics annual survey of occupational injuries and illnesses, discussed the duty of employers to answer the survey, and explained the effect of the BLS survey on the States operating their own State plans.

Both OSHA and the BLS collect occupational injury and illness information, each for separate purposes. The BLS collects data from a statistical sample of employers in all industries and across all size classes, using the data to compile the occupational injury and illness statistics for the Nation. The Bureau gives each respondent a pledge of confidentiality (as it does on all BLS surveys), and the establishment-specific injury and illness data are not shared with the public, other government agencies, or OSHA. The BLS's sole purpose is to create statistical data.

OSHA collects data from employers from specific size and industry classes, but collects from each and every employer within those parameters. The establishment-specific data collected by OSHA are used to administer OSHA's various programs and to measure the performance of those programs at individual workplaces.

OSHA proposed to replace sections 1904.20, .21, and .22 of the former rule with a single reporting provision that would combine the requirements for BLS and OSHA survey reports into a single section (61 FR 4039). However, since the time of the proposal, OSHA has determined that the BLS and OSHA information collections warrant separate coverage because they occur at different times and collect data for different purposes. When OSHA published final Section 1904.17, Annual OSHA Injury and Illness Surveys (62 FR 6434, Feb. 11, 1997), the Agency made clear that its surveys are separate from any collections of injury and illness data by the BLS. Accordingly, the final rule includes two separate sections: section 1904.41, which is devoted entirely to the collection of employer-generated injury and illness data by OSHA, and section 1904.42, which is devoted to the collection of such data by the Bureau of Labor Statistics.

Many commenters discussed the need for accurate government statistics about occupational death, injury and illness; however, very few of the comments specifically addressed the proposed provisions relating to employer participation in the BLS survey. The comments OSHA did receive on this point addressed the burden imposed by requests for employer records and the potential duplication between the data collections of OSHA and the BLS (see, *e.g.*, Exs. 15: 9, 163, 184, 390, 402). The comments of the U.S. West Company (Ex. 15: 184) are typical:

> [U]S WEST acknowledges the need for the Secretary of Labor to periodically request reports, including recordkeeping data, from employers. However, US WEST does ask that OSHA carefully consider the need for such reports and work to streamline the process and reduce redundancies. Specifically, US WEST requests that OSHA move to implement systems that will allow employers to electronically provide data, such as the data requested in the BLS Survey of Occupational Injuries and Illnesses. Such a method will be more effective, in terms of receiving consistently formatted data, and will be more cost efficient for both employers and the Department of Labor.
>
> In addition, the DOL should work to avoid duplicate internal efforts that are costly and time-consuming for the government and employers. By way of example, US WEST has in the past received requests from BLS to complete the Survey and from OSHA to complete the Occupational Injury and Illness Report (Form 196B) for the same facility. Both surveys collect similar information.

OSHA and the BLS have worked together for many years to reduce the number of establishments that receive both surveys. These efforts have largely been successful. However, OSHA and BLS use different databases to select employers for their surveys. This makes it difficult to eliminate the overlap completely. We are continuing to work on methods to reduce further the numbers of employers who receive both BLS and OSHA survey requests.

OSHA and BLS are also pursuing ways to allow employers to submit occupational injury and illness data electronically. In 1998, the OSHA survey allowed employers for the first time to submit their data electronically, and this practice will continue in future OSHA surveys. The BLS has not yet allowed electronic submission of these data due to security concerns, but continues to search for appropriate methods of electronic submission, and hopes to allow it in the near future.

In this final rule, OSHA has replaced former sections 1904.20 to 1904.22 with a new section 1904.42, which is stated in the form of a basic requirement and four implementing questions and answers about the BLS survey. Former section 1904.20 ''Description of statistical program,'' is not carried forward in the final rule because it merely described BLS's general legal authority and sampling methodology and contained no regulatory requirements.

Section 1904.21 of the former rule, titled ''Duties of employers,'' required an employer to respond to the BLS annual survey: ''Upon receipt of an Occupational Injuries and Illnesses Survey Form, the employer shall promptly complete the form in accordance with the instructions contained therein, and return it in accordance with the aforesaid instructions.''

Paragraphs 1904.42(a), (b)(1) and (b)(2) of the final rule being published today replace former section 1904.21. Paragraph 1904.42(a) states the general obligation of employers to report data to the BLS or a BLS designee. Paragraph 1904.42(b)(1) states that some employers will receive a BLS survey form and others will not, and that the employer should not send data unless asked to do so. Paragraph 1904.42(b)(2) directs the employer to follow the instructions on the survey form when completing the information and return it promptly.

Paragraph 1904.42(b)(3) of this final rule notes that the BLS is authorized to collect data from all employers, even those who would otherwise be exempt, under section 1904.1 to section 1904.3, from keeping OSHA injury and illness records. This enables the BLS to produce comprehensive injury and illness statistics for the entire private sector. Paragraph 1904.42(b)(3) combines the requirements of former rule paragraphs 1904.15(b) and 1904.16(b) into this paragraph of the final rule.

In response to the question ''Am I required to respond to a BLS survey form if I am normally exempt from keeping OSHA injury and illness records?,'' the final rule states ''Yes. Even if you are exempt from keeping injury and illness records under § 1904.1 to § 1904.3, the BLS may inform you in writing that it will be collecting injury and illness information from you in the coming year. If you receive such a survey form, you must keep the injury and illness records required by § 1904.4 to § 1904.12 and make survey reports for the year covered by the survey.''

Paragraph 1904.42(b)(4) of this final rule replaces section 1904.22 of the former rule. It provides that employers in the State-plan States are also required to fill out and submit survey forms if the BLS requests that they do so. The final rule thus specifies that the BLS has the authority to collect information on occupational fatalities, injuries and illnesses from: (1) employers who are required to keep records at all times; (2) employers who are normally exempt from keeping records; and (3) employers under both Federal and State plan jurisdiction. The information collected in the annual survey enables BLS to generate consistent statistics on occupational death, injury and illness for the entire Nation.

Subpart F. Transition From the Former Rule to the New Rule

The transition interval from the former rule to the new rule involves several issues, including training and outreach to familiarize employers and employees about the now forms and

requirements, and informing employers in newly covered industries that they are now required to keep OSHA Part 1904 records. OSHA intends to make a major outreach effort, including the development of an expert software system, a forms package, and a compliance assistance guide, to assist employers and recordkeepers with the transition to the new rule. An additional transition issue for employers who kept records under the former system and will also keep records under the new system is how to handle the data collected under the former system during the transition year. Subpart F of the final rule addresses some of these transition issues.

Subpart F of the new rule (sections 1904.43 and 1904.44), addresses what employers must do to keep the required OSHA records during the first five years the new system required by this final rule is in effect. This five-year period is called the transition period in this subpart. The majority of the transition requirements apply only to the first year, when the data from the previous year (collected under the former rule) must be summarized and posted during the month of February. For the remainder of the transition period, the employer is simply required to retain the records created under the former rule for five years and provide access to those records for the government, the employer's employees, and employee representatives, as required by the final rule at sections 1904.43 and 44.

The proposal did not spell out the procedures that the employer would have to follow in the transition from the former recordkeeping rule to the new rule. OSHA realizes that employers will have questions about how they are required to handle the data collected under the former system during this transition interval. The final rule maintains the basic structure and recordkeeping practices of the former system, but it employs new forms and somewhat different requirements for recording, maintaining, posting, retaining and reporting occupational injury and illness information. Information collection and reporting under the final rule will continue to be done on a calendar year basis. The effective date for the new rule is January 1, 2001. OSHA agrees with the commenter who stated that beginning the new recordkeeping system on ''Any other date [but January 1] would create an insurmountable number of problems * * *'' (Ex. 27). Accordingly, employers must begin to use the new OSHA 300 and 301 forms and to comply with the requirements of this final rule on January 1, 2002.

Some commenters stressed the need for an orderly transition from the former system to the new system, and pointed out that adequate lead time is needed to understand and assimilate the changes, make adjustments in their data management systems, and train personnel who have recordkeeping responsibilities (see, *e.g.*, Exs. 15: 9, 36, 119, 347, 409).

The transition also raises questions about what should be done in the year 2002 with respect to posting, updating, and retaining the records employers compiled in 2001 and previous years. In the transition from the former rule to the present rule, OSHA intends employers to make a clean break with the former system. The new rule will replace the old rule on the effective date of the new rule, and OSHA will discontinue the use of all previous forms, interpretations and guidance on that date (see, *e.g.*, Exs. 21, 22, 15: 184, 423). Employers will be required to prepare a summary of the OSHA Form 200 for the year 2001 and to certify and post it in the same manner and for the same time (one month) as they have in the past. The following time table shows the sequence of events and postings that will occur:

Date	Activity
2001	Employers keep injury and illness information on the OSHA 200 form
January 1, 2002	Employers begin keeping data on the OSHA 300 form
February 1, 2002	Employers post the 2001 data on the OSHA 200 Form
March 1, 2002	Employers may remove the 2001 posting
February 1, 2003	Employers post the 2002 data on the OSHA 300A form
May 1, 2003	Employers may remove the 2002 posting

The final rule's new requirements for dual certification and a 3-month posting period will not apply to the Year 2000 Log and summary. Employers still must retain the OSHA records from 2001 and previous years for five years from the end of the year to which they refer. The employer must provide copies of the retained records to authorized government representatives, and to his or her employees and employee representatives, as required by the new rule.

However, OSHA will no longer require employers to update the OSHA Log and summary forms for years before the year 2002. The former rule required employers to correct errors to the data on the OSHA 200 Logs during the five-year retention period and to add new information about recorded cases. The former rule also required the employer to adjust the totals on the Logs if changes were made to cases on them (Ex. 2, p. 23). OSHA believes it would be confusing and burdensome for employers to update and adjust previous years' Logs and Summaries under the former system at the same time as they are learning to use the new OSHA occupational injury and illness recordkeeping system.

Subpart G. Definitions

The Definitions section of the final rule contains definitions for five terms: ''the Act,'' ''establishment,'' ''health care professional,'' ''injury and illness,'' and ''you.'' To reduce the need for readers to move back and forth from the regulatory text to the Definitions section of this preamble, all other definitions used in the final rule are defined in the regulatory text as the term is used. OSHA defines the five terms in this section here because they are used in several places in the regulatory text.

The Act

The Occupational Safety and Health Act of 1970 (the ''OSH Act'') is defined because the term is used in many places in the regulatory text. The final rule's definition is essentially identical to the definition in the proposal. OSHA received no comments on this definition. The definition of ''the Act'' follows:

The Act means the Occupational Safety and Health Act of 1970 (84 Stat. 1590 et seq., 29 U.S. 651 et seq.), as amended. The definitions contained in section (3) of the Act and related interpretations shall be applicable to such terms when used in this Part 1904.

Employee

The proposed rule defined ''employee'' as that term is defined in section 3 of the Act and added a Note describing the various types of employees covered by this

recordkeeping rule (*e.g.*, ''leased employees,'' ''seasonal employees''). In the final rule, OSHA has decided that it is not necessary to define ''employee'' because the term is defined in section 3 of the Act and is used in this rule in accordance with that definition.

Employer

The proposed rule included a definition of ''employer'' that was taken from section 3 of the Act's definition of that term. Because the final rule uses the term ''employer'' just as it is defined in the Act, no separate definition is included in the final rule.

Establishment

The final rule defines an establishment as a single physical location where business is conducted or where services or industrial operations are performed. For activities where employees do not work at a single physical location, such as construction; transportation; communications, electric, gas and sanitary services; and similar operations, the establishment is represented by main or branch offices, terminals, stations, etc. that either supervise such activities or are the base from which personnel carry out these activities.

The final rule also addresses whether one business location can include two or more establishments. Normally, one business location has only one establishment. However, under limited conditions, the employer may consider two or more separate businesses that share a single location to be separate establishments for recordkeeping purposes. An employer may divide one location into two or more establishments only when: each of the proposed establishments represents a distinctly separate business; each business is engaged in a different economic activity; no one industry description in the Standard Industrial Classification Manual (1987) applies to the joint activities of the proposed establishments; and separate reports are routinely prepared for each establishment on the number of employees, their wages and salaries, sales or receipts, and other business information. For example, if an employer operates a construction company at the same location as a lumber yard, the employer may consider each business to be a separate establishment.

The final rule also deals with the opposite situation, and explains when an establishment includes more than one physical location. An employer may combine two or more physical locations into a single establishment only when the employer operates the locations as a single business operation under common management; the locations are all located in close proximity to each other; and the employer keeps one set of business records for the locations, such as records on the number of employees, their wages and salaries, sales or receipts, and other kinds of business information. For example, one manufacturing establishment might include the main plant, a warehouse serving the plant a block away, and an administrative services building across the street. The final rule also makes it clear that when an employee telecommutes from home, the employee's home is not a business establishment for recordkeeping purposes, and a separate OSHA 300 Log is not required.

The definition of ''establishment'' is important in OSHA's recordkeeping system for many reasons. First, the establishment is the basic unit for which records are maintained and summarized. The employer must keep a separate injury and illness Log (the OSHA Form 300), and prepare a single summary (Form 300A), for each establishment. Establishment-specific records are a key component of the recordkeeping system because each separate record represents the injury and illness experience of a given location, and therefore reflects the particular circumstances and hazards that led to the injuries and illnesses at that location. The establishment-specific summary, which totals the establishment's injury and illness experience for the preceding year, is posted for employees at that establishment and may also be collected by the government for statistical or administrative purposes.

Second, the definition of establishment is important because injuries and illnesses are presumed to be work-related if they result from events or exposures occurring in the work environment, which includes the employer's establishment. The presumption that injuries and illnesses occurring in the work environment are by definition work-related may be rebutted under certain circumstances, which are listed in the final rule and discussed in the section of this preamble devoted to section 1904.5, Determination of work-relatedness. Third, the establishment is the unit that determines whether the partial exemption from recordkeeping requirements permitted by the final rule for establishments of certain sizes or in certain industry sectors applies (see Subpart B of the final rule). Under the final rule's partial exemption, establishments classified in certain Standard Industrial Classification codes (SIC codes) are not required to keep injury and illness records except when asked by the government to do so. Because a given employer may operate establishments that are classified in different SIC codes, some employers may be required to keep OSHA injury and illness records for some establishments but not for others, *e.g.* if one or more of the employer's establishments falls under the final rule's partial exemption but others do not.

Fourth, the definition of establishment is used to determine which records an employee, former employee, or authorized employee representative may access. According to the final rule, employees may ask for, and must be given, injury and illness records for the establishment they currently work in, or one they have worked in, during their employment.

The proposed rule defined an establishment as:

(1) A single physical location that is in operation for 60 calendar days or longer where business is conducted or where services or industrial operations are performed. (For example: A factory, mill, grocery store, construction site, hotel, farm, ranch, hospital, central administrative office, or warehouse.) The establishment includes the primary work facility and other areas such as recreational and storage facilities, restrooms, hallways, etc. The establishment does not include company parking lots.

(2) When distinct and separate economic activities are performed at a single physical location, each activity may represent a separate establishment. For example, contract construction activities conducted at the same physical location as a lumber yard may be treated as separate establishments. According to the Standard Industrial Classification (SIC) Manual, Executive Office of the President, Office of Management and Budget, (1987) each distinct and separate activity should be considered an establishment when no one industry description from the SIC manual includes such combined activities, and the employment in each such economic activity is significant, and separate reports can be prepared on the number of employees, their wages and salaries, sales or receipts, or other types of establishment information.

The final rule modifies this definition in several ways: it deletes the ''60 days in operation'' threshold, adds language to the definition to address the concerns of employers who operate geographically dispersed establishments, describes in greater detail what OSHA means by separate establishments at one location, and defines which locations must be considered part of the establishment, and which employee activities must be considered work-related, for

recordkeeping purposes. Each of these topics is discussed below.

Subpart G of the final rule defines ''establishment'' as ''a single physical location where business is conducted or where services or industrial operations are performed. For activities such as construction; transportation; communications, electric and gas utility, and sanitary services; and similar operations, the establishment is represented for recordkeeping purposes by main or branch offices, terminals, stations, etc. that either supervise such activities or are the base from which personnel carry out these activities.'' This part of the definition of ''establishment'' provides flexibility for employers whose employees (such as repairmen, meter readers, and construction superintendents) do not work at the same workplace but instead move between many different workplaces, often in the course of a single day.

How the definition of ''establishment'' must be used by employers for recordkeeping purposes is set forth in the answers to the questions posed in this paragraph of Subpart G:

(1) Can one business location include two or more establishments?

(2) Can an establishment include more than one physical location?

(3) If an employee telecommutes from home, is his or her home considered a separate establishment?

The employer may consider two or more economic activities at a single location to be separate establishments (and thus keep separate OSHA Form 300s and Form 301s for each activity) only when: (1) Each such economic activity represents a separate business, (2) no one industry description in the Standard Industrial Classification Manual (1987) applies to the activities carried out at the separate locations; and (3) separate reports are routinely prepared on the number of employees, their wages and salaries, sales or receipts, and other business information. This part of the definition of ''establishment'' allows for separate establishments when an employer uses a common facility to house two or more separate businesses, but does not allow different departments or divisions of a single business to be considered separate establishments. However, even if the establishment meets the three criteria above, the employer may, if it chooses, consider the physical location to be one establishment.

The definition also permits an employer to combine two or more physical locations into a single establishment for recordkeeping purposes (and thus to keep only one Form 300 and Form 301 for all of the locations) only when (1) the locations are all geographically close to each other, (2) the employer operates the locations as a single business operation under common management, and (3) the employer keeps one set of business records for the locations, such as records on the number of employees, their wages and salaries, sales or receipts, and other business information. However, even for locations meeting these three criteria, the employer may, if it chooses, consider the separate physical locations to be separate establishments. This part of the definition allows an employer to consider a single business operation to be a single establishment even when some of his or her business operations are carried out on separate properties, but does not allow for separate businesses to be joined together. For example, an employer operating a manufacturing business would not be allowed to consider a nearby storage facility to be a separate establishment, while an employer who operates two separate retail outlets would be required to consider each to be a separate establishment.

OSHA received many comments on the proposed definition of ''establishment.'' These are organized by topic and discussed below.

How long must an establishment exist to have a separate OSHA Log. The proposed rule would have required an establishment to be in operation for 60 days to be considered an ''establishment'' for recordkeeping purposes. Under the proposed definition, employers with establishments in operation for a lesser period would not have been required to keep a log for that operation. The proposed 60-day threshold would have changed the definition of ''establishment'' used in OSHA's former recordkeeping rule, because that rule included a one-year-in-operation threshold for defining establishments required to keep a separate OSHA log (Ex. 2, p. 21). The effect of the proposed change in the threshold would have been to increase the number of short-duration operations required to maintain separate injury and illnesses records. In particular, the proposed change would have affected construction employers and utility companies.

The majority of the comments OSHA received on this issue opposed the decrease in the duration of the threshold from one year to 60 calendar days. A few commenters, however, supported the proposed 60-day rule (see, *e.g.*, Exs. 15: 9, 133, 310, 369, 425), and some urged OSHA to adopt an even shorter time-in-operation threshold (see, *e.g.*, Exs. 15: 369, 418, 429). Typical of the comments favoring an even shorter period was one from the International Brotherhood of Teamsters (IBT):

> [t]he International Brotherhood of Teamsters is encouraged by OSHA's modification to the definition of an establishment, especially reducing the requirement for an operation in a particular location from one year to sixty days. The IBT would strongly support reducing the requirement to thirty days to cover many low level housing construction sites, and transient operations, similar to mobile amusement parks (Ex. 15: 369).

The AFL–CIO agreed: ''* * * [t]he 60-day time period is still too long. We believe that to truly capture a majority of these transient worksites, a 30-day time period would be more realistic. A 30-day time period as the trigger would capture construction activities such as trenching, roofing, and painting projects which will continue to be missed if a 60-day time period is used'' (Ex. 15: 418).

Those commenters objecting to the proposed 60-day threshold usually did so on grounds that requiring temporary facilities to maintain records would be burdensome and costly and would not increase the utility of the records (see, *e.g.*, Exs. 21, 15: 21, 43, 78, 116, 122, 123, 145, 170, 199, 213, 225, 254, 272, 288, 303, 304, 305, 308, 338, 346, 349, 350, 356, 358, 359, 363, 364, 375, 389, 392, 404, 412, 413, 423, 424, 433, 437, 443, 475). For example, the Associated Builders and Contractors, Inc. (ABC) remarked:

> ABC agrees with OSHA's sentiment of making injury and illness records useful, but disagrees that sites in existence for as little as 60 days need separate injury and illness records. The redefinition of ''establishment'' will cause enormous problems for subcontractors in a variety of construction industries. Even employers with small workforces could be on the site of several projects at any one time, and in the course of the year could have sent crews to hundreds of sites. Though they may be on such sites for only brief periods of time, they will be required under this proposal to create separate logs for each site, increasing greatly their paperwork requirements without increasing the amount of information available to their employees. Projects which last less than 90 days do not need separate logs. Requiring separate logs for short-term projects only increases inefficiency and costs, while doing nothing for safety (Ex. 15: 412).

Many of these commenters argued that a 60-day threshold would be especially burdensome if it captured small work sites where posting of the annual summary or mailing the summary to employees would make little sense because so few cases would

be captured on each Log. The majority of these commenters suggested that OSHA retain the former one-year duration threshold in the definition of establishment (see, *e.g.*, Exs. 15: 78, 123, 225, 254, 305, 356, 389, 404).

Other commenters expressed concern that the proposed 60-day threshold would create an unreasonable burden on employers in service industries like telecommunications and other utilities, whose employees typically report to a fixed location but perform tasks at transient locations that remain in existence for more than 60 days and would thus be classified as new ''establishments'' for OSHA recordkeeping purposes (see, *e.g.*, Exs. 15: 65, 170, 199, 213, 218, 332, 336, 409, 424).

OSHA has reviewed all of the comments on this issue and has responded by deleting any reference to a time-in-operation threshold in the definition of establishment but specifying a one-year threshold in section 1904.30 of the final rule. In response to comments, OSHA has thus continued the former one-year threshold rather than adopting the 60-day threshold proposed. Under the final rule, employers will be required to maintain establishment-specific records for any workplace that is, or is expected to be, in operation for one year or longer. Employers may group injuries and illnesses occurring to workers who are employed at shorter term establishments onto one or more consolidated logs. These logs may cover the entire company; geographic regions such as a county, state or multi-state area; or individual divisions of the company. For example, a construction company with multi-state operations might have separate logs for each state to show the injuries and illnesses of short-term projects, as well as separate logs for each construction project expected to last for more than one year.

OSHA finds, based on the record evidence, that the one-year threshold will create useful records for stable establishments without imposing an unnecessary burden on the many establishments that remain in existence for only a few months. OSHA concludes that the one-year threshold and permitting employers to keep one Log for geographically dispersed or short-term facilities will also provide more useful injury and illness records for workers employed in transient establishments. This will be the case because the records will capture more cases, which enhances the informational value of the data and permits analysis of trends.

Geographically Dispersed Workplaces. A number of commenters raised issues of particular importance to the construction and utility industries (see, *e.g.*, Exs. 15: 43, 116, 122, 123, 145, 170, 199, 213, 225, 272, 288, 303, 305, 350, 359, 364, 392, 412, 433, 443). In addition to objections about the 60-days-in-operation threshold in the definition of establishment, these commenters raised concerns about the difficulty of keeping records for a mobile and dispersed workforce. Representative of these comments is the statement by Con Edison (Ex. 15: 213):

> Con Edison believes that OSHA's proposal to tie its redefinition of a permanent establishment to a 60-day time frame, as opposed to the present one-year limit, would be costly, overly burdensome and in some cases unworkable. On many occasions work must be performed on city streets or in out of the way areas during the erection of overhead transmission and distribution lines. These projects may carry on for periods greater than the 60-day period specified above for designation as an establishment. No permanent structures are erected at these sites and to require maintenance of records there is impractical. Con Edison believes that the definition of establishment as set forth in the 1987 Standard Industrial Classification Manual (see below) should apply.
>
> ''For activities such as * * * electric * * * and similar physically dispersed operations, establishments are represented by those relatively permanent main or branch offices, terminals, stations, etc. that are (2) the base from which personnel operate to carry out these activities. Hence, the individual sites, projects, fields, networks, lines, or system of such dispersed activities are not ordinarily considered to be establishments.'' (SIC Manual, 1987, p. 265).

OSHA agrees that the recordkeeping system must recognize the needs of operations of this type and has adopted language in the final rule to provide some flexibility for employers in the construction, transportation, communications, electric and gas utility, and sanitary services industries, as well as other employers with geographically dispersed operations. The final rule specifies, in Subpart G, that employers may consider main or branch offices, terminals, stations, etc. that are either (1) responsible for supervising such activities, or (2) the base from which personnel operate to carry out these activities, as individual establishments for recordkeeping purposes. This addition to the final rule's definition of establishment allows an employer to keep records for geographically dispersed operations using the existing management structure of the company as the recording unit. Use of this option will also mean that each Log will capture more cases, which will, as discussed above, improve the chances of discovering patterns of occupational injury and illness that can be used to make safety and health improvements. At the same time, by requiring records to be kept for any individual construction project that is expected to last for one year or longer, the final rule ensures that useful records are generated for more permanent facilities.

More than one establishment at a single location. OSHA's former rule recognized, for recordkeeping purposes, that more than one establishment can exist at a single location, although most workplaces consist of a single establishment at a single location. The final rule also recognizes that, in some narrowly defined situations, a business may have side-by-side operations at a single location that are operated as separate businesses because they are engaged in different lines of business. In these situations, the Standard Industrial Classification Manual (OMB 1987) allows a single business location to be classified as two separate establishments, each with its own SIC code. Like all government agencies, OSHA follows the OMB classification method and makes allowances for such circumstances.

The proposal stated that distinct, separate economic activities performed at a single physical location may each be classified, for recordkeeping purposes, as a separate establishment. The proposed definition stated that each distinct and separate economic activity may be considered an establishment when (1) no one industry description from the Standard Industrial Classification (SIC) manual includes such combined activities, (2) the employment in each economic activity is significant, and (3) separate reports can be prepared on the number of employees, their wages and salaries, sales or receipts, or other types of establishment information. The final rule is essentially unchanged from the proposal on this point, but the language has been modified to make it clear that the employer may employ this option only in the enumerated circumstances.

Several commenters were in favor of OSHA's proposed definition of separate establishments as places engaged in separate economic activities (see, *e.g.*, Exs. 15: 185, 297, 375) and agreed that when distinct and separate economic activities are performed at a single physical location, each activity should be considered a separate establishment.

Others, however, disagreed with the proposed definition of multiple establishments at a single location (see, *e.g.*, Exs. 15: 194, 305, 322, 346, 347, 348, 389, 409, 424, 431). The comments

of the Ford Motor Company (Ex. 15: 347) and the American Automobile Manufacturing Association (AAMA) (Ex. 15: 409) are representative:

> [a]ll economic activities performed at a single location should be allowed to be placed on a single log. Many of these locations have only one medical department, payroll, or management. At many of these locations, separate reports cannot be prepared on the number of employees per establishment, and at times many of the employees will work at separate sites within the same single physical location. To break down the economic activities to record injuries and illness on different logs is confusing, difficult, and overly burdensome.

United Parcel Service (UPS) (Ex. 15: 424) added:

> [t]he proposal should be amended to make clear that treatment of a different activity as a separate establishment is optional, not mandatory—the proposal currently results in unnecessary ambiguity by saying first that separate activities ''may'' be separate establishments, and then describing situations in which they ''should be'' considered an establishment. A requirement that such vaguely defined ''economic activities'' be treated as separate ''establishments'' would be mistaken: employers would be left to guess what is an ''economic activity'' and when it is ''separate'' from another. Moreover, such mandatory separate recordkeeping would unnecessarily burden employers with determining when separate records are required, and with maintaining such separate records.

These commenters understood the proposed language as requiring employers to keep separate logs if separate economic activities were being conducted at a single establishment; what OSHA intended, and the final rule makes clear in Subpart G, is that an employer whose activities meet the final rule's definition may keep separate logs if he or she chooses to do so. Thus the final rule includes a provision that allows an employer to define a single business location as two separate establishments only under specific, narrow conditions. The final rule allows the employer to keep separate records only when the location is shared by completely separate business operations involved in different business activities (Standard Industrial Classifications) for which separate business records are available. By providing specific, narrow criteria, the final rule reduces ambiguity and confusion about what is required and sets out the conditions that must be met in order for employers to deviate from the one place-one establishment concept.

OSHA expects that the overwhelming majority of workplaces will continue to be classified as one establishment for recordkeeping purposes, and will keep just one Log. However, allowing some flexibility for the rare cases that meet the specified criteria is appropriate. The employer is responsible for determining whether a given workplace meets the criteria; OSHA will consider an employer meeting these criteria to be in compliance with the final rule if he or she keeps one set of records per facility. This policy allows an employer to keep one set of records for a given location and avoid the additional burden or inconvenience associated with keeping separate records.

The McDonnell Douglas Corporation (Ex. 15: 297) and the American Textile Manufacturers Institute (ATMI) (Ex. 15: 156) commented on a different scenario, one in which a single establishment could encompass more than one physical location. ATMI remarked that:

> [O]SHA's definition of establishment as ''a single physical location'' is too restrictive. We believe that OSHA should be more flexible since many industries have primary facilities with secondary work facilities that have the same local management. For example, in the textile industry, a plant may use a warehouse that is not physically attached but the plant manager is responsible for the both facilities. We suggest that the text of the rule be modified to read: ''A single physical location or multiple physical locations under the same management * * *.''

OSHA agrees that there are situations where a single establishment that has a satellite operation in close physical proximity to the primary operation may together constitute a single business operation and thus be a single establishment. For example, a business may have a storage facility in a nearby building that is simply an adjunct to the business operation and is not a separate business location.

OSHA believes that there are situations where establishments in separate physical locations constitute a single establishment. However, under the final rule, employers will only be allowed to combine separated physical locations into a single establishment when they operate the combined locations as a single business operation under common management and keep a single set of business records for the combined locations, such as records on the number of employees, their wages and salaries, sales or receipts, and other types of business information.

How OSHA defines an establishment also has implications for the way company parking lots and recreation facilities, such as company-provided gymnasiums, ball fields, and the like are treated for recordkeeping purposes. The 1986 *Guidelines* excluded these areas from the definition of establishment and thus did not require injuries and illnesses occurring to employees at these locations to be recorded unless the employee was actually performing work in those areas (Ex. 2, p. 33). The final rule includes these areas in the definition of establishment but does not require employers to record cases occurring to employees engaged in certain activities at these locations. For example, injuries and illnesses occurring at the establishment while the employee is voluntarily engaged in recreation activities or resulting from a motor vehicle accident while the employee is commuting to or from work would not have to be recorded (see section 1904.5). The following paragraphs discuss OSHA's reasons for taking this approach to the recording of injuries and illnesses occurring in these locations.

Company Parking Lots and Access Roads. Because the former rule excluded company parking lots and access roads from the definition of establishment, injuries and illnesses that occurred to their employees while on such parking lots and access roads were not considered work-related and did not have to be recorded on the Log; the proposed rule would have continued this practice. Many commenters urged OSHA not to consider injuries and illnesses occurring in these locations work-related, principally because, in the view of these commenters, employers have little control over safety and health conditions in their parking lots (see, *e.g.*, Exs. 15: 9, 65, 78, 95, 105, 107, 111, 119, 136, 137, 141, 154, 159, 194, 203, 204, 218, 224, 225, 260, 262, 265, 266, 277, 278, 288, 304, 337, 389, 401). The comments of the American Gas Association (AGA) are representative: ''AGA agrees with OSHA that parking lots and access roads should be excluded from the definition of establishment and therefore injuries occurring there are not work-related. Likewise, injuries and illnesses that occur during commuting must also continue to be excluded'' (Ex. 15: 225). The Texas Chemical Council (TCC) agreed with this position: ''[T]CC supports continuing these exceptions. Employers have limited to no control over variables that contribute to incidents occurring in parking lots or during commutes to and from work'' (Ex. 15: 159).

Other commenters, however, argued that cases occurring on company parking lots and access roads should be included in the establishment's Log (see, *e.g.*, Exs. 15: 61, 157, 310, 407, 432). The Laborer's Health and Safety

Fund of North America pointed to the difficulty of separating cases occurring on the parking lot from those occurring at other locations within the establishment:

[w]e do not believe that company parking lots should be excluded from the definition of establishment. The parking lot exclusion seems to be based on the assumption that parking lots are separate from loading dock and other work areas. On road construction sites, ''parking lots'' are sometimes right in the middle of the work zones where heavy equipment is operating. Pedestrian employees being hit by traffic and moving machinery are responsible for about 41.5% of the yearly fatalities in road construction and maintenance work. We believe that excluding parking lots from the definition of establishment would open the door to under reporting of workplace fatalities on construction sites, and discourage construction employers from establishing safe parking areas for their employees (Ex. 15: 310).

The National Institute for Occupational Safety and Health (NIOSH) presented statistical data demonstrating the importance of safety and health measures in employer-owned parking lots:

[N]IOSH does not support continuing the exemption of employer-owned parking lots from the definition of an establishment. NIOSH recommends that OSHA require employers to record cases meeting the work relationship criteria that occur in employer-owned parking areas. Employers have extensive control over the environmental conditions in their own parking areas. Environmental conditions that are under employer control include snow and ice accumulation in walk areas, vicinity lighting around parked cars and entrance ways, and security provisions in parking areas. In 1993, parking lots and garages were identified in a study of violence in the workplace as the location where 211 fatal injuries occurred [Toscano and Weber 1995]. Eighty-two of these deaths were homicides. Parking lots and garages accounted for 3.4% of fatal injuries and 7.8% of homicides. Data on the total number of injuries and illnesses occurring in parking lots and garages is unknown. However, in 1992 the category ''parking lots'' was listed as the source of injury or illness for 10,000 cases involving days away from work [U.S. Department of Labor l995a]. The proportion of parking lots and garages owned by the employer where fatal and nonfatal injuries occurred is not known (Ex. 15: 407).

OSHA agrees with NIOSH that company parking lots can be highly hazardous and that employers have considerable control over conditions in such lots. In addition, OSHA believes that having data on the kinds of injuries and illnesses occurring on company parking lots and access roads will permit employers to address the causes of these injuries and illnesses and thus to provide their employees with better protection. Accordingly, for recordkeeping purposes, the final rule includes company parking lots and access roads in the definition of establishment. However, the final rule recognizes that some injuries and illnesses occurring on company parking lots and access roads are not work-related and delineates those that are work-related from those that are not work-related on the basis of the activity the employee was performing at the time the injury or illness occurred. For example, when an employee is injured in a motor vehicle accident that occurs during that employee's commute to or from work, the injury is not considered work-related. Thus, the final rule allows the employer to exclude from the Log injuries and illnesses occurring on company parking lots and access roads while employees are commuting to or from work or running personal errands in their motor vehicles (see section 1904.5). However, other injuries and illnesses occurring in parking lots and on access roads (such as accidents at loading docks, while removing snow, falls on ice, assaults, etc.) are considered work-related and must be recorded on the establishment's Log if they meet the other recording criteria of the final rule (*e.g.*, if they involve medical treatment, lost time, etc.).

OSHA concludes that the activity-based approach taken in the final rule will be simpler for employers to use than the former rule's location-based approach and will result in the collection of better data. First, the activity-based approach eliminates the need for employers to determine where a parking lot begins and ends, i.e., what specific areas constitute the parking lot, which can be difficult in the case of combined, interspersed, or poorly defined parking areas. Second, it ensures the recording of those injuries and illnesses that are work-related but simply happen to occur in these areas. If parking lots and access roads are totally excluded from the definition of establishment, employers would not record *any* injury or illness occurring in such locations. For example, employers could fail to record an injury occurring to an employee performing work, such as building an attendant's booth or demarcating parking spaces, from the Log.

Recreation facilities. Although the proposed rule would have included recreational facilities in the definition of establishment, it would have excluded, for recordkeeping purposes, injuries and illnesses occurring to employees who were voluntarily participating in wellness activities at fitness or recreational facilities maintained by the employer. As discussed above, OSHA believes that including in the final rule a list of activities that employers can use to rebut the presumption of work-relatedness for recordkeeping purposes will greatly simplify the system for employers and result in the collection of more meaningful data. Including a list of such activities in the final rule was supported by many commenters (see, *e.g.*, Exs. 15: 65, 151, 152, 170, 179, 180, 204, 246, 350, 392). The comments of the Tosco Corporation are representative: ''[w]e agree that the recreational facilities should not be automatically excluded, but rather that the voluntary use of the facilities govern the work relatedness as OSHA has indicated. This will make the OSHA regulation consistent with workers compensation rulings'' (Ex. 15: 246).

An even larger number of commenters disagreed with OSHA's proposed approach, however, arguing that a location-based, rather than activity-based, exclusion was more appropriate for recordkeeping purposes (see, *e.g.*, Exs. 15: 9, 95, 111, 119, 136, 137, 141, 154, 156, 184, 194, 203, 213, 218, 224, 232, 266, 271, 277, 278, 288, 304, 317, 345, 347, 389, 409, 414, 423, 428, 431). For example, the law firm of Constangy, Brooks & Smith, LLC, argued that excluding facilities is simpler than excluding activities: ''* * * [t]he current requirements allow a more simplified analysis of the recreational facility issue and this analysis should be retained in place of the more complicated analysis that would be imposed under the Proposed Recordkeeping Rule'' (Ex. 15: 345).

Other employers stressed the concept that changing the exclusion for recreational facilities would reduce the incentive for employers to provide such facilities for their employees' use (see, *e.g.*, Exs. 15: 136, 137, 141, 213, 224, 266, 278). The remarks of the Society for Human Resource Management (SHRM) are typical: ''[t]o presume that the employee's usage of weight room facilities is involuntary may be unrealistic and would likely result in the closure of employer provided weight rooms, golf courses, and other facilities which benefit the employees * * *'' (Ex. 15: 431).

In the final rule, OSHA has decided to include recreational areas in the definition of establishment but to include voluntary fitness and recreational activities, and other wellness activities, on the list of excepted activities employers may use to rebut the presumption of work-relatedness in paragraph 1904.5(b)(2). OSHA finds that this approach is

simpler and will provide better injury and illness data because recreational facilities are often multi-use areas that are sometimes used as work zones and sometimes as recreational areas. Several of the interpretations OSHA has provided over the years address this problem. For example, the loading dock or warehouse at some establishments has an area with a basketball hoop that is used for impromptu ball games during breaks, while at other establishments employees may use a grassy area to play softball, an empty meeting room for aerobics classes, or the perimeter of the property as a jogging or bicycling track. Providing an exception based on activity will make it easier for employers to evaluate injuries and illnesses that occur in mixed-use areas of the facility.

This approach is also consistent with OSHA's overall approach in the final rule of using specific activity-based exemptions to allow the employer to rebut the presumption of work relationship rather than providing exemptions by modifying the definition of establishment. OSHA also does not believe that this approach will provide an incentive for employers to eliminate recreational and fitness opportunities for their employees. Both approaches exempt the same injuries from recording, but the final rule's approach provides employers with a more straightforward mechanism for rebutting the presumption of work relationship.

OSHA believes that injuries and illnesses occurring to employees who are present in recreational areas as part of their assigned work duties should be recorded on the Log; the final rule thus only permits employers to exclude recreational activities that are being performed by the employee voluntarily from their Logs. For example, an injury to an exercise instructor hired by the company to conduct classes and demonstrate exercises would be considered work related, as would an injury or illness sustained by an employee who is required to exercise to maintain specific fitness levels, such as a security guard.

Private homes as an establishment. Two commenters raised the issue of whether or not private homes could constitute an establishment (see, *e.g.*, Exs. 21, 15: 304, 358). The National Federation of Independent Business (NFIB) stated: ''[N]FIB believes that the definition of establishment as applied to extremely small work sites, including private homes, needs to be reexamined'' (Ex. 15: 304). The Organization Resource Counselors (ORC) added: ''[d]efinition of establishment as applied to extremely small work sites including private homes needs to be reexamined. The sixty day rule by itself does not seem unreasonable except that it captures these small work sites where the requirements for posting or mailing summaries make little sense'' (Ex. 21).

In the final rule, OSHA has not excluded private homes from the definition of establishment because many private homes contain home offices or other home-based worksites, and injuries and illnesses occurring to employees during work activities performed there on behalf of their employer are recordable if the employer is required to keep a Log. However, the final rule makes clear that, in the case of an employee who telecommutes from his or her home, the home is not considered an establishment for OSHA recordkeeping purposes and the employer is not required to keep a separate Log for the home office. For these workers, the worker's establishment is the office to which they report, receive direction or supervision, collect pay, and otherwise stay in contact with their employer, and it is at this establishment that the Log is kept. For workers who are simply working at home instead of at the company's office, i.e., for employees who are telecommuting, OSHA does not consider the worker's home to be an establishment for recordkeeping purposes, and the definition of establishment makes this fact clear. OSHA has recently issued a compliance directive clarifying that OSHA does not and will not inspect home offices in the employee's home and would inspect a home-based worksite other than a home office only if the Agency received a complaint or referral. A fuller discussion concerning the determination of the work-relatedness of injuries and illnesses that occur when employees are working in their homes can be found in the discussion of § 1904.5 Determination of work-relatedness.

Miscellaneous issues. Two commenters recommended that OSHA consider excluding injuries and illnesses occurring to employees while they were present in other areas as well (Exs. 15: 203, 389). The International Dairy Foods Association (IDFA) suggested:

> [i]n addition, facilities such as cafeterias/lunch/break/rest/locker rooms should be exempted except for the employees who work in those areas. While it is true that other workers may occasionally be injured in these areas, the inclusion of all injury/illness information that occurs in these areas only distorts the data. OSHA should be concerned with the accuracy of any information it requires and/or collects and should eliminate any non-relevant or extraneous information. We believe that this anomaly is easily correctable, and the result will be a more accurate assessment of hazards associated with a specific workplace (Ex. 15: 203).

OSHA does not agree with this commenter that injuries and illnesses occurring in such areas are not work-related. For example, many injuries occurring in lunch rooms involve slippery floors, which the employer can address by establishing a system for immediate spill cleanup. However, the final rule does contain an exception from recordability of cases where the employee, for example, chokes on his or her food, is burned by spilling hot coffee, etc. (see paragraph 1904.5(b)).

The United Parcel Service (UPS) recommended that OSHA craft its rule to coincide with the company's personnel records system, stating ''[t]he unit for which an employer maintains personnel records is presumptively appropriate and efficient; accordingly, OSHA should not mandate a rule that conflicts with a company's current personnel units policy'' (Ex. 15: 424). OSHA recognizes that employers would prefer OSHA to allow companies to keep records in any way they choose. However, OSHA believes that allowing each company to decide how and in what format to keep injury and illness records would erode the value of the injury and illness records in describing the safety and health experience of individual workplaces and across different workplaces and industries. OSHA has therefore decided not to adopt this approach in the final rule.

Two commenters raised the issue of centralized recordkeeping as it related to the proposed definition of establishment. The General Electric Company (GE) stated:

> [G]E does not support the redefinition of establishment to mean a single physical location that is in operation for 60 calendar days or longer. GE field staff frequently establish such establishments and the illness and injury recording and reporting for these sites has been done at central locations. The required data therefore is already collected but the new definition would substantially increase the administrative burden for employers, without providing any additional value. Currently, field employees can report an injury to one well-trained individual who is able to properly administer the program and keep all required documentation. Under this new rule, the employer would need to train a significantly greater number of employees on the proper method for recording injuries and illnesses, keeping documentation, and ensuring the submission of this information to the central office for long-term retention. Further, turnover in the field service operations necessitates an ongoing training program. GE would prefer to train field service employees on GE's

expectations for safe performance and how to perform their jobs safely, rather then training field service employees on OSHA recordkeeping regulations (Ex. 15: 349).

OSHA will continue to allow employers to keep their records centrally and on computer equipment, and nothing in the final rule would preclude such electronic centralization. OSHA believes that the definition of establishment in the final rule will have no impact on the ability of the employer to keep records centrally; however, the final rule does continue to require employers to summarize and post the records for each establishment at the end of the year.

The North Carolina Department of Labor (Ex. 15: 186) suggested that OSHA add a note cross-referencing the rule's exceptions for work relationship in parking lots, to assist readers in locating them. OSHA has not added a note to the definition but believes that the list of exceptions to the presumption of work-relationship will achieve the objective this commenter intended. In addition, OSHA has included a table showing changes from the former system to the new system in the compliance assistance and training materials it is distributing to employers and employees.

Health Care Professional

The final rule defines health care professional (HCP) as ''a physician or other state licensed health care professional whose legally permitted scope of practice (i.e. license, registration or certification) allows the professional independently to provide or be delegated the responsibility to provide some or all of the health care services described by this regulation.''

The proposed rule used the term ''health care provider,'' defined as a person operating within the scope of his or her health care license, registration or certification. The final rule uses the term ''health care professional'' to be consistent with definitions used in the medical surveillance provisions of other OSHA standards (see, *e.g.*, the methylene chloride final rule (29 CFR 1910.1052).

OSHA recognizes that injured employees may be treated by a broad range of health care practitioners, especially if the establishment is located in a rural area or if the worker is employed by a small company that does not have the means to provide on-site access to an occupational nurse or a physician. Although the rule does not specify what medical specialty or training is necessary to provide care for injured or ill employees, the rule's use of the term health care professional is intended to ensure that those professionals providing treatment and making determinations about the recordability of certain complex cases are operating within the scope of their license, as defined by the appropriate state licensing agency.

The rulemaking record reflects a wide diversity of views on this topic. Many commenters thought the proposed definition was much too broad, leaving ''[t]he door open for unqualified individuals to make medical diagnoses'' (see, *e.g.*, Exs. 15: 342, 201). Many commenters also argued that the proposed definition could be misinterpreted (see, *e.g.*, Exs. 31, 15: 131, 342, 397). Specifically, many employers thought the definition could be interpreted to permit untrained or unlicensed individuals to treat employees or to make medical diagnoses that would determine the recordability of certain an injuries or illnesses (see, *e.g.*, Exs. 15: 304, 355, 433). Additionally, some commenters interpreted the proposed definition to mean that any time an individual who was certified or trained in cardiopulmonary resuscitation (CPR) or first aid administered treatment, the case would automatically be recordable (see, *e.g.*, Exs. 15: 116, 132, 323, 341, 356). For example, the National Federation of Independent Business noted:

[u]nlike licensed practitioners, those who are registered or certified are not consistently judged against stringent objective criteria. Oftentimes registration is obtained by paying a fee and certification usually entails attending training courses on how to administer first aid. In any given place of employment it is common to find at least one employee who is trained and certified in first aid care. Simple actions on the part of such an employee could become recordable instances under this proposal. This would only serve to erroneously inflate statistics thus making the work site log an inaccurate reflection of occupational injuries and illnesses (Ex. 15: 304).

Consequently, many commenters advocated qualifying the proposed definition by limiting it to providers with specific types of training, such as licensed physicians (see, *e.g.*, Exs. 15: 42, 105) or other providers, such as dentists, psychiatrists, or clinical psychologists (see, *e.g.*, Exs. 15: 126, 312, 342, 410, 433, 443) and/or practitioners operating under their direction, such as physician assistants and nurses (see, *e.g.*, Exs. 15: 116, 131, 334, 344, 441).

Some commenters proposed eliminating the words ''registration'' and ''certification'' from the definition because these terms have different meanings in different states, and in some states, some providers can pay to be certified or registered even though their credentials are inadequate (see, *e.g.*, Exs. 15: 199, 272, 303, 375). A few commenters also noted that some registrations and certifications are given by professional associations rather than state agencies. For example, according to the American Academy of Physician Assistants:

[w]hile many health care providers receive professional certification through a private certifying body (*e.g.* board certification in cardiology for a doctor), this ''certificate'' is not automatically tied to any state recognized credential or scope of practice permitting the provision of health care services. PAs, for example, are certified by the National Commission on Certification of Physician Assistants. This certification is not synonymous with a state certificate or license. As the proposed rule is currently worded, an NCCPA-certified PA or a physician who is board certified in cardiology would qualify as a ''health care provider.'' However, OSHA would not be assured that the PA or physician was practicing medicine with a license and in compliance with their state scope of practice. Further, it would be illegal in all states for a PA or a physician to provide health care services based solely on their professional certification (Ex. 15: 81).

Still others feared that registered or certified ''alternative medicine'' providers, such as acupuncturists and massage therapists, might influence an employer's recordkeeping decision (see, *e.g.*, Exs. 15: 184, 317, 430).

The proposed definition was, however, supported by several unions, large and small employers, and professional associations representing those health care personnel who might be excluded by a more restrictive definition (see, *e.g.*, Exs. 15: 9, 72, 137, 170, 204, 278). These commenters generally advocated a broader definition because such a definition would recognize the various types of health care personnel who may be called on to attend an injured employee (see, *e.g.*, Exs. 15: 181, 350, 376, 392, 417). Typical of these comments was one from The Fertilizer Institute:

[O]SHA should not qualify and limit this definition to personnel with specific training due to the wide variation in health care support and training available throughout the country. Because not all facilities are located in large metropolitan areas where a wide variety of medical training is available, it may be difficult, if not impossible to satisfy Administration-specified minimal training (Ex. 15: 154).

These commenters did agree, however, that to ensure the availability of quality health care to employees, health care professionals must be licensed or

certified by the state(s) in which they practice and must operate within the scope of that license or certification (see, *e.g.*, Exs. 24, 15: 81, 181, 350, 417). In particular, several commenters stressed the need to define the term ''health care professional'' as one practicing ''in accordance with the laws of the applicable jurisdiction'' (Ex. 15: 409; see also Exs. 15: 308, 349).

Additionally, the AFL–CIO cautioned that using a broad definition of the term ''health care provider'' in this recordkeeping rule should not supersede or in any way affect the provisions of many OSHA health standards that specifically require a physician to perform medical surveillance of occupationally exposed employees:

[a]ll of OSHA's 6(b) health standards, except for Bloodborne Pathogens, require that the medical examinations required by the rules be carried out by a physician or under the supervision of a licensed physician. Many of these standards further require that a physician evaluate the results of the exam and provide a diagnosis and opinion as to whether any adverse medical condition has been detected. Some standards such as lead, benzene, and formaldehyde also require the physician to determine whether or not an employee should be removed from his or her job due to occupational exposures.

[In contrast], the proposed recordkeeping rule would allow diagnoses for conditions covered by these standards (*e.g.*, lead poisoning, asbestosis, byssinosis) to be made by any health care provider operating within the scope of their license. We are concerned that this discrepancy and inconsistency may lead to confusion about the requirements for medical surveillance under OSHA's health standards (Ex. 15: 418).

Therefore, the AFL–CIO recommended that OSHA insert a provision in the proposed recordkeeping rule that would ensure that it is not interpreted as superseding the requirements of those standards. OSHA shares this concern and does not intend the use of the term ''health care professional'' in this rule to modify or supersede any requirement of any other OSHA regulation or standard.

On the basis of the record, OSHA finds that there is a broad consensus among commenters that only qualified health care professionals should make diagnoses and treat injured employees, and that state licensing agencies are best suited to determine who may practice and the legal scope of that practice (see, *e.g.*, Exs. 15: 31, 65, 95, 154, 184, 201, 288, 308, 335, 349, 409, 425). The definition in the final rule ensures that, although decisions about the recordability of a particular case may be made by a wide range of health care professionals, the professionals making those decisions must be operating within the scope of their license or certification when they make such decisions.

Injury or Illness

The final rule's definition of injury or illness is based on the definitions of injury and illness used under the former recordkeeping regulation, except that it combines both definitions into a single term ''injury or illness.'' Under the final rule, an injury or illness is an abnormal condition or disorder. Injuries include cases such as, but not limited to, a cut, fracture, sprain, or amputation. Illnesses include both acute and chronic illnesses, such as, but not limited to, a skin disease, respiratory disorder, or systemic poisoning. The definition also includes a note to inform employers that some injuries and illnesses are recordable and others are not, and that injuries and illnesses are recordable only if they are new, work-related cases that meet one or more of the final rule's recording criteria.

Former rule's definition. The former rule also defined these terms broadly, as did the proposal. The text of the former recordkeeping rule did not include a definition of injury or illness; instead, the definitions for these terms were found on the back of the OSHA 200 Log and in the former *Recordkeeping Guidelines* (Ex. 2, p. 37). The definition of occupational injury found in the *Guidelines* was:

Occupational injury is any injury such as a cut, fracture, sprain, amputation, etc., which results from a work accident or from an exposure involving a single incident in the work environment.

Note: Conditions resulting from animal bites, such as insect or snake bites, or from one-time exposure to chemicals are considered to be injuries.

An occupational illness was defined as:

[a]ny abnormal condition or disorder, other than one resulting from an occupational injury, caused by exposure to environmental factors associated with employment. It includes acute and chronic illnesses or diseases which may be caused by inhalation, absorption, ingestion, or direct contact.

The former rule's definitions of injury and illness captured a very broad range of injuries, including minor injuries such as scratches, bruises and so forth, which the employer then tested for work-relatedness and their relationship to the recording criteria. The former rule's definition of illness was even broader, including virtually any abnormal occupational condition or disorder that was not an occupational injury. However, the recording of illnesses under the former rule was more inclusive than is the case for the final rule being published today because the former rule required employers to record every occupational illness, regardless of severity. The final rule applies the same recording criteria to occupational illnesses as to occupational injuries, and thus rules out minor illnesses (see the Legal Authority section and the preamble discussion accompanying section1904.4).

The former rule's broad definition of illness was upheld in a 1989 Occupational Safety and Health Review Commission decision concerning the recording of elevated levels of lead in the blood of workers employed at a battery plant operated by the Johnson Controls Company. In that decision (OSHRC 89–2614), the Occupational Safety and Health Review Commission found that:

[a]s the Secretary states in his brief on review ''The broad applicability of the term ''illness'' adopted in the BLS Guidelines serves this purpose [to set explicit and comprehensive recording requirements designed to obtain accurate and beneficial statistics regarding the causes of occupational disease] by including health related conditions which may not look like, or may not yet be, treatable illnesses.'' Accordingly, for the purposes of the Secretary's recordkeeping regulations promulgated pursuant to sections 8(c)(1) and (2) of the Act, we accept the Secretary's interpretation of ''illness'' that includes blood lead levels at or above 50 ug/100g.

Proposed rule's definition. OSHA proposed a new, broad definition that encompassed both occupational injury and occupational illness. This approach was consistent with one of the goals of the proposal, to eliminate the distinction between injury and illness entirely for recordkeeping purposes. OSHA's proposed definition of an injury or illness was:

''Injury or illness'' is any sign, symptom, or laboratory abnormality which indicates an adverse change in an employee's anatomical, biochemical, physiological, functional, or psychological condition (61 FR 4058).

Comments on the proposed definition. Many commenters remarked that the proposed definition of injury and illness was too broad and all encompassing (see, *e.g.*, Exs. 25, 33, 15: 95, 120, 156, 174, 176, 199, 201, 213, 231, 273, 282, 301, 305, 318, 331, 346, 348, 375, 383, 386, 395, 420, 424, 425, 430). The views of the National Association of Manufacturers (NAM) are representative of this view:

[a] second option is to re-examine the scope of the proposed definition of the term ''injury or illness,'' which appears to go well beyond the normal understanding of the medical profession. That definition is so broad it includes virtually any change in the status of the employee. In contrast, Dorland's

Illustrated Medical Dictionary defines the term ''illness'' as a condition marked by ''pronounced deviation from the normal healthy state.'' Accordingly, the NAM believes the proposed definition of the term ''injury or illness'' would be far more accurate and credible if it were modified to read substantially as follows ''Any sign, symptom, or laboratory abnormality which evidences a significant adverse change in an employee's anatomical, biochemical, physiological, functional, or psychological condition, and which evidences a state of ill-health or a reasonable probability that ill-health will result (Exs. 25, 15: 305).

The American Iron and Steel Instute (AISI) also objected to the definition, stating that:

OSHA also fails to provide any guidance as to what constitutes a ''change'' in an employee's condition. If a person is tired at the end of the day, does that constitute a change in his physical condition? If a person is grumpy at the end of a long shift, has he undergone a change in his psychological condition? If a person gains weight, has his ''anatomical'' condition ''changed''? OSHA's proposed definition would force employers to address these questions but provides none of the answers. * * * Finally, in addition to inviting gross intrusions into employees' lives, the concept of an ''adverse'' psychological change is so vague and burdened with value judgments that it simply is beyond definition.

Several other commenters urged OSHA to add the word ''significant'' and the phrase ''and which evidences a state of ill-health or a reasonable probability that ill-health will result'' to the final rule's definition of injury or illness (see, *e.g.*, Exs. 15: 169, 174, 199, 282, 305, 318, 346, 348, 375, 386, 420, 425).

A number of commenters stated that they did not understand the word ''functional'' in the definition, and particularly how its meaning differs from that of the word ''physiological'' in the definition (see, *e.g.*, Exs. 15: 313, 352, 353, 424). Several commenters also suggested the deletion from the definition of an occupational injury or illness any reference to signs, symptoms or laboratory abnormalities (see, *e.g.*, Exs. 33, 15: 176, 231, 273, 301). The Pacific Maritime Association (Ex. 15: 95) suggested that OSHA delete the proposed definition of injury or illness and replace it with the following: ''[an injury or illness] is any condition diagnosed by a health care provider.'' Two commenters suggested excluding psychological conditions from the definition of injury or illness (Exs. 15: 395, 424). A discussion of mental conditions and OSHA's reasons for including them in the definition is included in the preamble discussion of work-relationship at section 1904.5, Determination of work relatedness. OSHA has decided to continue to include psychological conditions in the final rule's definition of injury and illness because many such conditions are caused, contributed to, or significantly aggravated by events or exposures in the work environment, and the Agency would be remiss if it did not collect injury and illness information about conditions of these types that meet one or more of the final rule's recording criteria.

In the final rule, OSHA has relied primarily on the former rule's concept of an abnormal condition or disorder. Although injury and illness are broadly defined, they capture only those changes that reflect an adverse change in the employee's condition that is of some significance i.e. that reach the level of an abnormal condition or disorder. For example, a mere change in mood or experiencing normal end-of-the-day tiredness would not be considered an abnormal condition or disorder. Similarly, a cut or obvious wound, breathing problems, skin rashes, blood tests with abnormal results, and the like are clearly abnormal conditions and disorders. Pain and other symptoms that are wholly subjective are also considered an abnormal condition or disorder. There is no need for the abnormal condition to include objective signs to be considered an injury or illness. However, it is important for employers to remember that identifying a workplace incident as an occupational injury or illness is only the first step in the determination an employer makes about the recordability of a given case.

OSHA finds that this definition provides an appropriate starting point for decision-making about recordability, and that the requirements for determining which cases are work-related and which are not (section 1904.5), for determining which work-related cases reflect new injuries or illnesses rather than recurrences (section 1904.6), and for determining which new, work-related cases meet one or more of the general recording criteria or the additional criteria (sections 1904.7 to 1904.12) together constitute a system that ensures that those cases that should be recorded are captured and that minor injuries and illnesses are excluded. In response to the desire of many commenters for greater clarity, OSHA has added language to the definition of injury and illness to make it clear that many injuries and illnesses are not recordable, either because they are not work-related or because they do not meet any of the final rule's recording criteria.

In general, all of those commenters who opposed the proposed definition wished OSHA to revise the definition so that it would provide an initial screening mechanism for excluding minor injuries and illnesses, even before the status of the case vis-a-vis the geographic presumption or recording criteria was assessed. OSHA recognizes that the proposed language referring to any adverse change was too broad, and has returned to the former language requiring that the change reach the ''abnormal condition'' level. OSHA recognizes that this is still a broad definition—deliberately so. After reviewing this issue thoroughly, OSHA finds that a system that initially defines injury and illness broadly and then applies a series of screening mechanisms to narrow the number of recordable incidents to those meeting OSHA and statutory criteria has several advantages. First, by being inclusive, this system avoids the problem associated with any ''narrow gate'' approach: that some cases that should be evaluated are lost even before the evaluation process begins. Second, this approach is consistent with the broad definitions of these terms that OSHA has used for more than 20 years, which means that the approach is already familiar to employers and their recordkeepers. Third, adding terminology like ''significant'' and ''reasonable probability that ill-health will result,'' as commenters suggested, would unnecessarily complicate the first step in the evaluation process.

Accordingly, the definition of injury and illness in the final rule differs from the former definition only in minor respects. The definition is based on the former rule's definitions, simply combining the separate definitions of injury and illness into a single category, to be consistent with the elimination of separate recording thresholds for occupational injuries and occupational illnesses. As discussed above, OSHA has elected to continue to use a broad definition of illness or injury. The definition in the final rule also makes it clear that each injury and illness must be evaluated for work-relatedness, to decide if it a new case, and to determine if it is recordable before a covered employer must enter the case in the OSHA recordkeeping system.

''You''

The last definition in the final rule, of the pronoun ''you,'' has been added because the final rule uses the ''you'' form of the question-and-answer plain-language format recommended in Federal plain-language guidance. ''You,'' as used in this rule, mean the employer, as that term is defined in the Act. This definition makes it clear that employers are responsible for implementing the requirements of this

final rule, as mandated by the Occupational Safety and Health Act of 1970 (29 U.S.C. 651 *et seq.*)

VIII. Forms

This section of the preamble includes a copy of the final forms package. For a discussion of the contents, the old forms, the proposed forms, and comments to the proposed forms, refer to the preamble discussion of Subpart C. 1904.6 Forms. The forms fit on 11″ by 14″ legal sized paper. The forms do not appear in the **Federal Register** due to printing considerations. To obtain a copy contact OSHA's Publications Office at (202) 693–1888, order the forms from the OSHA Internet home page *(http://www.osha.gov)* or download the forms from the OSHA home page.

IX. State Plans

The 25 States and territories with their own OSHA approved occupational safety and health plans must adopt a rule comparable to the 29 CFR part 1904 recordkeeping and reporting occupational injuries and illnesses regulation being published today, with the exception of the requirements of § 1904.41 Annual OSHA Injury and Illness Survey of Ten or More Employers. These 25 States are: Alaska, Arizona, California, Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, Virgin Islands, Washington, and Wyoming; and Connecticut and New York (for State and local Government employees only).

The former 29 CFR 1952.4 regulation required that States with approved State-Plans under section 18 of the OSH Act (29 U.S.C. 667) must adopt occupational injury and illness recording and reporting regulations which were ''substantially identical'' to those set forth in 29 CFR part 1904 because the definitions used by the Federal and State governments for recordkeeping purposes must be identical to ensure the uniformity of the collected information. In addition, former § 1952.4 provided that employer variances or exceptions to State recordkeeping or reporting requirements in a State-Plan State would be approved by the Bureau of Labor Statistics. Similarly, a State was permitted to require supplemental reporting or recordkeeping data, but that State was required to obtain approval from the Bureau of Labor Statistics to ensure that the additional data would not interfere with ''the primary uniform reporting objectives.''

The proposed revision of 29 CFR 1952.4 would have retained the same substantive requirements for the State-Plan States, but reflected the organizational shift of some recordkeeping responsibilities from the Bureau of Labor Statistics to OSHA in 1990. See also the memorandum of understanding between OSHA and BLS effective July, 1990 (Ex. 6).

OSHA received no comments directed specifically to proposed section 1952.4. Section 1952.4 of the final rule parallels the provisions of § 1904.37, State Recordkeeping Regulations, the section of the final rule implementing the requirements proposed as § 1904.14, Recordkeeping Under Approved State Plans. The discussion of the comments and OSHA's decisions on the few issues associated with this section can be found in the preamble discussion for § 1904.37, State Recordkeeping Regulations. Section 1952.4 of the final regulation differs from that of the former regulation in that (1) the final rule requires the States to consult with and obtain approval from OSHA rather than BLS when promulgating supplementary fatality, injury or illness recording and reporting requirements; (2) the final rule allows the State to grant variances from the fatality, injury and illness reporting and recording requirements for State and local governments with Federal approval; and (3) Federal OSHA rather than the BLS is responsible for issuing all private sector and federal variances from the 29 CFR part 1904 requirements.

OSHA Data Initiative Surveys

In 1997, OSHA issued a final rule at § 1904.17, OSHA Surveys of 10 or More Employers that required employers to submit occupational injury and illness data to OSHA when sent a survey form. The 1904.17 rule enabled the Agency to conduct a mandatory survey of the 1904 data, which has been named the OSHA Data Initiative. Section 1904.41 of the final rule, Annual OSHA Injury and Illness Survey of Ten or More Employers, simply carries forward the employer reporting requirements of the former § 1904.17, with only minor editorial changes.

When OSHA issued the 1997 rule, the Agency determined that the States were not required to adopt a rule comparable to the federal § 1904.17 rule (62 FR 6441). Paragraph 1952.4(d) has been added to the final rule to continue to provide the States with the flexibility to participate in the OSHA Data Initiative under the Federal requirements or the State's own regulation. At its outset, Federal OSHA conducted the OSHA data collection in all of the states, including those which administer approved State-Plans. However, in recent years, Federal OSHA has collected data only in the State-Plan States that wish to participate. For example, in 2000, the states of Oregon, South Carolina, Washington, and Wyoming elected not to participate in the annual OSHA survey and employers in those States were not surveyed. OSHA plans to continue to allow the individual States to decide, on an annual basis, whether or not they will participate in the OSHA data collection.

If a State elects to participate, the State may either adopt and enforce the requirements of section 1904.41 as an identical or more stringent State regulation, or may defer to the Federal regulation and Federal enforcement with regard to the mandatory nature of the survey. If the State defers to the Federal section 1904.41 regulation, OSHA's authority to implement the survey is not affected either by operational agreement with a State-Plan State or by the granting of final State-Plan approval under section 18(e). OSHA's authority under the Act to take appropriate enforcement action if necessary to compel responses to the survey and to ensure the accuracy of the data submitted by employers will be exercised in consultation with the State in State-Plan states.

X. Final Economic Analysis

1. Introduction

A. Background

OSHA is revising its regulation on Recording and Reporting Occupational Injuries and Illnesses, which is codified at 29 CFR part 1904. Executive Order 12866, issued by President Clinton on September 30, 1993, requires OSHA to assess the benefits and costs of regulations, and to design regulations to impose the least burden on society consistent with achieving the Agency's regulatory objective. This economic analysis, therefore, was developed to describe the potential impacts of the final revisions to 29 CFR part 1904.

The final revisions to 29 CFR part 1904 reflect the results of studies of occupational injury and illness reporting and recordkeeping. One study of the accuracy and quality of occupational safety and health statistics was conducted by the National Research Council of the National Academy of Sciences (NAS), under contract to the Bureau of Labor Statistics (BLS).[4] The NAS report focused on changes to the

[4] National Research Council of the National Academy of Sciences, *Counting Injuries and Illnesses in the Workplace: Proposal for a Better System,* 1987.

overall strategy for occupational health and safety statistics and reporting, rather than on specific methods for improving the existing recordkeeping system. Reform of the occupational health and safety recordkeeping system was also the topic of a conference convened by the Keystone Center, an independent, non-profit organization that specializes in mediating multi-party disputes in the areas of science, technology, environmental, and health concerns. The Keystone Conference brought together 46 representatives from labor unions, corporations, the health professions, government agencies, Congressional staff, and academia to engage in a year-long dialogue. The Conference's final report[5] was an important source of ideas for some of the changes being made in OSHA's final recordkeeping rule.

In 1990, the Department of Labor transferred from the Bureau of Labor Statistics (BLS) to OSHA the responsibility for developing recordkeeping regulations and their accompanying guidelines. Although BLS continues to compile occupational injury and illness statistics, OSHA determines what information needs to be recorded by employers.

This economic analysis measures the potential regulatory impacts of the final revisions to 29 CFR part 1904. Much of the data for this analysis derives from a study conducted for OSHA by Meridian Research.[6] The data in the Meridian study, however, have been updated to reflect more recent data on the numbers of establishments affected and on rates of occupational illnesses and injuries, as well as the evidence submitted to the record in the course of this rulemaking.

B. Overview of the Final Regulation

The final regulation revises an existing rule, Recording and Reporting Occupational Injuries and Illnesses (29 CFR part 1904). Specific changes include changes in coverage, editorial and formatting changes, and changes in specific provisions that affect the requirements for recording and reporting. Changes are summarized in Table X–1.

(1) Editing and Format Changes

Language and Structure of the Rule. The final regulation reflects a complete rewriting of 29 CFR part 1904. The new version of the rule is written in plain language, using a question and answer format. This style is designed to make the rule clearer, more accessible, and easier to understand. In addition, the final rule contains many questions that employers frequently ask about recordkeeping, and it provides answers to those questions. By including these questions and answers in the rule itself, OSHA has provided employers with a readily available source of information on how to record particular cases. This means that the quality of the data being recorded will be higher than was the case in the past.

TABLE X–1: CHANGES IN RECORDKEEPING REQUIREMENTS

Section of final rule	Section of former or other source	Rule change
1904.2	1904.16	Cover parts of SICs 55, 57, 59, 65, 72, 73, 83, & 84; Exempt parts of SICs 52, 54, 76, 79, & 80.
1904.5	Guidelines	Include specific exemptions from recording for certain cases, such as common cold or flu.
		Limit parking lot exemption to commuting.
		Require recording of preexisting injury or illness only if workplace exposure "significantly" aggravates the injury or illness.
1904.7	1904.12	Replace term "lost workdays" in recording criteria with "days away" or "days restricted or transferred"; count days as calendar days, rather than scheduled work days; cap count at 180 days; do not record restricted, transferred, or lost time occurring only on day of injury or illness as restricted work, job transfer, or a day away. Define routine duties for restricted work purposes as work activities done at least once per week. Define medical treatment beyond first aid to include all non-prescription drugs given at prescription strength and first and subsequent physical therapy or chiropractic treatment and to exclude use of Steri-Strips™ and hot or cold therapy.
1904.7	(New)	Narrow criteria for recording illnesses by excluding minor illnesses.
1904.8	(New)	Record all needlestick/sharps injury cases involving exposure to blood or other potentially infectious materials.
1904.10	Interpretation	Record all hearing loss cases at 10 dB shift, rather than 25 dB shift.
1904.11	Interpretation	Narrow criteria for recording positive tuberculosis test.
1904.12	1904.12	Make criteria for recording MSD cases the same as those for all other injuries and illnesses.
1904.29	1904.2	Replace old Log form with simplified Form 300.
		Require that cases be recorded within 7 calendar days rather than 6 working days.
1904.29	1904.4	Require more information on new Form 301 than on former Form 101.
1904.29	(New)	Define new category of "privacy concern cases" and require maintenance of separate, confidential list of names for such.
1904.29	(New)	Require employer to protect privacy of injured or ill workers by withholding names, with certain exceptions.
1904.32	1904.5 (New)	Post Annual Summary for 3 months rather than 1 month.
		Review records for accuracy at end of year.
		Require descriptive and statistical totals in Annual Summary.
		Require certification of accuracy of the Log by responsible company official.
1904.34	1904.11	With change of ownership, require seller to turn over OSHA records to buyer.
1904.35	(New)	Inform employees how to report injuries or illnesses to employer.
		Provide union representative access to some, but not all, Form 301 information.
1904.39	1904.8	Delete requirement for common carrier and motor vehicle incidents to be reported.

[5] Keystone Center, *Keystone National Policy Dialogue on Work-Related Illness and Injury Recording*, 1989.

[6] Meridian Research, Inc., Economic Analysis of Proposed Changes to OSHA's Recordkeeping Requirements (29 CFR 1904), 1991.

The rule also has been completely restructured. Its provisions have been put into a logical sequence, with topics addressed as an employer would encounter them when complying with the rule. The numbering of sections within 29 CFR part 1904 has been entirely revised.

The final rule includes considerable detail not found in the former rule. This detail generally reflects interpretations that OSHA has made over time. By including these in the rule itself, OSHA intends to make the rule far clearer. Interpretations and related details are formatted as check lists, for ease of interpretation.

(2) Specific Changes in Regulatory Provisions

(a) Changes in Coverage

Former rule. The former rule exempted all employers with 10 or fewer employees and all employers in specific low-hazard retail and service industry sectors from routinely keeping OSHA records. The industry exemptions were based on injury and illness data at the 2-digit SIC code level.

Final rule. The final rule continues the former rule's exemption of all employers with 10 or fewer employees from routine recordkeeping requirements. The final rule also exempts all employers in specific lower-hazard retail and service industry sectors, as the former rule did, from maintaining OSHA records routinely. The final rule exempts 3-digit SIC industries if their average lost workday injury (LWDI) rate was at or below 75% of the overall private sector LWDI average rate in the most recent BLS occupational injury and illness data.

Change. Updating the list of exempted industry categories by relying on 3-digit, rather than 2-digit, data in the final rule results in 17 formerly exempt industries being covered under the final rule (see Table X–2). Employers in 16 industries that were covered by the former rule are exempted by the final rule (see Table X–3). The exemptions in the final rule are better targeted than those in the former rule, because high-hazard 3-digit industries embedded within lower-hazard 2-digit industries are not exempted, while low-hazard 3-digit industries embedded within higher-hazard 2-digit industries are exempted. Employers in the newly covered industries will experience additional costs and benefits from these new requirements, while newly exempted employers will also experience changes in costs and benefits. These costs and benefits are quantified in this economic analysis.

(b) Changes to the OSHA Forms

Former rule. The former rule required the employer to maintain two forms, the OSHA 200 Log and Summary of Occupational Injuries and Illnesses (one form including both a Log and Summary), and the OSHA 101 Supplementary Record of Occupational Injuries and Illnesses. The employee who supervised the production of the annual summary was required to certify it.

Final rule. The final rule requires the employer to maintain up to four records: the OSHA 300 Log of Work-Related Injuries and Illnesses, the OSHA 300-A Summary of Work-Related Injuries and Illnesses, the OSHA 301 Injury and Illness Incident Report, and, if one or more employees experiences an injury or illness case classified as a ''privacy concern'' case, a confidential list of those employees. (See discussion of privacy provisions below.)

Change. The new OSHA 300 Log is smaller than the Former OSHA 200 Log, fits on legal sized pages (8 ½'' x 14''), has fewer columns and a more logical, user friendly design. Each injury and illness must be recorded within 7 calendar days, rather than the 6 working days allowed under the former rule. Although the 300 Log requires essentially the same information as the former 200 Log, it is easier to complete, which will result in cost savings for employers. These savings are quantified in this economic analysis.

The OSHA 300–A Summary Form replaces the summary portion of the former OSHA 200 Log and Summary Form. Each covered employer must complete the summary at the end of the year and post it for 3 months, while the former rule required posting for one month. The longer posting period will result in only minimal additional costs. The final rule also requires the employer to review the records at year end for accuracy before summarizing them, requires additional certification of accuracy by a company executive, and requires additional data on the average employment and hours worked at the establishment. These changes will result in higher quality data, and will also add costs for employers. These costs are quantified in this economic analysis.

The OSHA 301 Incident Report is only slightly different from the OSHA 101 Form that it replaces. Some data elements have been added to the form. In addition, the form has been redesigned to obtain better responses to the questions and to accommodate employee access to the forms while still protecting privacy (see discussion below). Costs of recording additional data elements are quantified in this economic analysis.

(c) Changes in the Recording Criteria

The final rule includes a number of changes that will affect the number of recorded cases, and thus potentially affect the costs and costs savings associated with the regulation. Some of these changes will result in more cases being recorded, as follows: (1) Changes to the definitions of medical treatment and first aid, (2) change to the criterion for recording cases of hearing loss, and (3) change to the criterion for recording needlestick and sharps injuries.

Other changes will result in fewer cases being recorded, as follows: (1) Exemptions from the requirement to consider certain cases work-related, (2) elimination of different recording criteria for injuries and illnesses, (3) changes to the requirements for recording injuries and illnesses with days away or job restriction/transfer, (4) changes to the criteria for recording cases of tuberculosis, and (5) elimination of separate recording criteria for musculoskeletal disorders.

Because the final rule makes a number of changes, some of which increase the number of recordable injuries and illnesses and some of which decrease the number of recordable cases, it is difficult to estimate the precise impact of each change. OSHA expects that these changes, with two exceptions, will generally have the effect of offsetting each other, with the result that approximately the same number of injury and illness cases will be recorded under the final rule as were recorded under the former rule. The costs and cost savings associated with each small definitional change have not been quantified in this economic analysis. However, the changes made in the recording of hearing loss cases and the recording of needlestick and sharps injury cases will result in quantifiable increases in the number of recorded injuries. The cost effects of these changes are specifically identified in this economic analysis.

OSHA recognizes that individual employers will be affected differently by the changes made in the final rule and that some employers will record more cases under the final rule while others will record fewer. OSHA also finds that the overall effect of the changes made to the final rule is to greatly ease the determination of recordability, and has quantified these cost savings in this economic analysis.

(i) Changes to the Determination of Work-Relationship

Former rule. Under the former rule, work-relationship was established if work either caused or contributed to the injury or illness, or aggravated a pre-existing condition. Injuries and illnesses that occurred on the employer's premises were presumed to be work-related, with three exceptions: cases that occurred in a parking lot or recreational facility, cases that occurred while the employee was present at the workplace as a member of the general public and not as an employee, and cases where injury or illness symptoms arose at work but were the result of a non-work-related injury or illness were not required to be recorded.

Final rule. Work relationship is established if work either caused or contributed to the injury or illness, or significantly aggravated a pre-existing condition. The final rule continues the former rule's geographic presumption of work relationship but adds several additional exceptions to the need to record cases involving: voluntary participation in wellness programs, eating and drinking food or beverages for personal consumption, intentionally self-inflicted wounds, personal grooming, or the common cold or flu. The final rule also contains an exception that limits the recording of mental illness cases.

Change. The final rule changes the requirement to record cases in which any degree of aggravation of a preexisting injury or illness has occurred; now, the work environment must have significantly aggravated a pre-existing injury or illness before the case becomes work-related. The final rule also adds several new exceptions to the geographic presumption of work relationship. Both of these changes will result in fewer cases being recorded under the final rule.

(ii) Elimination of Different Recording Criteria for Injuries and Illnesses

Former rule. Under the former rule, employers were required to record all work-related deaths, all illnesses, and injuries that resulted in days away from work, restricted work, transfer to another job, medical treatment beyond first aid, or loss of consciousness. The employer was required to decide if the case was either an injury or illness; injuries included all back cases and any case caused by an instantaneous event, while illnesses were any abnormal condition or disorder caused by a non-instantaneous event. The employer was required to record every illness case, regardless of severity.

Final rule. Under the final rule, the employer is not required to determine whether a case is an injury or illness to decide whether or not to record the case. A case is recordable if it results in death, days away from work, job restriction or transfer, medical treatment beyond first aid, loss of consciousness, or if the case is a significant injury or illness diagnosed by a physician or other licensed health care professional. Additional criteria are included for cases of hearing loss, tuberculosis, and needlestick injuries and the rule clarifies how to record musculoskeletal disorders and cases involving medical removal or work restriction under OSHA's standards.

Change. The new general recording criteria eliminate the recording of minor illness cases, which will result in fewer cases being recorded by employers, and lower costs. The new criteria for recording hearing loss and needlestick cases will increase the number of cases and the costs associated with recording.

(iii) Days Away and Job Restriction/Transfer

Former rule. Under the former rule, employers were required to record lost workday cases, which were defined as any case that resulted in days away from work and/or days of restricted work or job transfer. Restricted work included any case when because of injury or illness (1) the employee was assigned to another job on a temporary basis, (2) the employee worked at a permanent job less than full time, or (3) the employee worked at his or her permanently assigned job but could not perform his or her routine duties. Routine duties were defined as any activity the employee would be expected to perform even once during the course of the year. The employer was required to record any case that involved restricted work, even if the restriction occurred only on the day the injury or illness occurred.

Employers were also required to count days as the number of scheduled days away or restricted, i.e., to use a counting system that included only scheduled work days and excluded any days off, such as weekends and days the plant was closed.

Final Rule. The final rule continues to require employers to record cases with days away from work, restricted work or transfer to another job. For restricted work/job transfer, the final rule focuses on whether or not the employee is permitted to perform his or her routine job functions, defined as the duties he or she would have performed at least once per week before the injury or illness. If the work restriction is limited to the day of the injury or illness, and none of the other recording criteria are met, the case is not recordable.

The final rule continues to require the employer to count days away from work and days of restricted work/job transfer. However, the days are counted using calendar days, and employers may stop the count at 180 days. The employer also may stop counting restricted days if the employer permanently modifies the employee's job in a way that eliminate the routine functions the employee was restricted from performing.

Change. The final rule shifts the focus of the definition of restricted work to the routine functions of the job and away from the former rule's focus on any activity the injured or ill employee might have performed during the work year, and eliminates the requirement to record cases that involve restrictions only on the day of injury or illness. These changes will result in fewer cases being recorded, and will have the effect of reducing costs for employers.

The final rule's changes to the method of counting days, i.e., relying on calendar days instead of scheduled work days, will simplify the counting requirements and produce more reliable information on injury and illness severity. Both the change to the calendar day counting method and the capping of days away and days restricted or transferred at 180 days will have the effect of reducing costs for employers.

(iv) Changes to the Definitions of Medical Treatment and First Aid

Former rule. The former rule defined medical treatment as any treatment, other than first aid treatment, administered to injured or ill employees. Medical treatment involved the provision of medical or surgical care for injuries through the application of procedures or systematic therapeutic measures.

The former regulation defined first aid as ''any one-time treatment, and any follow up visit for the purpose of observation, of minor scratches, cuts, burns, splinters, and so forth, which do not ordinarily require medical care. Such one-time treatment, and follow up visits for the purpose of observation are considered first aid even though provided by a physician or registered professional personnel.''

The former *Recordkeeping Guidelines* provided two lists of treatments employers could use to determine whether a particular treatment was first aid or medical treatment for recordkeeping purposes. For example, the use of prescription drugs was generally considered medical treatment, except when only a single dose was

prescribed. Physical therapy, hot or cold therapy, or soaking therapy was considered medical treatment if it was used on a second or subsequent visit to medical personnel. Treatment of any third or second degree burn was considered medical treatment. The former rule's lists provided a useful starting point for determining which treatments were first aid or medical treatment, but also caused some confusion because, if a particular treatment was not on either list, the employer was not sure how to classify the treatment.

Final rule. The final rule defines medical treatment as the management and care of a patient to combat disease or disorder. For the purposes of Part 1904, medical treatment does not include: visits to a physician or other licensed health care professional solely for observation or counseling; the conduct of diagnostic procedures, such as x-rays and blood tests, including the administration of prescription medications used solely for diagnostic purposes (*e.g.*, eye drops to dilate pupils); or first aid.

The final rule then defines first aid by listing 14 first aid treatments, such as using non-prescription drugs at non-prescription strength, using bandages or butterfly bandages, using hot or cold therapy, using splints or slings to transport an accident victim, and drinking liquids for relief of heat stress.

Change. The final rule changes the definitions of which treatments are considered first aid and medical treatment. Each change will result in some change in the number of cases that are recorded, as shown in the following table.

Changes from the former rule to the final rule	Impact on number of cases recorded
Medical treatment now includes all non-prescription drugs at prescription strength and any dose of a prescription drug.	More cases
First aid now includes hot or cold therapy, regardless of how often applied.	Fewer cases
Medical treatment now includes any physical therapy/chiropractic treatment.	More cases
First aid now includes use of butterfly bandages and Steri-Strips for any purpose.	Fewer cases
Medical treatment now includes any use of oxygen.	More cases
Second degree burns are now not automatically recordable.	Fewer cases

The overall effect of the changes to the definitions of medical treatment and first aid is difficult to determine. OSHA believes that they generally offset each other, but data to confirm this are not available.

(v) Changes in the Recording of Needlestick and Sharps Injuries

Former rule. Under the former rule, an employer was required to record a needlestick or sharps injury involving human blood or other potentially infectious material if the case resulted in death, days away from work, restricted work, medical treatment beyond first aid, or loss of consciousness, or if the employee seroconverted (contracted HIV or hepatitis infection).

Final rule. Under the final rule, an employer is required to record *all* needlestick or sharps injuries involving human blood or other potentially infectious material. These cases are recorded as privacy concern cases.

Change. The final rule will require the recording of an additional estimated 501,640 needlestick and sharps injury cases. The costs associated with this change have been quantified in this economic analysis. This change will also significantly simplify recording for those employers who recorded 88,925 needlestick and sharps injuries under the former rule, resulting in cost savings for those cases. These cost savings have been quantified in this economic analysis.

(vi) Changes in the Recording of Hearing Loss

Former rule. Under OSHA's interpretations of the former rule, an employer was required to record a hearing loss of 25 decibels in one or both ears, averaged over three frequencies, compared to the employee's baseline audiogram. Work-relatedness was presumed if the employee was exposed to noise at or above an 8-hour time weighted average of 85 decibels.

Final rule. The final rule requires an employer to record any hearing loss that reaches the level of a standard threshold shift (STS), defined by the occupational noise standard as a 10 decibel shift in hearing, averaged over three frequencies, in one or both ears, compared to the employee's baseline audiogram. Work-relatedness is presumed if the employee was exposed to noise at or above an 8-hour time weighted average of 85 decibels.

The employer must check a separate box on the OSHA Log to identify hearing loss cases.

Change. The additional check box will result in improved statistical data on occupational hearing loss. The change to a more sensitive threshold (10 decibel shift rather than 25 decibel shift) for recording occupational hearing loss will result in the recording of additional cases. Based on audiometric data collected from 22 companies in SICs 20 through 29, 33, 34, 35, 39, 49, and 90, OSHA estimated that, with the new threshold, 250,000 more workers in manufacturing and 25,000 more workers elsewhere in general industry would sustain recordable hearing loss annually. The costs associated with this increase have been quantified in this economic analysis.

(vii) Changes in the Recording of Tuberculosis

Former rule. Under OSHA's interpretation of the former rule, an employer was required to record an active case of tuberculosis (TB) or a positive TB skin test. If the employee was employed in one of five high risk industries, as defined by the Centers for Disease Control and Prevention (CDC), the case was presumed to be work related.

Final rule. Under the final rule, a case of tuberculosis is recorded if the employee has active TB or has a positive skin test. The case is considered work-related if the employee has been occupationally exposed at work to another person (client, patient, co-worker) with a known, active case of tuberculosis. The employer may subsequently remove or line out the case if a medical investigation shows that the case was caused by a non-occupational exposure.

Change. The final rule eliminates the ''special industries'' presumption of work-relatedness. OSHA believes that this change will reduce the number of recorded TB cases, and thus reduce costs somewhat. However, data to estimate the cost savings associated with this change are not available.

(viii) Changes in the Recording of Musculoskeletal Disorders (MSD)

Former rule. Under the former rule, MSD cases were recorded differently based on whether they were occupational injuries or occupational illnesses. If the case was an MSD *injury,* it was recorded if it resulted in days away from work, restricted work, job transfer, or medical treatment beyond

first aid. If the case was an MSD *illness,* it was recorded if it resulted in:

(1) Objective findings:

—A diagnosis by a health care provider (carpal tunnel, tendinitis, etc.)

—Positive test results (Tinel's, Finkelstein's, Phalen's, EMG)

—Signs (redness, swelling, loss of motion, deformity)

OR

(2) Symptoms combined with days away from work, restricted work, or medical treatment beyond first aid.

Injury MSD cases were considered to be ''new cases'' if they resulted from new (additional) workplace events or exposures. Illness MSD cases were treated in the same way or were subjected to a ''30 day rule'' whereby if an ill employee did not return to the health care provider for care after 30 days the case was considered resolved. If the same employee reported later with additional MSD problems, the case was evaluated for recordability as a new illness.

Final rule. Under the final rule, MSD cases are recorded using the same criteria as those for other injuries and illnesses. Cases are recorded if they result in days away from work, restricted work/job transfer, or medical treatment beyond first aid. Recurrences are also handled just as other types of injuries and illnesses are.

The employer must check a separate box on the Log for MSD cases to permit separate data on these disorders to be collected.

Change. The final rule simplifies the recording of MSDs and collects improved statistical information on these disorders on the 300 Log. Because the final rule does not require the automatic recording of diagnosed disorders, physical signs, and positive test results, it will generally require employers to record fewer MSD cases, resulting in some cost savings. However, the magnitude of these cost savings is not known.

(d) Change in Ownership

Former rule. Under the former rule an employer who acquired a business establishment was required to retain the OSHA records of the prior owner. Each owner was responsible for the records only for that period of the year that each owned the business.

Final rule. Under the final rule, when a business establishment changes owners, each owner is responsible for the OSHA records only for that period of the year that each owned the business. The prior owner is required to transfer the records to the new owner, and the new owner is responsible for retaining those records.

Change. The final rule differs from the former rule by requiring the prior owner to transfer the records to the new owner. Any new costs imposed by this requirement are extremely small and have not been quantified in this economic analysis.

(e) Employee Involvement

Former rule. The former rule involved employees in the recordkeeping process in two ways: through posting of the annual summary of occupational injuries and illnesses for one month, and by allowing access to the OSHA 200 Log by employees, former employees, and their representatives.

Final rule. The final rule involves employees in the process to a greater extent than formerly: it requires the employer to set up a system for accepting injury and illness reports from employees and requires the employer to tell each employee how to report a work-related injury or illness. The final rule also requires the employer to post the annual summary for three months. Employees, former employees, and their representatives have the right to one free copy of the 300 Log, the injured or ill employee or a personal representative has a right to one free copy of the 301 (Incident Report) for his or her case, and authorized employee representatives have a right to one free copy of a portion of the 301 form for all injuries and illnesses at the establishment he or she represents.

Change. The final rule will improve employee reporting of work-related injuries and illnesses and allow improved access to the information in the records, including one free copy of each record requested. OSHA finds that these provisions will increase costs for employers, and these costs have been quantified in the economic analysis.

(f) Privacy Protections

Former rule. The former rule had no provisions to protect the privacy of injured or ill workers when a coworker or employee representative was allowed access to the OSHA 200 Log. The employer was required to provide the Log with names intact.

Final rule. The final rule protects the privacy of injured or ill workers when a coworker or employee representative accesses the records by prohibiting the employer from entering the employee's name for certain ''privacy concern'' cases. A separate, confidential list of case numbers and employee names must be kept for these cases. An employee representative can access only part of the information from the 301 form, and the employer must withhold the remainder of the information when providing copies. With certain exceptions, if the employer provides the information to anyone other than a government representative, an employee, a former employee, or an employee representative, the names and other personally identifying information must be removed from the forms. In addition, separation of the summary form will eliminate accidental disclosure of employee names during the posting of the summary information.

Change. The final rule protects injured or ill employees' privacy in several ways, *e.g.,* by limiting the distribution of injured or ill employees' names, by not recording the employee's name in privacy concern cases, and by providing employee representatives access to only part of the Form 301. The costs of keeping a separate, confidential list for privacy concern cases have been quantified in the economic analysis.

(g) Computerized and Centralized Records

Former rule. The former rule allowed the employer to keep the OSHA 200 Log on computer equipment or at a location other than the establishment, and required that the employer have available a copy of the Log current to within 45 calendar days. The former rule had no provisions for keeping the OSHA 101 form off site or on computer equipment.

Final rule. The final rule allows all forms to be kept on computer equipment or at an alternate location, providing the employer can produce the data when it is needed to provide access to a government inspector, employee, or an employee representative. There is no need to keep records at the establishment at all times.

Change. The final rule provides the employer with greater flexibility for keeping records on computer equipment and at off-site locations. These costs savings have been quantified in the economic analysis.

Reporting of Fatality and Catastrophe Incidents

Former rule. The former rule required the employer to report any workplace fatality, or any incident involving the hospitalization of 3 or more employees to OSHA within 8 hours.

Final rule. The final rule requires the employer to report any workplace fatality, or any incident involving the hospitalization of 3 or more employees to OSHA within 8 hours. The final rule does not require the employer to report to OSHA fatal or multiple hospitalization incidents that occur on commercial airlines, trains and buses; or fatality/catastrophe incidents from a

motor vehicle accident on a public highway.

Change. The final rule requires employers to report fewer incidents to OSHA, which will result in cost savings. These cost savings have not been quantified in the economic analysis.

(3) Qualitative Overview of Impacts

Forms

The largest impact of the final rule's revised provisions on recordkeeping at the individual establishment will be in the direction of cost savings and will come from the plain language rewriting of the rule itself and the new forms. These changes in language, organization, and format will reduce the burden on employers and recordkeepers in several ways. The clearer language and streamlining will allow the entire rule to be read more quickly and with greater comprehension. It will also be possible to obtain a good understanding of the rule in a single reading (which will be particularly helpful for establishments with very few or no recordable incidents). Finally, the organization and format make it far easier to get quick answers to specific questions, because the answers are part of the final rule itself rather than being included in a separate document, the *Recordkeeping Guidelines for Occupational Injuries and Illnesses* (the ''Blue Book'').

2. Industry Profile

OSHA's former regulation for Recording and Reporting Occupational Injuries and Illnesses, 29 CFR part 1904, covered most industries in the economy. The principal exceptions were the finance, insurance, and real estate sector, some retail trade industries, and some service industries. This chapter describes the changes in coverage, as well as key characteristics of the industries that will be covered under the final rule.

A. Changes in Industries Covered

The former rule (with one exception) covered or exempted industries at the two-digit SIC level. The final rule fine tunes this coverage in the finance, insurance, and real estate, retail trade, and service sectors by extending coverage to some high-hazard three-digit SICs in two-digit SICs that were not covered by the former rule and exempting some low-hazard three-digit SICs in two-digit industries that were covered by the former rule. These changes, by two-digit SICs, are as follows:

Industries covered under the former rule that would continue to be covered under the final rule:[7]

Agriculture (SIC 01–02),
Forestry, and Fishing (SIC 07–09),
Oil & Gas Extraction (SIC 13),
Sulfur Mining (SIC 1479, part),
Construction (SIC 15–17),
Manufacturing (SIC 20–39),
Transportation (SIC 41–42),
United States Postal Service (SIC 43),
Public Utilities (SIC 44–49),
Wholesale Trade (SIC 50–51),
General Merchandise Stores (SIC 53),
Hotels and Other Lodging Places (SIC 70), and
Automotive Repair, Services, and Parking (SIC 75).

Industries exempted under the former rule that would continue to be exempted:

Apparel and Accessory Stores (SIC 56),
Eating and Drinking Places (SIC 58),
Depository Institutions (SIC 60),
Nondepository Institutions (SIC 61),
Security and Commodity Brokers (SIC 62),
Insurance Carriers (SIC 63),
Insurance Agents, Brokers, and Services (SIC 64),
Holding and Other Investment Offices (SIC 67),
Motion Pictures (SIC 78),
Legal Services (SIC 81),
Educational Services (SIC 82),
Membership Organizations (SIC 86),
Engineering, Accounting, Research, Management & Related Services (SIC 87), and
Services, not elsewhere classified (SIC 89).

Two-digit industries that were not covered under the former rule but will have some three-digit industries within them covered under the final rule:

Automobile Dealers (SIC 55),
Furniture Stores (SIC 57),
Miscellaneous Retail Stores (SIC 59),
Real Estate (SIC 65),
Personal Services (SIC 72),
Business Services (SIC 73),
Social Services (SIC 83), and
Museums (SIC 84).

Two-digit industries that were covered under the former rule but will have some or all three-digit industries within them exempted under the final rule:

Building Materials & Garden Supplies (SIC 52),
Food Stores (SIC 54),
Miscellaneous Repair Services (SIC 76),
Amusement and Recreation Services (SIC 79), and
Health Services (SIC 80).

Table X–2 shows the specific three-digit industries that were formerly exempted and to which the final rule will extend coverage. Table X–3 shows the specific three-digit industries that were formerly covered and which the final rule will exempt.

Exempting an industry means that employers with establishments in that industry do not have to keep the OSHA Form 300 (the Log of Occupational Injuries and Illnesses), the Annual Summary (OSHA 300-A), and OSHA Form 301 (the Incident Record) or their equivalents. The final rule does not exempt establishments from the obligation to report fatalities or multiple hospitalization accidents to OSHA, nor does it exempt an employer from the requirement to maintain records if notified by the Bureau of Labor Statistics that it is a participant in the annual Occupational Injuries and Illnesses Survey or by OSHA that it has been selected to report under the OSHA Data Initiative.

B. Characteristics of Covered Establishments

(1) Number of Establishments

Table X–4 shows the estimated number of establishments, by industry, covered by the final regulation. Data for agriculture (SICs 01 and 02) are taken from the 1997 Census of Agriculture. Data for the remaining SICs are taken from a compilation of 1996 data by the U.S. Census Bureau for the Small Business Administration (SBA) to reflect parent company control of establishments. Firms that have 10 or fewer employees,[8] which are exempt from the final regulation because of their size, are excluded from Table X–4.

[7] In addition, state and local government employers will continue to be covered in State Plan states.

[8] The SBA data have size classes of 5–9 employees and 10–19 employees. Establishments with 10 employees were assumed to account for ten percent of the 10–19-employee size class. Since the distribution is skewed by size, rather than being uniform, this assumption slightly overstates the number of establishments covered by the regulation.

TABLE X–2.—FORMERLY EXEMPT INDUSTRIES THAT THE FINAL RECORDKEEPING RULE COVERS

Two-digit industry*	Three-digit industry that OSHA's final rule covers
SIC 55	SIC 553, Auto and Home Supply Stores
	SIC 555, Boat Dealers
	SIC 556, Recreational Vehicle Dealers
SIC 57	SIC 571, Home Furniture and Furnishings Stores
	SIC 572, Household Appliance Stores
SIC 59	SIC 593, Used Merchandise Stores
	SIC 596, Nonstore Retailers
	SIC 598, Fuel Dealers
SIC 65	SIC 651, Real Estate Operators and Lessors
	SIC 655, Subdividers and Developers
SIC 72	SIC 721, Laundry, Cleaning, and Garment Service
SIC 73	SIC 734, Services to Buildings
	SIC 735, Miscellaneous Equipment Rental/Leasing
	SIC 736, Personnel
SIC 83	SIC 833, Job Training and Related Services
	SIC 836, Residential Care
SIC 84	SIC 842, Botanical and Zoological Gardens

* Only the 3-digit SICs shown in the second column are covered by the rule; those within the 2-digit SIC that are not listed are still exempt from the requirement to keep OSHA records routinely.

TABLE X–3.—FORMERLY COVERED INDUSTRIES EXEMPTED BY THE FINAL RULE

Two-digit industry	Three-digit industry that OSHA's final rule exempts
SIC 52	SIC 525, Hardware Stores
SIC 54	SIC 542, Meat and Fish Markets
	SIC 544, Candy, Nut, and Confectionery Stores
	SIC 545, Dairy Product Stores
	SIC 546, Retail Bakeries
	SIC 549, Miscellaneous Food Stores
SIC 76	SIC 764, Reupholstry and Furniture Repair
SIC 79	SIC 791, Dance Studios, Schools, and Halls
	SIC 792, Producers, Orchestras, and Entertainers
	SIC 793, Bowling Centers
SIC 80	SIC 801, Offices and Clinics of Medical Doctors
	SIC 802, Offices and Clinics of Dentists
	SIC 803, Offices of Osteopathic Physicians
	SIC 804, Offices of Other Health Practitioners
	SIC 807, Medical and Dental Laboratories
	SIC 809, Health and Allied Services, nec

TABLE X–4—ESTABLISHMENTS REQUIRED BY THE FINAL RULE ROUTINELY TO KEEP OCCUPATIONAL INJURY/ILLNESS RECORDS

Industry establishments		Estimated number of establishments required to keep records	Estimated number of recordable cases annually in these
Agricultural Production	SIC 01–02	56,367	46,770
Agricultural Svcs, Forestry, Fishing	SIC 07–09	16,271	54,022
Oil and Gas Extraction	SIC 13	5,367	13,851
Construction	SIC 15–17	114,470	415,500
Manufacturing	SIC 20–39	196,643	2,060,900
Transportation, Postal, Utilities	SIC 41–49	157,390	516,653
Wholesale Trade	SIC 50–51	219,678	403,240
Building Materials/Garden Supplies	SIC 52[a]	22,339	56,091
General Merchandise Stores	SIC 53	28,519	180,909
Food Stores	SIC 54[b]	64,443	126,780
Automotive Dealers	SIC 55[c]	23,342	22,662
Furniture Stores	SIC 57[d]	25,580	24,302
Miscellaneous Retail Stores	SIC 59[e]	19,913	23,750
Real Estate	SIC 65[f]	17,925	22,702
Hotels and Other Lodging Places	SIC 70	23,956	103,423
Personal Services	SIC 72[g]	14,768	18,072
Business Services	SIC 73[h]	51,525	58,659
Automotive Repair, Svcs, Parking	SIC 75	41,575	40,359
Miscellaneous Repair Services	SIC 76[i]	12,294	17,686
Amusement and Recreation Services	SIC 79[j]	20,602	79,623

TABLE X–4—ESTABLISHMENTS REQUIRED BY THE FINAL RULE ROUTINELY TO KEEP OCCUPATIONAL INJURY/ILLNESS RECORDS—Continued

Industry establishments		Estimated number of establishments required to keep records	Estimated number of recordable cases annually in these
Health Services	SIC 80[k]	38,996	995,122[l]
Social Services	SIC 83[m]	25,998	25,349
Museums	SIC 84[n]	236	2,408
State and Local Government Employers in State Plan States		167,788	519,646
TOTAL: Final Rule[o]		1,365,985	5,828,477
TOTAL: Former Rule[o]		1,306,418	4,907,081

[a] Consists of Lumber & Other Building Materials (SIC 521); Paint, Glass, & Wallpaper Stores (SIC 523); Retail Nurseries & Garden Stores (SIC 526); and Mobile Home Dealers (SIC 527).
[b] Consists of Grocery Stores (SIC 541) and Fruit and Vegetable Markets (SIC 543).
[c] Consists of Auto and Home Supply Stores (SIC 553); Boat Dealers (SIC 555); and Recreational Vehicle Dealers (SIC 556).
[d] Consists of Furniture & Homefurnishings Stores (SIC 571) and Household Appliance Stores (SIC 572).
[e] Consists of Used Merchandise Stores (SIC 593); Nonstore Retailers (SIC 596); and Fuel Dealers (SIC 598).
[f] Consists of Real Estate Operators and Lessors (SIC 651) and Subdividers and Developers (SIC 655).
[g] Consists of Laundry, Cleaning, and Garment Services (SIC 721).
[h] Consists of Services to Buildings (SIC 734); Miscellaneous Equipment Rental and Leasing (SIC 735); and Personnel Supply Services (SIC 736).
[i] Consists of Electrical Repair Shops (SIC 762); Watch, Clock and Jewelry Repair (SIC 763); and Miscellaneous Repair Shops (SIC 769).
[j] Consists of Commercial Sports (SIC 794) and Miscellaneous Amusement & Recreation Services (SIC 799).
[k] Consists of Nursing and Personal Care Facilities (SIC 805); Hospitals (SIC 806); and Home Health Care Services (SIC 808).
[l] Includes estimated 501,640 needlesticks and sharps not now recordable that are covered by the final rule.
[m] Consists of Job Training and Related Services (SIC 833) and Residential Care (SIC 836).
[n] Consists of Botanical and Zoological Gardens (SIC 842).
[o] Sulfur mining (part of SIC 1479) is excluded because information is not available.
Sources: U.S. Census Bureau compilation of 1996 establishment and employment data by parent firm, performed for the Small Business Administration; Bureau of Labor Statistics 1998 Survey of Occupational Injuries and Illnesses.

The final regulation covers an estimated total of 1,365,985 establishments belonging to 699,712 employers. The number of establishments covered by the rule represents a net increase of 4.6 percent over the 1,306,418 establishments covered by the former regulation. This increase in the number of establishments covered results from the changes made to the scope of the final rule.

(2) Number of Recordable Cases

Table X–4 also shows the number of recordable cases of occupational injury and illness, by industry, covered by the final regulation. These are taken from unpublished data from the 1998 BLS Survey of Occupational Injury and Illness.

The final regulation will annually capture an estimated total of 5,828,477 occupational injury and illness cases. Of these cases, 275,000 represent additional hearing loss cases and 501,640 represent additional needlestick and sharps injuries anticipated to occur in SIC 80. The needlestick and sharps number represents 85 percent of the estimated 590,165 needlestick and sharps injuries occurring in SIC 80 (63 FR 48250, September 9, 1998; Ex. 3–172V, Docket No. H370A), since OSHA estimates that approximately 15 percent of such injuries were being recorded under the former rule. Since not all of SIC 80 is covered by the final rule, this figure is likely to overstate the number of recordable cases to some extent.

Exclusive of the 275,000 additional hearing loss cases and the 501,640 additional needlestick and sharps injuries, the final regulation will capture an estimated 5,051,837 cases annually. This is an increase of 3 percent over the 4,907,081 cases captured by the former rule. This increase in capture reflects changes in the scope of the rule that are designed to target the regulation more precisely to high-risk industries in the retail and service sectors of the economy. This increase in the rule's capture efficiency, or cost-effectiveness, is reflected by the fact that the industries that are newly covered under the final rule average 2.6 times as many cases per covered establishment as the industries the final rule would newly exempt.

3. Costs

A. Overview of the Analysis

(1) Background

This chapter assesses the changes in compliance costs associated with the changes the Occupational Safety and Health Administration (OSHA) is making to 29 CFR part 1904, the Agency's Recording and Reporting Occupational Injuries and Illnesses rule, and its associated forms and instructions. The analysis relies in part on methodology and estimates provided in a study conducted for OSHA by Meridian Research, Inc. The Meridian analysis has been updated to reflect more recent data as well as changes that OSHA has made to the regulation in the interval since the Meridian report was prepared, and to reflect comments on the proposed rule.

The great majority of the establishments covered by the rule are small, i.e., have fewer than 20 employees. On average, a covered establishment records 4 occupational injury and illness cases per year, and the recordkeeping decisions involved in these cases are generally straightforward and easy to make (*e.g.*, the injuries involve lacerations, slips and falls, or fractures). Unlike other OSHA rules, the recordkeeping rule does not require employers to implement engineering controls, change employee work practices, provide protective equipment, or take other costly actions to protect their employees' safety and health. Instead, the costs of this rule are based on the costs associated with the time the recordkeeper and others spend in maintaining the records and overseeing the recordkeeping system. OSHA's estimates of the time necessary to perform each step of the recordkeeping process, including the time to consider and record each case, maintain the Log, and perform other recordkeeping tasks, have been reviewed and commented on

by the public and approved by the Office of Management and Budget in connection with the process required by the Paperwork Reduction Act of 1995. Even if OSHA's estimates of the time involved in making, determining, and overseeing the records involved in the recordkeeping system are low, for example, by a factor of two or so, the costs imposed by the final rule are low in comparison with the benefits of the system and are readily affordable by covered establishments. (See the Impacts section of this economic analysis.)

Because the final regulation makes a number of changes, some of which increase the amount of information employers must maintain and others that simplify recordkeeping and reduce the burden, it is difficult to estimate the precise impact of a given change on establishments in particular industries. Moreover, most individual changes have only a minor impact on burdens, whether positive or negative. Accordingly, the analysis groups together changes to a specific portion of the recordkeeping activities, such as maintaining the Log or filling out the individual report of injury, and (for the most part) assesses the net impact of the group of provisions, rather than the impact of each provision individually.

The analysis reflects the fact that the final regulation is a revision of a former regulation. Thus many of the impacts are changes in the burden of doing something that is already required. Wherever this is the case, the burden under the former and final regulations will be the same if the activities are unchanged. In addition, small changes in burden estimates, both positive and negative, may offset each other.

(2) Analytical Approach

Scope. The costs of the final rule depend in part on the scope of the rule, i.e., on the industries that are covered. As noted in Chapter II, affected industries fall into three groups, depending on their inclusion or exemption under the former and final rules. Impacts differ for each of these three groups:

—For industries covered under the former rule and the final rule, impacts are the costs employers will incur to comply with changes made in a regulatory provision.

—For industries covered by the former rule but exempted under the final rule, impacts consist of cost savings equal to the cost of compliance employers incurred under the former rule.

—For industries exempted under the former rule but covered by the final rule, impacts are the total cost of compliance employers will incur under the final rule.

In examining the costs of this rule, it is critical to remember certain basic characteristics of affected facilities. On average, facilities subject to recordkeeping have about 50 employees and record about four injuries and illnesses a year. Because the size distribution of facilities is somewhat skewed, the majority of establishments record fewer than four injuries and illnesses a year and have fewer than 20 employees. Some commenters appeared to be unaware of the small number of injuries and illnesses recorded by the typical affected establishment when commenting on the proposal. For example, the comment of one commenter that the typical establishment will need to train 2 to 4 recordkeepers (Ex. 15–375) is clearly not reasonable because the typical establishment covered by this rule employs about 50 employees and records a total of four injuries and illnesses a year.

The impacts of changes in specific regulatory provisions are generally related to one of two factors:

• Costs that are essentially fixed costs for an establishment are estimated on a per-establishment basis and multiplied by the number of affected establishments.

• Costs that vary with the number of cases recorded are estimated on a per-case-recorded basis and multiplied by the number of such cases recorded.

Other Parameters. Burdens are estimated as number of minutes (per establishment or per case) to comply with each provision. Most of the costs are based on the assumption that recordkeeping tasks will be conducted by someone with the skill level of a personnel specialist who would be qualified both to obtain and to enter the necessary data. The wage rate for a Personnel Training and Labor Relations Specialist—$19.03, or $26.32 including fringe benefits [9]—is used for this cost. Where the time of a company official is called upon, the estimated labor cost is based on the hourly rate for an Industrial Production Manager—$26.38, or $36.48 including fringe benefits.

Cost estimates for many specific tasks are also influenced by the fact that almost all establishments will also have to gather information on work-related injuries and illnesses for insurance and workers' compensation purposes. In many cases, the data that employers must collect and provide for these purposes are considerably more detailed than those required by OSHA. Even OSHA recordable injuries and illnesses that turn out, in the end, not to be workers' compensation claims are likely to be investigated to determine their status in relation to the workers' compensation system. As a result, much of the basic data gathering necessary to the recording of injuries and illnesses has already been done independent of the OSHA recordkeeping requirements, and, in most cases, making the OSHA record simply involves copying information from other sources to the OSHA form.

(3) Overview of Estimates

The estimated net impact of the revisions to the recordkeeping rule is a cost of $38.6 million per year. Estimated net costs for establishments covered by the former rule that will continue to be covered by the final rule are relatively minor, and the estimated 119,720 establishments that OSHA has exempted from the final rule will incur substantial savings. The chief cost increases will be to the 179,287 establishments brought under the scope of OSHA's recordkeeping rule for the first time.

B. Initial Costs of Learning the Recordkeeping System

(1) Initial Costs to Establishments Already Covered of Becoming Familiar With the Revised Recordkeeping System

Recordkeepers in establishments that were covered by the former regulation and that will continue to be covered under the final regulation will need to become familiar with the changes in the recordkeeping system associated with the final rule even before an injury or illness occurs. OSHA originally estimated that this initial familiarization would require 15 minutes per such establishment. Some commenters objected to this estimate as too low. (See, for example, Exs. 15: 119, 15: 357, 15: 375, 15: 395.) For example, one commenter (Ex. 15: 395) stated that ''No person could give even a superficial reading to this material [the proposed rule] in 15 minutes.'' Another commenter (Ex. 15: 375) stated that this was ''not enough time for one person to even read through the rule and the preamble one time.'' OSHA does not believe that experienced recordkeepers will need to read the entire preamble, or even the entire rule, in order to familiarize themselves with the new recordkeeping changes. For the most part, the new system continues the concepts, practices, and interpretations developed under the former rule and

[9] Benefits and overhead are computed at 38.3 percent of the hourly wage.

thus is well known to recordkeepers. OSHA believes that most recordkeepers will avail themselves of the summaries of the changes in the rule provided by OSHA or by a wide variety of other sources. The recordkeepers' thorough knowledge of the recordkeeping system will suffice to cover most aspects of the rule. Nor does OSHA agree that the typical recordkeeper, who needs to record only 4 injuries and/or illnesses a year, needs to study every change. For example, a recordkeeper relying on OSHA's summary information on the differences between the former and the revised rule only needs to make a mental note to the effect that injuries and illnesses occurring in parking lots are treated differently under the revised rule, but would not have to know the details of the changes until (if ever) the recordkeeper actually has an injury or illness that occurred in a parking lot. Nevertheless, as a result of the comments received on the prior proposed time estimates, OSHA has raised its familiarization estimate to 20 minutes per establishment for facilities with prior OSHA recordkeeping experience. This estimate covers the time needed for an experienced recordkeeper to learn the basics of the new system, but assumes that such a recordkeeper, who records an average of four cases per year, need not learn the details of the system for dealing with unusual cases until, and if, they arise; instead, this recordkeeper is assumed to examine specific issues later and as needed, when issues arise in the course of the recording of actual cases. The time attributed in this analysis to the recording of individual cases (discussed below) includes the time needed to understand the details of the individual case. It is assumed that this subsequent learning will occur as recordkeepers enter the data; that is, the time that OSHA estimates will be initially required to complete both Form 300 and Form 301 entries includes the time that the Agency estimates will be needed for additional familiarization with issues related to the entry being made. The costs for this subsequent recording activity are discussed in Part D of this section of the economic analysis. The initial familiarization cost is a one-time cost that will not recur. Accordingly, this cost was annualized over ten years using a 7 percent discount rate. The net annualized costs of this initial familiarization activity are $1,482,384.[10]

(2) Costs of Learning the Basics of the Recordkeeping System *De Novo*

Establishments required to keep OSHA records will incur the costs associated with learning about the recordkeeping system from scratch whenever a new person takes over the recordkeeping job as a result of staff turnover. OSHA assumes that 20 percent of covered establishments will experience such staff turnover in any given year. Establishments that are newly covered by the regulation will also incur the costs of learning the recordkeeping system *de novo.* Establishments that are newly exempted under the regulation, of course, will save the staff turnover costs formerly associated with recordkeeping.

At the time of the proposal, OSHA estimated that, under the former regulation, new personnel would require a 30-minute orientation to learn the basics of the recordkeeping system and 25 minutes to learn the newer, simpler recordkeeping system. Many commenters believed that these estimates were too low. (See, for example, Exs. 15: 119, 15: 170, 15: 357, 15: 375.) After reviewing the record, OSHA agrees that the estimates in the Preliminary Economic Analysis did not adequately capture the average amount of time required to learn the system for a person without previous knowledge of OSHA recordkeeping. OSHA has revised its average estimate of the time for learning the new recordkeeping system *de novo* to one hour and has revised the average estimate of the time it would have taken a recordkeeper to learn the previous recordkeeping system to 1.5 hours. (In other words, OSHA believes that its prior estimate of the average amount of time required to learn the former recordkeeping system—30 minutes—was too low.)

Although OSHA's revised average estimates are lower than the estimates made by some commenters, OSHA believes that the Agency's estimates appropriately reflect the average amount of time new recordkeepers will need to learn the basics of the system. Again, new recordkeepers are assumed not to learn all the details of the new system up front, such as exactly when an off-site injury is considered work-related or how to classify injuries occurring in lunch rooms, until such a case actually arises in the workplace. Since unusual cases and those falling within the exceptions are relatively rare, recordkeepers will generally choose to obtain detailed case-specific information only when it is needed. New recordkeepers need only to know that such exceptions exist and that further study of the rule will be necessary in the relatively unlikely event that such an injury or illness occurs. OSHA's estimates of the time required to record each case (discussed further below) include the time for the recordkeeper to study the instructions to learn how to address specific issues that may arise when recording specific types of injuries or illnesses (*e.g.*, noise-induced hearing loss or work-related TB cases).

OSHA believes that the new system is much simpler than the old. Many simplifications, *e.g.*, the use of calendar days, capping of days away cases, have been made to the rule to save effort. This additional simplicity, as well as improved outreach materials to explain the new regulation, will, OSHA believes, result in significantly reducing the length of time required to learn the system. OSHA estimates that learning the basics will take, on average, one hour. This will save 30 minutes compared to the learning time that would have been required for the former system.

Continuously Covered Establishments. Establishments that were covered under the former regulation and continue to be covered under the final regulation will save 30 minutes, compared with the time needed under the former rule, whenever staff turnover requires a new recordkeeper. At a 20 percent turnover rate, the net annualized savings for this learning activity under the final rule are $3,123,394.[11]

Newly Exempted Establishments. Establishments that were covered under the former regulation but are exempted under the final regulation will incur a saving of 90 minutes whenever staff turnover would have required a new recordkeeper. At a 20 percent turnover rate, the net annualized savings of eliminating the need for this learning activity are $945,309.[12]

Newly Covered Establishments. Establishments that were exempt under the former regulation but are covered under the final regulation will incur two types of costs: All establishments will incur an initial learning cost of one hour per establishment. Since this is a one-time cost that will not recur, the cost was annualized over ten years using a 7 percent discount rate. In addition, these establishments will incur an ongoing cost of 60 minutes whenever staff turnover requires a new recordkeeper to become familiar with the system. The net annualized costs of this learning activity are $671,856 + $943,756 = $1,615,612.[13]

[10] $1,482,384 = (1,186,698 Establishments) × (20 Minutes/Establishment) × ($26.32/Hr.) × [0.07/(1 − (1/(1.07)^{10}))]

[11] $3,123,394 = (1,186,698 Establishments) × (0.2) × (30 Minutes/Establishment) × ($26.32/Hour)

[12] $945,309 = (119,720 Establishments) × (0.2) × (90 Minutes/Establishment) × ($26.32/Hour)

[13] $1,615,612 = (179,287 Establishments) × (60 Minutes/Establishment) × ($26.32/Hour) × [0.07/(1 − (1/(1.07)^{10}))] + (179,287 Establishments) × (0.2) × (60 Minutes/Establishment) × ($26.32/Hour)

(3) Total Cost Impact

Table X–5 summarizes the total annualized cost impacts of initially learning the recordkeeping system under the final regulation. The total net annualized impact is estimated to be a saving of $970,757.

C. Fixed Costs of Recordkeeping

A number of the cost items associated with the final rule do not vary with the size of the establishment or the number of cases reported. These include the costs of setting up the Log, posting the Summary, certifying the Summary, and providing data from the Log to OSHA inspectors. Impacts in this category are related to the number of establishments covered and the specific changes in recordkeeping requirements.

TABLE X–5—FAMILIARIZATION COSTS ASSOCIATED WITH THE FINAL RULE

Cost element/industry status under the final rule	Estimated number of establishments	Change in level of effort		Total cost
		(Minutes)	Hours	
Shift to the New Recordkeeping System:				
Formerly & Still Covered	1,186,698	20	395,566	[a,b]$1,482,384
Initally Learn the Basics of the Recordkeeping System:				
Newly Covered	179,287	60	179,287	[a,b]671,856
Re-learn the Basics of the Recordkeeping System:				
Formerly & Still Covered	237,340	−30	-118,670	[a] −3,123,394
Newly Exempted	23,944	−90	−35,916	[a] −945,309
Newly Covered	35,857	60	35,857	[a]943,756
Total Annual Cost			[c]456,124	970,757

[a] Based on an hourly cost of $26.32.
[b] One-time cost that is annualized over 10 years at a discount rate of 7 percent.
[c] Includes 574,853 hours that will be required in the first year only.

(1) Setting Up the Log and Posting the Summary

Both the former rule and the final rule require that the Log be set up at the beginning of the year and that the Annual Summary be posted on February 1 of the year following the year to which the data pertain. The final regulation requires that the Summary remain posted for three months, while the former regulation required that it remain posted for only one month.

OSHA estimates that the process of setting up the Log and filling out and posting the Summary under the former regulation required 8 minutes. OSHA has no reason to believe that this burden will change as a result of the final rule. Most of the concern expressed in the comments on the proposed recordkeeping rule related to the burden commenters perceived to be associated with updating the posted Summary form when revisions were made and mailing out the Summary as an alternative to posting (see, *e.g.*, Exs. 15: 288, 303, 395). Updating the posted Summary was never OSHA's intent, and the final rule has dropped the mailing alternative, so that both of these concerns are now moot. Any possible increase in burden due to the longer posting periods for the Summary (posting for 3 months rather than 1 month) should be offset by greater simplicity in keeping the Log using the new forms.

The final rule's changes in posting requirements will have no impact on establishments that were covered under the former rule and will be covered under the final rule. Establishments that are newly exempted by the final rule will have an annual savings of 8 minutes each, however. Establishments that are newly covered will incur an annual cost of 8 minutes each. The total estimated impact of these changes in scope is a net cost of −$420,146 + $629,180 = $209,034.[14]

(2) The Annual Summary

The final rule adds a requirement for employers to record on the Log Summary the average number of employees working in the establishment over the past year and the total hours worked by all employees during that year. OSHA initially estimated that recording these data on the Summary would add 5 minutes of labor per establishment to the cost of maintaining each Log. Many commenters noted that this step might be difficult, and some stated that it might be more time consuming than estimated. (See, *e.g.*, Ex. 15: 170.) One commenter stated that this information was sufficiently valuable for management purposes that firms would benefit from having the data if they did not already compile these data (Ex. 15: 395). The commenters who argued that this requirement would be burdensome were generally large multi-establishment firms (see, *e.g.*, Exs. 15: 218, 15: 423). Since OSHA's estimate of this cost is per establishment, these firms would indeed bear higher costs. OSHA does not believe that this requirement will necessitate modifications to data systems for the vast majority of firms; finding where the data are on existing systems should suffice. OSHA also believes that the final rule has clarified that the average number of employees and hours worked need not be precise and can simply be an estimate, which should reduce the amount of effort required to generate this number. The Agency thus finds that this procedure will be relatively simple for most single-establishment firms that maintain personnel records that already have this information for a variety of other purposes. However, OSHA also recognizes that firms with more than one establishment may keep this information only on a firm, not establishment, basis, and may need to perform calculations to compile or revise the data available from their management systems. To account for this, OSHA has raised its average estimate of the time required for the additional information to 20 minutes.

This burden is estimated to fall on all establishments covered by the rule, but not on newly exempted establishments. The total estimated cost of this additional data requirement is $10,411,297 + $1,572,936 = $11,984,233.[15]

The former rule required the recordkeeper to certify that the entries on the Summary were true, accurate, and complete. The final rule requires a company executive to certify that he or she has examined this document and ''reasonably believes, based on his or her knowledge of the process by which the information was recorded, that the annual summary is correct and complete.''

OSHA estimated, at the time of the proposal, that the former requirement that the recordkeeper certify the Summary cost an average of 2 minutes, because all the recordkeeper had to do was sign the form. The final rule drops the requirement for recordkeeper certification.

Having the Summary certified by a company executive was estimated at the time of the proposal to require only 5 minutes.[16] OSHA now estimates that certification by a

[14] $209,034 = (−119,720 + 179,287 Establishments) × (8 Minutes/Establishment) × ($26.32/Hour)

[15] $11,984,233 = (1,186,698 + 179,287 Establishments) × (20 Minutes/Establishment) × ($26.32/Hour)

[16] The proposal would have replaced certification by the recordkeeper with certification by a plant manager. Many commenters stated that this would have required the plant to become personally familiar with the information being certified, and that this would have entailed considerably more time than 5 minutes (see, *e.g.*, Exs. 15–9, 15–355, 15–428, 15–395).

company executive will require 30 minutes, because the Agency believes that the company executive will briefly review the records, perhaps speak with the recordkeeper, and generally take whatever steps are necessary to assure himself/herself that the records are accurate. Although, as noted above, the typical firm covered by the rule only records 4 cases per year and these cases are generally straightforward, OSHA believes that the certifying executive will need this amount of time, on average, to perform this task thoughtfully. Again, this estimate is an average estimate—it will take longer for some very large firms and less time for small firms. Estimated impacts on the different classes of establishments are as follows:

Continuously Covered Establishments. Establishments that were covered by the former rule and will be covered by the final regulation will save the costs for certification by the recordkeeper, but will incur new costs for certification by a responsible company official. This change in requirements results in an estimated total annual cost of $20,604,232.[17]

Newly Exempted Establishments. Establishments that were covered by the former regulation but are exempted from the final regulation will realize a cost saving of 2 minutes of recordkeeper time. The estimated total annual savings will be $105,043.[18]

Newly Covered Establishments. Establishments that were exempt under the former regulation but are covered by the final regulation will incur costs of 30 minutes of company official time. The total annual cost is estimated to be $3,270,213.[19]

The total impact of the final rule's certification requirement is estimated to be $23,769,204.

(3) Provision of Data to OSHA Inspectors

Like the former rule, the final rule requires employers to provide the Log and Incident Reports to an OSHA inspector during a compliance visit. Employers are now required by the final rule to provide a copy of these forms to the inspector on request. OSHA believes that providing copies has in fact been the practice in the past, even though the former rule did not spell this out specifically. OSHA thus does not believe that this small change in the regulation will result in burdens or costs for employers.

(4) Informing Employees How To Report Occupational Injuries and Illnesses

The final regulation requires employers to set up a way for employees to report work-related injuries and illnesses and inform employees about the approach they have chosen. OSHA assumes that it will take a Personnel Training and Labor Relations Specialist (or equivalent) at each establishment an average of twenty minutes to decide on a system and inform employees of it. The ''way'' will usually simply involve directing supervisors to inform their subordinates, as part of their usual communication with them, to report work-related injuries and illnesses to their supervisor. Most, if not all, establishments require employees routinely to report problems of any kind to their supervisors, and reporting injuries and illnesses is simply one of the kinds of things employees report. OSHA believes there will be no additional cost associated with the supervisors' forwarding of these reports to the person in charge of recordkeeping, because this is already part of supervisors' duties. This is a one-time cost, which OSHA has annualized over ten years using a 7 percent discount rate. The net annualized costs of setting up the system are $1,706,285.[20]

(5) Total Cost Impact

Table X–6 summarizes the total annualized cost impacts of fixed, establishment-level costs resulting from the final regulation. The total net annualized costs are estimated to be $37,668,954.

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[17] $20,604,232=(1,186,698 Establishments) × (−2 Minutes/Establishment) × ($26.32/Hour) + (30 Minutes/Establishment) × ($36.48/Hour)

[18] $105,043=(119,720 Establishments) × (2 Minutes/Establishment) × ($26.32/Hour)

[19] $3,270,213=(179,287 Establishments) × (30 Minutes/Establishment) × ($36.28/Hour)

[20] $1,706,285=(1,365,985 Establishment) × (20 Minutes/Establishment) × ($26.32/Hr.) × [0.07/(1 − (1/(1.07)^{10}))]

TABLE X-6
FIXED ANNUAL COSTS TO ESTABLISHMENTS

Cost Element/ Industry Status under Final Rule	Estimated Number of Establishments	Change in Level of Effort (Minutes)	Total Hours	Total Cost
Set Up Log and Post Summary				
Newly Exempted	119,720	- 8	- 15,963	-$ 420,146[a]
Newly Covered	179,287	8	23,905	$ 629,180[a]
Additional Data Requirements on Summary				
Formerly & Still Covered	1,186,698	20	395,566	$10,411,297[a]
Newly Covered	179,287	20	59,762	$ 1,572,936[a]
Certification of Summary				
Formerly & Still Covered	1,186,698	- 2	- 39,557	$ 1,041,140[a]
		30	593,349	$21,645,372[b]
Newly Exempted	119,720	- 2	- 3,991	- $ 105,043[a]
Newly Covered	179,287	30	89,644	$ 3,270,213[b]
Way to Inform Employees	1,365,985	20	455,328	$ 1,706,285 [a,c]
TOTAL ANNUAL COST			1,588,043[d]	$37,668,954

[a] Based on an hourly cost of $26.32.

[b] Based on an hourly cost of $36.48.

[c] One-time cost that is annualized over 10 years at a discount rate of 7 percent.

[d] Includes 227,664 hours that will be required in the first year only.

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D. Costs of Maintaining Records

The costs of maintaining the Log and Incident Reports are related to the number of cases recorded. There are numerous changes to the final rule that result in very small increases or decreases in the number of cases that will need to be recorded. With two exceptions, OSHA concludes that the average establishment keeping records under both the former rule and the final rule will experience an overall decrease in the number of occupational injury and illness cases entered into its OSHA records. These decreases will result from the addition of several exemptions to the presumption of work-relatedness for cases occurring in the work environment and from definitional changes (*e.g.*, medical treatment, first aid, restricted work, aggravation) that will make fewer cases recordable. However, for this analysis, OSHA makes the conservative assumption that these will net out to a zero change. This assumption means that the costs presented in this economic analysis are somewhat overstated.

The two exceptions to the overall decrease in the number of cases recorded are the result of the change to a more sensitive standard threshold shift for recording hearing loss, which will increase the number of cases in all industries except construction, and the new requirement to record needlesticks and sharps injuries, which will result in a relatively large increase in the number of cases recorded in SIC 80.

The costs for SIC 80 are analyzed separately. The analysis uses the following classes of industries:

For industries covered by the former regulation and now covered by the new regulation, except for SIC 80, OSHA assumes that the number of needlestick cases recorded will essentially be unchanged by the final regulation.

For industries (except in SIC 80) covered by the former regulation, but exempted under the final regulation, recorded cases will fall to zero, resulting in commensurate savings.

For industries exempted under the former regulation but covered by the final regulation, the impact will be the full cost of recording such cases.

In SIC 80, recorded cases in three-digit industries that are newly exempted (see Table X–3) will fall to zero, resulting in commensurate savings. The industries that will continue to be covered (SIC 805, Nursing and Personal Care Facilities, SIC 806, Hospitals, and SIC 808, Home Health Care Services) will bear the full cost of recording the expected increase in needlesticks and sharps cases. This increase in cases will be analyzed in the same manner as cases in newly covered industries.

(1) Impacts on Costs of the Final Rule's Changes in Scope

The changes in the scope of the final rule's industry coverage will bring commensurate changes in the costs of the regulation. OSHA estimates that, under the former regulation, it required an average of 15 minutes per recorded case to maintain the Log, plus 20 minutes to fill out a 101 form, for those employers who did not use an equivalent form.

The addition of new elements to Form 301, as will be described shortly, raises OSHA's estimate of the total time required to fill out an individual report of injury or illness to 22 minutes. Based on data collected during approximately 400 recordkeeping audit inspections, OSHA assumes that 82 percent of incidents will be recorded on forms other than the new Form 301, such as workers' compensation forms.

The average for the Log takes into account a wide range of cases. For clearly work-related injuries involving an absence of 10 work days and involving no additional restricted time, for example, essentially all of the necessary information can be obtained from workers' compensation-related files. In such a case, entering the data on the Log will simply require pulling the workers' compensation file and entering the key information on the Log—a three minute task. OSHA assumes that the time required to make an entry will increase when either (1) information is not already kept for other purposes, or (2) making the entry requires the recordkeeper to study the regulation. Examples of situations where the necessary information would not already have been recorded elsewhere are cases that are not recorded as workers' compensation cases, or cases involving restricted work days (which are not recorded in workers' compensation data and may not be part of the affected worker's payroll or personnel files). Examples of situations where it would be necessary to study the regulation are those involving questions about the recordability of the incident or its work-relatedness. Changes in scope will have different impacts on the different classes of industries, as follows:

- Continuously Covered Establishments. By definition, establishments in industries formerly covered and still covered by the final regulation will have no changes in costs related to industry scope.
- Newly Exempted Establishments. Establishments that were covered by the former regulation but are exempt from the final regulation will realize for each currently recorded case a cost saving of 15 minutes for the Log entry plus, for 18% of the cases, a saving of 20 minutes for the 301 form. The estimated total annual savings will be $405,499.[21]
- Newly Covered Establishments. Establishments that were exempt under the former regulation but are covered by the final regulation will incur for each currently recorded case costs of 15 minutes for the Log entry plus, for 18% of the cases, 22 minutes for the 301 form. The total annual cost is estimated to be $1,646,000.[22]
- Additional Hearing Loss Cases. Establishments will incur for each additional hearing loss case costs of 15 minutes for the Log entry plus, for 18% of the cases, 22 minutes for the 301 form, or an estimated total annual cost of $2,287,208.[23]
- SIC 80. Establishments in SIC 80 will incur for each additional needlesticks and sharps case costs of 5 minutes for the Log entry[24] plus, for 18% of the cases, 22 minutes for the 301 form, or an estimated total annual cost of $1,971,664.[25]

(The costs of the ''log of percutaneous injuries from contaminated sharps'' specified in the revision of the Bloodborne Pathogens standard in conformance with the requirements of the Needlestick Safety and Prevention Act have been captured in the analysis of that rule. No offset has been taken in the economic analysis of this rule for costs common to these two rules for recording needlestick injuries.)

The estimated total cost impact related to changes in scope of the recordkeeping rule is $5,499,373.

(2) Maintenance of the Log

Form 300 will replace Form 200 as the Log of injuries and illnesses. The revisions to this form represent the greatest source of cost savings to employers required to record work-related injuries and illnesses. The major modifications that result in time and cost savings are simplifications of Form 300 and changes and simplifications in the criteria for recordable cases.

Simplification of the Log. Compared to the form that it will replace, Form 300 has a more logical progression, makes available considerably more space, and eliminates unnecessary columns. OSHA estimates that this will take an average of one minute off the time required to record cases (except for

[21] $405,499 = ((49,698 Cases) × (15 Minutes/Case) + (8,946 Cases) × (20 Minutes/Case)) × ($26.32/Hours).

[22] $1,646,000 = ((197,904 Cases) × (15 Minutes/Case) + ($35.623 Cases) × (22 Minutes/Case)) × ($26.32/Hours).

[23] $2,287,208 = (275,000 Cases) × (15 Minutes/Case) × ($26.32/Hour) + (49,500 Cases) × (22 Minutes/Case)) × ($26.32/Hour).

[24] Under the simplified criteria of the final rule, needlesticks and sharps cases are among the very easiest cases to document and record.

[25] $1,971,664 = ((501,640 Cases) × (5 Minutes/Case) + (90,295 Cases) × (22 Minutes/Case)) × ($26.32/Hour).

those that involve needlesticks or sharps, which will be analyzed separately in this analysis). This simplification of the Log will produce a saving of $2,177,240.[26]

Simplification of Decisionmaking about Recordability. In estimating the savings in time associated with the simplification of recordability decisionmaking, OSHA focused primarily on the simplification of the steps needed to determine whether an injury or illness is serious enough to be recorded. When a work-related injury or illness results in days away from work or restricted workdays, then it is obvious under both the former and final regulations that the injury or illness must be recorded. Under the former regulation, however, the employer was required to consult several paragraphs of the Recordkeeping Guidelines to determine whether an injury that did not result in lost or restricted workdays would need to be counted. The final regulation will allow the employer to settle the issue quickly by looking at the list of first aid treatments in Section 1904.7(b)(4).

Of the cases in the 1998 BLS Survey of Occupational Injury and Illness that did not involve needlesticks or sharps, 52.34 percent did not involve lost or restricted workdays. In addition to the one minute saved for each case because of the forms simplification discussed on the previous page, OSHA estimates that the simplification of recordability decisionmaking under the final rule will save approximately 2 minutes for each such injury or illness case. Applying this unit cost saving to all industries covered by the final rule produces estimated total savings of $2,279,080.[27]

Under the final rule there will no longer be any need to examine in any detail the recordability of any cases involving needlesticks or sharps, since all such cases will have to be recorded. OSHA estimates that the average time required to record such cases will change from 15 minutes under the former rule to 5 minutes under the final rule. This would save covered establishments in SIC 80 an estimated $388,329.[28]

OSHA has also clarified the requirement to record medical removal cases by stating in the regulatory text that any case involving medical removal required by an OSHA health standard must be recorded as a case involving days away from work or restricted work/job transfer (as appropriate). OSHA had interpreted the former rule to have the same effect, but the former regulatory text did not clearly state the requirement. This clarification makes overall compliance with OSHA's rules simpler, because both the recordkeeping rule and the OSHA standards will rely on the same criteria, such as biological monitoring test results, employers' determinations, and physician's opinions, and the recording requirements are clearly stated in the regulatory text.

Under the final rule, days away from work and days of restricted work will be counted by calendar days rather than according to scheduled work days. One commenter (Ex. 57X, pp. 97–101, 117–118) argued that, in the automobile manufacturing industry alone, this could free up $5,000,000 to $6,000,000 worth of human resources per year for more productive uses of time. However, OSHA has not taken cost savings for this change because no data in the record suggest that the projections for this industry will be typical of other industries.

Privacy Concern Cases. The final rule requires maintenance of a separate, confidential list of case numbers and employee names for ''privacy concern cases,'' so that an employee's name does not appear on the Form 300. Privacy concern cases include injury or illness to an intimate body part or the reproductive system; injury or illness resulting from a sexual assault; mental illness; HIV infection, hepatitis, or tuberculosis; needlesticks and sharps injuries; and other illnesses (except MSD illnesses) that the employee requests be treated as a privacy concern case.

In 1997 BLS estimated that there were 621 days away from work cases involving the reproductive tract, 18 rapes, 5,542 mental disorders, and no hepatitis cases. (Data are available at www.bls.gov.) In 1997, OSHA estimated that there were approximately 34,630 occupational TB infections annually. It appears that TB cases have declined somewhat since then, but OSHA uses this number in this analysis as a conservative estimate.

The time to record HIV infection cases is included in the estimate of the time associated with recording 590,165 needlestick and sharps cases, but each of these cases will also require time for making an entry in the confidential list of case numbers and employee names. OSHA also assumes that employees in 10,000 other illness cases will ask that their names not appear on the Form 300.

OSHA estimates that it will take an average of 3 minutes to record each ''privacy concern case'' on the required separate, confidential list of case numbers and employee names. The estimated annual cost of this provision is thus $843,524.[29]

(3) Maintenance of Individual Reports of Injury and Illness

The final regulation substitutes the new Form 301 for the former Form 101 and provides other options.

New Elements on Individual Reports. The new form requires employers to record such additional items as the injured or ill employee's date of hire, emergency room visits, the starting time of the employee's shift, and time of the accident. OSHA estimates that these additional elements will raise time required to fill out an individual report of injury or illness from 20 minutes for the old Form 101 to 22 minutes for the new Form 301. This change will cost employers in industries formerly covered and still covered by the final regulation an estimated $889,169.[30]

Changes that will reduce burden include:

An option to keep Form 301s off-site; and

An option to keep Form 301s on electronic media.

Keeping Form 301s Off-site. Keeping Form 301s off-site will provide the greatest cost savings to small, isolated establishments that are owned by larger firms that already keep personnel data at headquarters or at another site. For such firms, OSHA estimates that the ability to maintain records off-site could save as much as 5 minutes per record. These savings in time and effort would result from reductions in the amount of time necessary to copy the Form 301 at headquarters, send it to the small establishment, receive it there, and file it. There would also be a saving in postage. Under the final rule, such small establishments would have to go through all of these steps only when an inspection occurred. Even if only 2 percent of the estimated recordable cases in establishments that are covered under the final regulation were affected by this provision (which OSHA believes is likely to be an underestimate), the resulting cost savings would be $294,141.[31]

Storing Form 301s on Electronic Media. The final rule permits employers to store Form 301s on electronic media, provided that they are able to produce the records in hard copy within four

[26] $2,177,240 = (4,963,312 Cases) × (1 Minute/Case) × ($26.32/Hour).

[27] $2,279,080 = (2,597,736 Cases) × (2 Minutes/Case) × ($26.32/Hour).

[28] $388,329 = (88,525 Cases) × (10 Minutes/Case) × ($26.32/Hour).

[29] $843,524 = (640,976 Cases) × (3 Minutes/Case) × ($26.32/Hour).

[30] $889,169 = (1,013,503 Cases) × (2 Minutes/Case) × ($26.32/Hour).

[31] $294,141 = (5,630,573 Cases) × (0.02) × [(5 Minutes/Case) × ($26.32/Hour) + ($0.33/Case)].

hours of a request by a government representative permitted access under the regulation. OSHA estimated that electronic storage would be advantageous for establishments that handle more than 100 cases per year. OSHA used as a proxy variable for this number the number of establishments with 1,000 or more employees. In the 1998 BLS survey, establishments in this size category had a total of 899,700 recordable cases. OSHA estimates that for each case the ability to store case information electronically would save 2 minutes of time, plus $.05, for making a paper copy. The estimated cost savings from this change would amount to approximately $825,027 per year.[32] OSHA believes that this may be an underestimate, because having even as few as 30 to 40 cases a year might be enough incentive to prompt a firm to keep its records electronically. To the extent that these much smaller firms turn to electronic storage, the cost savings associated with this provision could be many times greater than the estimate.

(4) Employee and Employee Representative Access

The final regulation requires employers to provide employees and their representatives access to Form 301s and to pay the cost of one copy. (It also requires them to allow access to the Log, but this is not a change from the former rule.) OSHA assumes that employers would require five minutes to pull, copy (at $0.05), and replace the relevant form. OSHA assumes that (a) at one-tenth of covered establishments, one employee would request access to his or her own Form 301, and (b) at one percent of covered establishments, a union representative would request access to all Form 301s at the establishment. OSHA further assumes that there would be an average of ten Form 301s at such establishments.[33] The estimated total cost of this provision is $612,860.[34]

(5) Access to Other Parties

The final regulation requires that if employers voluntarily disclose Forms 300 or 301 to persons other than government representatives, employees, former employees, of authorized representatives, they must remove or hide the employees' names, with certain exceptions. Since employers may accomplish this by simply covering part of the form before they copy it, OSHA considers this requirement to impose no costs.

(6) Total Cost Impact

Table X–7 summarizes the cost impacts of maintaining records attributable to the final regulation. The net impact is an estimated annual cost of $1,881,080.

E. Summary of Costs

Table X–8 summarizes the total annualized cost impacts of the entire final rule. This summary indicates that:

The largest sources of costs are: New certification requirements ($23.8 million), additional data requirements ($12.0 million), expansion in the scope of the rule ($5.5 million), and transitional costs of the new rule ($1.5 million).

The largest sources of savings are: Simplified maintenance of the Log ($4.8 million), less time required to relearn the recordkeeping system ($3.1 million), simplified maintenance of individual reports ($1.1 million).

The net impact of these changes is an estimated annual cost of about $38.6 million.

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[32] $825,027 = (889,700 Cases × [(2 Minutes/Case) × ($26.32/Hour) + ($0.05/Case)].

[33] This is a conservative estimate. The average number of cases per covered establishment was only about 4 in 1998. Further, some employers already provide copies of Form 301s to union representatives. [Transcript, March 29, 1996, p. 14].

[34] $612,860 = (273,197 Forms × [(5 Minutes × ($26.32/Hour) + $.05/Copy)].

TABLE X-7
ANNUAL COSTS OF MAINTAINING RECORDS

Cost Element/ Industry Status Under the Final Rule	Estimated Number of Recorded Cases	Change in Level of Effort (Minutes)	Total Hours	Total Cost
Changes in Scope				
Effects on Number of Log Entries:				
Newly Exempted	49,698	- 15	- 12,425	- $ 327,013[a]
Newly Covered	197,904	15	49,476	$1,302,208[a]
Additional Hearing Cases	275,000	15	68,750	$1,809,500[a]
Additional Needlestick Cases	501,640	5	41,803	$1,100,255[a]
Effects on Number of 301 Forms:				
Newly Exempted	8,946	- 20	- 2,982	- $ 78,486[a]
Newly Covered	35,623	22	13,062	$ 343,792[a]
Additional Hearing Cases	49,500	22	18,150	$ 477,708[a]
Additional Needlestick Cases	90,295	22	33,108	$ 871,409[a]
Maintenance of the Log				
Covered under Final Rule[b]	4,963,312	- 1	- 82,722	- $2,177,240[a]
Non- Lost Work Day Cases				
Covered under Final Rule[b]	2,597,736	- 2	- 86,591	- $2,279,080[a]
Previous Needlestick Cases	88,525	- 10	- 14,754	- $ 388,329[a]
Privacy Concern Cases				
Covered under Final Rule	640,976	3	32,049	$ 843,524[a]
Maintenance of Individual Reports:				
New Elements on Form 301				
Formerly & Still Covered	1,013,503	2	33,783	$ 889,169[a]
Form 301 Off-Site				
Covered under New Rule	116,569	- 5	- 9,714	- $ 294,141[a]
Electronic Media				
Covered under New Rule	889,700	- 2	- 29,657	- $ 825,057[a]
Employee Access				
Covered under New Rule	273,197	5	22,766	$ 612,860[a]
TOTAL ANNUAL COST			109,138	$1,881,080

[a] Based on an hourly cost of $26.32

[b] Except needlesticks and additional hearing loss cases

TABLE X-8
NET ANNUAL COSTS ASSOCIATED WITH THE FINAL RULE, BY PROVISION

Cost Element	Total Net Hours	Total Net Cost
Initial Familiarization Costs		
Shift to the New Recordkeeping System	395,566[a]	$ 1,482,384
Initially Learn the Recordkeeping System	179,287[a]	$ 671,856
Relearn the Recordkeeping System	- 118,729	- $ 3,124,947
Fixed Recordkeeping Costs		
Set Up Log and Post Summary	7,942	$ 209,034
Additional Data Requirements	455,328	$11,984,233
Certification	639,445	$23,769,402
Way to Inform Employees	455,328	$ 1,706,285
Costs of Maintaining Records		
Changes in Scope	208,943	$ 5,499,373
Maintenance of the Log	- 184,067	- $ 4,844,648
Privacy Concern Cases	32,049	$ 843,524
New Elements on Individual Reports	33,783	$ 889,169
Maintenance of Individual Reports	- 39,371	- $ 1,119,198
Employee Access	22,766	$ 612,860
TOTAL ANNUAL COST	2,088,269[b]	$38,246,377

[a] One-time costs only.

[b] Includes 1,030,181 hours that will be required in the first year only.

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4. Benefits

OSHA's final Recording and Reporting Occupational Injuries and Illnesses rule is designed to provide an information base to assist employers and employees to maintain safe and healthy working conditions that protect workers. The importance of the contribution of accurate recordkeeping to lower injury and illness rates is indicated by experience with OSHA's Voluntary Protection Program (VPP), a program that recognizes employers with exemplary safety and health programs. VPP worksites, which have comprehensive safety and health management programs that include effective injury, illness, and accident recordkeeping, generally have lost-workday case rates ranging from one-fifth to one-third the rates experienced by most worksites in the same industry.[35] These sites also routinely rely on the Logs and other worksite data sources to evaluate their programs and correct deficiencies. This chapter describes the potential benefits associated with the changes OSHA is making to the recordkeeping requirements in 29 CFR 1904.

A. Overview of Benefits

The benefits of improved recordkeeping fall into two groups. Improved recordkeeping enhances the ability of employers and employees to prevent occupational injuries and illnesses. Improved recordkeeping and reporting also increases the utility of injury and illness records for OSHA's purposes.

(1) Enhanced Ability of Employers and Employees to Prevent Injuries and Illnesses

The additional or improved information about events and exposures to be collected on Form 301, including information on the location, the equipment, materials or chemicals being used, and the specific activity being performed, will increase the ability of employers and employees to identify hazardous conditions and to take remedial action to prevent future injuries and illnesses. Identifying the irritating substance that has caused an employee to experience a recordable case of occupational dermatitis, for example, could prompt an employer to re-examine available Material Safety Data Sheets to identify a non-irritating substitute material. On Form 301, details will be recorded in a logical sequence that will help structure the information and focus attention on problem processes and activities. Thus the establishment's records of injuries and illnesses will provide management with an analytical tool that can be used to control or eliminate hazards.

The process of using recorded information to control or eliminate hazards was well illustrated in a comment on the proposed rule.[36] This testimony described a training exercise where trainees used Log data to plot MSD injuries on a floor plan; went into the plant to look for risk factors and interview workers; formulated specific workplace design and work organization changes to eliminate or reduce risk factors; and refined their findings into an action plan.

If this enhanced ability to identify (and thus address) hazards translates into a reduction even as small as 0.5 to 1 percent of the estimated number of recordable cases, it would mean the prevention of 29,147 to 58,285 injuries and illnesses per year.[37]

(2) Increased Utility of Data to OSHA

The final rule's changes will also make injury records more useful to OSHA, as well as to employers and employees. Improvements in the quality and usefulness of the records being kept by employers would enhance OSHA's capacity to:

Focus compliance outreach efforts on the most significant hazards;

Identify types or patterns of injuries and illnesses whose investigation might lead to regulatory changes or other types of prevention efforts, such as enforcement strategies, information and training, or technology development; and

Set priorities among establishments for inspection purposes.

Employers and employees both stand to benefit from the more effective use of OSHA's resources. The enhanced ability of compliance officers to identify patterns of injuries will enable OSHA to focus on more serious problems. Identification of such patterns will also increase the ability of employers to control these hazards and prevent other similar injuries. To the extent that employers take advantage of this information, the burden of OSHA inspections should be reduced in the long run. Employees clearly will also benefit from these reductions in injuries.

B. Specific Benefits of the Final Regulation

(1) Changes in Scope of the Regulation

The changes in the scope of the final regulation in the retail and service sectors represent a refinement in coverage. The scope of the former rule is defined at the two-digit SIC level; the scope of the final rule is defined at the three-digit SIC level. OSHA is expanding the scope to include high-risk three-digit industries that were previously exempt and to reduce the scope to exempt low-risk three-digit industries that were previously covered.

The effect of this change is to make the regulation more cost-effective. This retargeting shifts the burden from industries with relatively few injuries and illnesses per establishment to industries with substantially larger numbers of injuries and illnesses per establishment. Thus the final rule will result in higher hazard identification benefits per dollar of regulatory burden. It is also likely to lead to a small reduction in injuries and illnesses at newly covered establishments that had not been keeping records at all.

The final rule's changes in scope will similarly increase the cost-effectiveness of OSHA's compliance activities. With the same expenditure of resources, OSHA will be better able to detect injury and illness trends and to assist employers to address the causes of these trends. OSHA expects this more efficient use of Agency resources to translate directly into reduced worker injuries and illnesses, reductions in costs to employers, and increased productivity.

(2) Forms Simplification and Definitions

The general reduction in burden associated with changes in the forms and in the data reported was discussed in the previous chapter under cost savings. The simplification of the forms also will have benefits in the form of improved information. The same is true of definitional changes, such as counting lost workdays or restricted work days as calendar days and capping the count at 180 days. Easier recording of data will make records of individual cases more complete and consistent. It is also possible that simplified recording will encourage more complete recording of job-related injuries and illnesses.

This process is illustrated by the change from days away from work to calendar days. This change represents an explicit decision to shift the emphasis from lost productivity to the seriousness of the injury or illness. Calendar days are a more accurate and consistent reflection of seriousness than

[35] **Federal Register,** January 26, 1989, p. 3904.

[36] Nancy Lessin, Testimony on behalf of Massachusetts Coalition for Occupational Safety and Health, May 3, 1996, Transcript, p. 48.

[37] (0.005 to .01) × 5,828,477.

are lost scheduled workdays. They are also directly comparable across establishments and industries, while days away from work are not. Thus, calendar days produce more useful information for the purpose of assessing patterns of injuries and illnesses. This variable is also generally much simpler to determine and record, so that the information is more likely to be complete and accurate. This combination of attributes, OSHA believes, will substantially improve the quality of the information available for analysis and enhance the resulting actions taken to reduce job-related injuries and illness.

(3) Recordable Injuries/Illnesses

The changes in the definition of the injuries and illnesses that are recordable have several different types of benefits. In general, they follow a pattern of simplification and/or more cost-effective targeting of recording requirements, which should produce the types of benefits discussed above. Changes that add to the information recorded have other benefits as well.

Specified Recording Thresholds. One change involves identifying the threshold at which a medical removal condition or restriction is to be recorded, and tying this to the level in a specific OSHA standard (lead, cadmium, ergonomics, etc.). This requirement involves no increase in cost, since the pre-removal or restriction conditions are already required under the specific OSHA standard.

Needlesticks and Sharps Injuries and Hearing Loss Cases. By far the most extensive change in recording is the requirement to report *all* needlesticks and sharps injuries involving exposure to blood or other potentially infectious materials in the covered industries. The benefits of this change are also quite extensive, however, and the costs are less than they might at first seem. In effect, OSHA is changing the emphasis on these injuries from the effects (the injury's medical treatment) to the actual injury caused by the incident (i.e., the needlestick or sharps injury).

Recording all needlesticks and sharps injuries will provide far more useful information for illness prevention purposes. Unlike many other conditions (*e.g.*, blood poisoning and hearing loss) that are progressive, AIDS and hepatitis are either present or they are not. In any given work setting, the risk is probabilistic and bimodally distributed; either one is infected by an injury or one is not. Under these circumstances, it is important to prevent all injuries that might lead to illness. For that prevention strategy to be successful, however, it is necessary to get a complete picture of the overall pattern of all needlesticks and sharps injuries. This requires recording all such injuries, whether or not they result in AIDS, hepatitis, or other bloodborne illness. The final regulation accomplishes this.

Because of their high mortality and disability potentials, AIDS and hepatitis are particularly frightening illnesses. One implication of this fact, however, is that the benefits per case of prevention are large. Another implication is that there are substantial employee morale benefits to a prevention program that is comprehensive and well informed. Recording all risky wounds and then using the data for prevention are actions that are reasonable. These provisions of the final rule are likely also to result in indirect benefits in the form of improved patient care.

Hearing loss cases also result in substantial disability and lead to safety accidents as well. OSHA believes that aligning the recording threshold for such cases with the Standard Threshold Shift criterion in the Agency's occupational Noise Standard will simplify recording for many employers who are already familiar with this criterion. The shift in this recording criterion will also increase the number of hearing loss cases captured by the recordkeeping system and provide more opportunities for employers to intervene to prevent other hearing loss cases.

(4) Procedural Changes and Informational Requirements

The relationship between costs and benefits varies for the final rule's procedural changes and for its requirements for additional information. Some provisions have positive but trivial costs. Others have more significant costs but substantial benefits.

De Minimis Costs. A number of changes have costs that are so low that the benefits of the change are clearly greater. Examples include the provisions discussed below.

Recording incidents within seven calendar days, rather than six working days, will impose costs for more rapid recording on establishments that work only five days a week. The reduced burden resulting from a simpler deadline—one week later—almost certainly outweighs this minuscule cost, however. Moreover, for establishments that operate six or seven days a week, this change does not impose any costs at all.

The requirement, upon change of ownership, for the seller to hand over records to the buyer of the business has extremely small costs. The seller, after all, is already required to maintain those records, and the buyer is required to take them over. The benefits of continuity of information are clearly much greater than this trivial cost.

The cost, if any, for posting (but not revising) the Annual Summary for three months, rather than one month, is extremely small—particularly considering that quite a number of other certificates and information (*e.g.*, elevator certificates, minimum wage information, etc.) must be posted at all times. The ability of employees to refer back to the Annual Summary information, as well as the availability of the information to new employees when they are hired, clearly produces benefits that exceed the costs.

Certification by a Company Executive. The requirement that a company executive certify the Summary will have the effect of increasing the oversight and accountability of higher management in health and safety activities. The certifying official will be responsible for ensuring that systems and processes are in place and for holding the recordkeeper accountable. OSHA believes that this increased awareness of job-related injuries and illnesses, and of their prevention, will translate into fewer accidents and injuries because the certifying executive will have a heightened sense of responsibility for safety and health, although quantifying this benefit is not possible at this time.

Additional Data Requirements for Form 301 and Form 300–A. The final rule will require employers to provide several additional pieces of information, at an estimated cost of two minutes per Form 301 and twenty minutes per Form 300–A.

Additional information related to incidents (on Form 301) includes: Employee's date of hire, emergency room visits, time the employee began work (starting time of the shift), and time of the accident.

Additional establishment information (on the Form 300–A Summary) includes:

Annual average number of employees employed in that year, and Total hours worked by all employees during the year.

Information on the injured employee's date of hire can provide insight into a number of factors that have been shown to relate to injury rates. Such factors may include inadequate training, inexperience on the job, etc. If OSHA were to link its injury data with information on the distribution of job tenure, for example, it could then calculate injury rates by job tenure category for different jobs. That information would help to identify areas

where better training would have the greatest potential to reduce injuries.

Data on starting times of shifts and the time of occurrence of the accident will facilitate research on whether accident rates vary by shift, and whether certain portions of a shift are particularly dangerous. This information will be helpful to OSHA as well as to the employer's own assessment of workplace safety and health. Most importantly, employees will receive the information they need to understand both the absolute and relative incidence of injuries and illnesses in their establishment. Such information is essential both for market-based mechanisms to influence safety and health and for meaningful employee participation in safety and health.

The inclusion of information concerning the average number of employees and total hours worked by all employees during the year will enable OSHA inspectors to calculate incidence rates directly from the posted summary. Employers will also benefit from their ability to obtain incidence information quickly and easily.

At the establishment level, occupational injury and illness records are examined at the beginning of an OSHA inspection and are used by compliance officers to identify safety and health problems that deserve to be focused on. The data on Form 300 and Form 301 will also be used to determine what areas of the site, if any, warrant particular attention during the inspection. Again, access to this improved information will be of direct benefit to employers and employees, who will be able to act on it to control hazards.

Employee Access to Form 301. Providing employees with access to the Form 301, as well as the Form 300, will allow them to monitor the accuracy of the data and to identify possible patterns of injuries and illnesses. Access to Form 301 is important because this form contains enough detailed information about the events surrounding the occurrence to enable workers analyzing it to identify the appropriate protective measures to prevent future accidents.

(5) Summary

Taken together, the changes that OSHA is making to its recording and reporting requirements are designed to achieve the Agency's primary goal of reducing job-related injuries, illnesses, and fatalities. The link between more accurate and better-targeted injury and illness recordkeeping and accident prevention has repeatedly been established and emphasized by the National Academy of Sciences, the Keystone Report, the testimony of safety and health professionals, and the Agency's own experience. The final rule's changes will thus benefit workers, their employers, and the Agency's accident prevention efforts.

5. Economic Feasibility and Small Business Impacts

Introduction

This section assesses the impact on affected firms of the costs of implementing the final recordkeeping rule. It is divided into four parts. The first part analyzes the economic feasibility of the rule for firms in all affected industries. The second part analyzes the economic impacts of the rule on small entities in the affected industries. The third part presents an Unfunded Mandates Analysis, which OSHA has conducted in accordance with the Unfunded Mandates Reform Act. The fourth part examines the potential environmental impacts of the regulation.

Analysis of Economic Feasibility

The final 1904 rule is a regulation promulgated under sections 8 and 24 of the OSH Act, and is not a standard, which would be promulgated under Section 6 of the Act. Nevertheless, OSHA has performed an analysis of the economic feasibility of the rule.

The courts have held that, to demonstrate that a standard is economically feasible, OSHA ''must construct a reasonable estimate of compliance costs and demonstrate a reasonable likelihood that these costs will not threaten the existence or competitive structure of an industry, even if it does portend disaster for some marginal firms'' [*United Steelworkers of America* v. *Marshall,* 647 F.2d 1189, 1272 (D.C. Cir. 1980) (the ''Lead decision'')]. In assessing the economic feasibility of the final recordkeeping rule, OSHA has followed the decisions of the courts in the Lead case and other OSHA cases, and has relied on information and data in the record to determine that the final standard is economically feasible for firms in all affected industries.

OSHA's estimates of the number of covered establishments in each affected industry are presented in Section 2 of this economic analysis, and the results of the Agency's analysis of annualized compliance costs are presented in Section 3. The Agency's analysis is based on comments to the record, supplemented, where needed, by public information sources such as the Census Bureau's *County Business Patterns.*

In this section, for each affected industry, estimates of per-firm annualized compliance costs are compared with (a) per-firm estimates of sales from a compilation of 1996 data performed by the U.S. Census Bureau for the Small Business Administration to reflect parent company control of establishments, and (b) per-firm estimates of profits derived from information in Dun & Bradstreet's ''Industry Norms and Key Business Ratios'' database for 1996 or by applying 1996 profit percentages from Robert Morris Associates to the Agency's per-firm estimates of sales. Based on the results of these comparisons, which identify the magnitude of the potential impacts of the final rule, OSHA then assesses the rule's economic feasibility for establishments in all affected industries.

To estimate the sales and profits of covered firms, OSHA identified the Standard Industrial Classifications (SICs) of every industry under the scope of the rulemaking. For each industry, OSHA then calculated the average sales per firm in the relevant SIC(s). The average rate of return on sales (from Dun and Bradstreet or, if necessary, from Robert Morris Associates) was used to estimate average profit per firm. (Throughout this section, the term ''average'' is used to mean the arithmetic mean.)

The cost estimates compared with estimated sales and profit data for firms in each affected industry ''screen'' for potential impacts. If sizeable impacts were identified by this screening analysis, additional analysis would be necessary.

Table X–9 shows compliance costs as a percentage of before-tax profits and of sales. This table presents the results of the screening analysis, which simply measures costs as a percentage of before-tax profits and sales; the screening analysis is used to determine whether the compliance costs potentially associated with the rule could lead to significant impacts on the affected firms under worst-case scenarios. Whether or not the costs of compliance actually lead to a significant impact on the profit and/or sales of firms in a given industry will depend on the price elasticity of demand for the products or services of firms in that industry.

Price elasticity refers to the relationship between the price charged for a product and the demand for that product: the more elastic the relationship, the less able firms are to pass the costs of compliance through to their customers in the form of a price increase and the more they must absorb the costs of compliance from their

profits. When demand is inelastic, firms can absorb all the costs of compliance simply by raising the prices they charge for that product; under this scenario, profits are untouched. On the other hand, when demand is elastic, firms cannot cover the costs simply by passing the cost increase through in the form of a price increase; instead, they must absorb some of the increase from their profits. In general, ''when an industry is subjected to a higher cost, it does not simply swallow it; it raises its price and reduces its output, and in this way shifts a part of the cost to its consumers and a part to its suppliers,'' in the words of the court in *American Dental Association* v. *Secretary of Labor,* [984 F.2d 823, 829 (Seventh Cir. 1993)] (the ''ADA decision'').

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TABLE X-9

ANNUAL COST OF THE FINAL RULE AS A PERCENT OF SALES AND PROFITS FOR ALL COVERED FIRMS, UNDER TWO WORST-CASE SCENARIOS

SIC	Industry	Average Cost per Firm	Average Sales per Firm	Cost as a Percent of Sales	Average Profit per Firm	Cost as a Percent of Profits
07	Agricultural Services	$ 26.27	$1,643,011	0.0016%	$98,581	0.027%
08	Forestry	$ 34.18	$4,517,500	0.0008%	$140,043	0.024%
09	Fishing, Hunting, & Trapping	$ 28.24	$6,318,183	0.0004%	$315,909	0.009%
13	Oil and Gas Extraction	$ 45.83	$34,757,006	0.0001%	$1,772,607	0.003%
15	Gen. Contractors & Op. Builders	$ 25.16	$8,733,493	0.0003%	$227,071	0.011%
16	Heavy Constr., except Building	$ 24.61	$8,891,657	0.0003%	$337,883	0.007%
17	Special Trade Contractors	$ 24.83	$3,021,903	0.0008%	$114,832	0.022%
20	Food and Kindred Products	$ 39.45	$55,449,039	0.0001%	$1,108,981	0.004%
21	Tobacco Products	$109.19	$611,873,720	*	$23,863,075	**
22	Textile Mill Products	$ 53.53	$27,804,977	0.0002%	$722,929	0.007%
23	Apparel & Other textile Products	$ 37.80	$6,533,106	0.0006%	$163,328	0.023%
24	Lumber and Wood Products	$ 31.92	$8,476,937	0.0004%	$305,170	0.010%
25	Furniture and Fixtures	$ 32.73	$10,819,231	0.0003%	$335,396	0.010%
26	Paper and Allied Products	$ 60.90	$50,060,367	0.0001%	$1,902,294	0.003%
27	Printing and Publishing	$ 41.86	$10,140,518	0.0004%	$415,761	0.010%
28	Chemicals & Allied Products	$ 78.02	$88,199,672	0.0001%	$3,704,386	0.003%
29	Petroleum & Coal Products	$ 96.77	$240,889,238	*	$7,467,566	0.001%
30	Rubber & Misc. Plastics Pdts	$ 40.67	$17,053,410	0.0002%	$613,923	0.007%
31	Leather and Leather Products	$ 38.35	$11,516,441	0.0003%	$207,296	0.018%
32	Stone, Clay, & Glass Products	$ 49.98	$12,963,602	0.0004%	$635,216	0.008%
33	Primary Metal. Industries	$ 33.15	$48,966,680	0.0001%	$2,301,434	0.001%
34	Fabricated Metal Products	$ 32.19	$11,131,190	0.0003%	$478,641	0.007%
35	Industrial Machinery & Equipment	$ 32.47	$13,603,234	0.0002%	$557,733	0.006%

TABLE X-9

ANNUAL COST OF THE FINAL RULE AS A PERCENT OF SALES AND PROFITS FOR ALL COVERED FIRMS, UNDER TWO WORST-CASE SCENARIOS

SIC	Industry	Average Cost per Firm	Average Sales per Firm	Cost as a Percent of Sales	Average Profit per Firm	Cost as a Percent of Profits
36	Electronic & Other Electrical Equip.	$ 49.71	$34,672,510	0.0001%	$1,733,626	0.003%
37	Transportation Equipment	$ (6.32)	$107,210,814	- *	$4,288,433	- **
38	Instruments & Related Products	$ 50.12	$29,545,846	0.0002%	$1,625,022	0.003%
39	Misc. Manufacturing Industries	$ 32.37	$7,712,561	0.0004%	$254,515	0.013%
41	Local & Interurban Pass. Transit	$ 34.78	$2,782,251	0.0012%	$164,153	0.021%
42	Trucking and Warehousing	$ 40.54	$6,828,568	0.0006%	$245,828	0.016%
43	United States Postal Service	$776,159	$60,005,000,00	0.0013%	N/A	N/A
44	Water Transportation	$ 38.83	$16,550,772	0.0002%	$827,539	0.005%
45	Transportation by Air	$ 20.57	$77,701,749	*	$3,185,772	0.001%
46	Pipelines, except Natural Gas	$350.74	$123,685,486	0.0003%	$6,060,589	0.006%
47	Transportation Services	$ 68.59	$4,212,194	0.0016%	$134,790	0.051%
48	Communication	$133.35	$45,842,134	0.0003%	$3,071,423	0.004%
49	Electric, Gas, & Sanitary Svs	$111.93	$112,358,783	0.0001%	$10,112,290	0.001%
50	Wholesale Trade - Durables	$ 51.39	$25,279,114	0.0002%	$606,699	0.008%
51	Wholesale Trade - Nondurables	$ 49.58	$42,689,772	0.0001%	$768,416	0.006%
521	Lumber & Other Bldg Materials	$ 52.26	$15,180,822	0.0003%	$288,436	0.018%
523	Paint, Glass & Wallpaper Stores	$142.20	$5,388,504	0.0026%	$48,497	0.293%
526	Retail Nurseries & Garden Stores	$ 38.87	$2,528,349	0.0015%	$55,624	0.070%
527	Mobile Home Dealers	$ 52.29	$8,631,626	0.0006%	$250,317	0.021%
53	General Merchandise Stores	$301.14	$141,333,177	0.0002%	$3,391,996	0.009%
541	Grocery Stores	$ 76.04	$18,148,027	0.0004%	$217,776	0.035%
543	Fruit & Vegetable Markets	$ 32.32	$3,033,727	0.0011%	$39,438	0.082%

TABLE X-9

ANNUAL COST OF THE FINAL RULE AS A PERCENT OF SALES AND PROFITS FOR ALL COVERED FIRMS, UNDER TWO WORST-CASE SCENARIOS

SIC	Industry	Average Cost per Firm	Average Sales per Firm	Cost as a Percent of Sales	Average Profit per Firm	Cost as a Percent of Profits
553	Auto & Home Supply Stores	$207.49	$6,295,269	0.0033%	$119,610	0.173%
555	Boat Dealers	$ 65.37	$5,020,251	0.0013%	$110,446	0.059%
556	Recreational Vehicle Dealers	$ 72.19	$9,137,789	0.0008%	$155,342	0.046%
571	Furniture & Furnishings Stores	$131.57	$5,126,403	0.0026%	$117,907	0.112%
572	Household Appliance Stores	$ 89.23	$5,087,527	0.0018%	$117,013	0.076%
593	Used Merchandise Stores	$143.80	$2,423,691	0.0059%	$111,490	0.129%
596	Nonstore Retailers	$103.25	$13,330,037	0.0008%	$266,601	0.039%
598	Fuel Dealers	$128.25	$6,046,113	0.0021%	$48,369	0.265%
651	Real Estate Oprs &Lessors	$ 81.54	$5,093,830	0.0016%	$784,450	0.010%
655	Subdividers & Developers	$ 84.66	$5,577,710	0.0015%	$507,572	0.017%
70	Hotels & Other Lodging Places	$ 34.95	$5,334,743	0.0007%	$373,432	0.009%
721	Laundry, Cleaning & Garment Svcs	$ 88.69	$1,661,452	0.0053%	$63,135	0.140%
734	Services to Buildings	$ 58.48	$1,486,505	0.0039%	$55,001	0.106%
735	Misc. Equip. Rental & Leasing	$140.26	$5,665,544	0.0025%	$521,230	0.027%
736	Personal Supply Services	$122.03	$6,371,536	0.0019%	$191,146	0.064%
751	Automotive Rental & Leasing	$122.70	$20,477,609	0.0006%	$1,167,224	0.011%
752	Automobile Parking	$346.96	$7,956,476	0.0044%	$381,911	0.091%
753	Automotive Repair Shops	$ 39.47	$1,712,369	0.0023%	$66,782	0.059%
754	Automotive Svs, except Repair	$ 45.15	$1,218,918	0.0037%	$79,230	0.057%
762	Electrical Repair Shops	$ 52.11	$4,100,382	0.0013%	$106,610	0.049%

TABLE X-9

ANNUAL COST OF THE FINAL RULE AS A PERCENT OF SALES AND PROFITS FOR ALL COVERED FIRMS, UNDER TWO WORST-CASE SCENARIOS

SIC	Industry	Average Cost per Firm	Average Sales per Firm	Cost as a Percent of Sales	Average Profit per Firm	Cost as a Percent of Profits
763	Watch, Clock & Jewelry Repair	$ 83.20	$1,714,533	0.0049%	$58,294	0.143%
769	Miscellaneous Repair Shops	$ 32.68	$2,867,239	0.0011%	$169,167	0.019%
794	Commercial Sports	$ 19.62	$10,882,419	0.0002%	$391,767	0.005%
799	Misc. Amusement & Rec. Svcs	$ 29.18	$3,061,718	0.0010%	$128,592	0.023%
805	Nursing & Personal Care Facilities	$ 86.55	$6,269,041	0.0014%	$269,569	0.032%
806	Hospitals	$256.90	$75,848,928	0.0003%	$3,868,295	0.007%
808	Home Health Care Services	$ 90.38	$4,861,272	0.0019%	$170,145	0.053%
833	Job Training & Related Svcs	$108.09	$2,420,399	0.0045%	$60,510	0.179%
836	Residential Care	$107.87	$2,223,194	0.0049%	$57,803	0.187%
842	Botanical & Zoological Gardens	$166.25	$4,411,468	0.0038%	$269,100	0.062%
All Covered Firms		$ 57.82				

* indicates absolute value is less than .00005%
** indicates absolute value is less than .0005%

Source: Department of Labor, Occupational Safety and Health Administration, Office of Regulatory Analysis

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Specifically, if demand is completely inelastic (i.e., the price elasticity is 0), then the impact of compliance costs that amount to 1 percent of revenues would be a 1 percent increase in the price of the product, with no decline in demand or in profits. Such a situation would be most likely when there are few, if any, substitutes for the product or services offered by the affected firms and the products or services of the affected firms account only for a small portion of the income of their consumers. If demand is perfectly elastic (i.e., the price elasticity is infinitely large), then no increase in price is possible, and before-tax profits would be reduced by an amount equal to the costs of compliance (minus any savings resulting from improved worker health and reduced insurance costs). Under this scenario, if the costs of compliance represent a large percentage of the firm's profits, some firms might be forced to close. This scenario is highly unlikely to occur, however, because it can only arise when there are other goods or services that are, in the eyes of consumers, perfect substitutes for the goods produced by the affected firms.

A common intermediate case would be a price elasticity of one. In this situation, if the costs of compliance amount to 1 percent of revenues, and prices are raised by 1 percent, then production would decline by 1 percent. In this situation, firms would remain in business and maintain the same profit as before, but would produce 1 percent less product. Consumers would effectively absorb the costs through a combination of increased prices and reduced consumption; this, as the court described in the ADA decision, is the more typical case.

As Table X–9 shows, the impacts potentially imposed by the final rule are not sizeable. On average, annual costs per firm are less than $58. (In one industry, Transportation Equipment, characterized by large workplaces, the potential reduction in costs that vary with the number of cases actually outweighs the potential increase in essentially fixed costs associated with the number of establishments, producing an average reduction in costs per firm.) In no industry do average compliance costs per firm amount to more than .006 percent of sales or 0.3 percent of profits. Even if no price increase were possible, a 0.3 percent decline in profits would not threaten the viability of any firm. For example, a firm with before-tax profits of 10 percent of sales would still have profits of 9.97 percent of sales, even under this extreme scenario. Thus, the final rule is clearly economically feasible in all industry groups.

Among the covered SICs, average compliance costs as a percent of sales range from less than .00005% in several industries, such as SIC 29, Petroleum and Coal Products, to .0059% in SIC 593, Used Merchandise Stores. Average compliance costs as a percent of profits ranges from less than .0005% in several industries, such as SIC 37, Transportation Equipment manufacturing, to .293% in SIC 523, Paint, Glass, and Wallpaper Stores.

Potential Economic Impacts of the Rule on Small Firms

As required by the Regulatory Flexibility Act (as amended in 1996), this section measures the potential economic impacts of the final rule on small businesses in the regulated community to determine whether the rule has a significant impact on a substantial number of small firms. It builds on the analysis of economic impacts developed in the Economic Feasibility part of this section. The Agency has analyzed the impact of the final recordkeeping rule on small entities, as defined by the Small Business Administration and in accordance with the Regulatory Flexibility Act.

Data on receipts were provided by the Commerce Department, in a data table specially commissioned by the Small Business Administration. Since the size definitions SBA has established do not precisely match the categories provided in these data, the Agency approximated the nearest data grouping, where necessary. The SBA-commissioned data were broken into size categories of firms defined by numbers of employees (1–4, 5–9, 10–19, 20–99, 100–499, >500). Where these size categories did not match SBA's assigned ''small'' firm definitions, the Agency approximated them to the closest category. For those industries where an ''annual receipts'' SBA definition was used, the Agency projected the analogous employment break by examining the ratio of employment to receipts per firm. For example, in Heavy Construction, SIC 16, the ratio of employment to receipts suggested that a $17 million firm would have approximately 104 employees. The Agency therefore examined firms with fewer than 100 employees. This process is shown in Table X–10.

The results of this analysis are shown in Table X–11. Over the entire range of SICs affected by the final rule, estimated cost per small firm averages only $31.63.

In order to ensure that even the smallest entities would not be significantly impacted, the Agency performed an analysis of impacts on very small firms, i.e., those with fewer than 20 employees. This analysis used the same sources for sales and profit data as Table X–11. The results of this analysis are shown in Table X–12.

Regardless of whether the SBA definitions or the fewer-than-20-employee definition was used, the results were the same—no significant impact. For the purposes of small-business impact assessment, OSHA defines as potentially significant annualized costs of compliance that amount to 1 percent of sales or 5 percent of profits. The impacts of the rule on sales and profits did not exceed 1 percent for firms in any covered industry, whether the analysis used the SBA's definitions or the fewer-than-20-employee size class definition. No small firm in any industry would need to increase its prices by more than 0.0105 percent, even under a full cost pass-through scenario. Alternatively, if a small firm had to pay for the costs of compliance entirely from profits, costs would account for no more than 0.406 percent of profits [38] in any industry. Impacts of this magnitude would not affect the viability of even the smallest firm.

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[38] It should be emphasized that a one percent decrease in profits represents a one percent decrease in profits, not in profit rate.

TABLE X-10

CONVERSION OF SBA SIZE DEFINITIONS TO CONFORM TO AVAILABLE DATA

SIC	Industry	Affected Firm Size Class *	Sales per Employee in 20-99 Employee Group	Estimated Number of Employees at Class Limit	Approximated Class Size Limit
07	Agricultural Services	$5 million	$ 51,635	97	99
08	Forestry	$5 million	$ 79,190	63	99
09	Fishing, Hunting, and Trapping	$3 million	$128,436	23	19
13	Oil and Gas Extraction	500 employees	NA	500	499
15	General Contractors & Operative Builders	$17 million	$246,233	69	99
16	Heavy Construction, except Building	$17 million	$163,694	104	99
17	Special trade Contractors	$ 7 million	$ 95,231	74	99
20	Food and Kindred Products	500 employees	NA	500	499
21	Tobacco Products	500 employees	NA	500	499
22	Textile Mill Products	500 employees	NA	500	499
23	Apparel and Other textile Products	500 employees	NA	500	499
24	Lumber and Wood Products	500 employees	NA	500	499
25	Furniture and Fixtures	500 employees	NA	500	499
26	Paper and Allied Products	500 employees	NA	500	499
27	Printing and Publishing	500 employees	NA	500	499
28	Chemicals and Allied Products	500 employees	NA	500	499
29	Petroleum and Coal Products	500 employees	NA	500	499
30	Rubber and Miscellaneous Plastics Pdts	500 employees	NA	500	499
31	Leather and Leather Products	500 employees	NA	500	499

TABLE X-10

CONVERSION OF SBA SIZE DEFINITIONS TO CONFORM TO AVAILABLE DATA

SIC	Industry	Affected Firm Size Class *	Sales per Employee in 20-99 Employee Group	Estimated Number of Employees at Class Limit	Approxi-mated Class Size Limit
32	Stone, Clay, and Glass products	500 employees	NA	500	499
33	Primary Metal. Industries	500 employees	NA	500	499
34	Fabricated Metal Products	500 employees	NA	500	499
35	Industrial Machinery and Equipment	500 employees	NA	500	499
36	Electronic & Other Electrical Equipment	500 employees	NA	500	499
37	Transportation Equipment	500 employees	NA	500	499
38	Instruments and Related Products	500 employees	NA	500	499
39	Miscellaneous Manufacturing Industries	500 employees	NA	500	499
41	Local and Interurban Passenger Transit	$ 5 million	$ 38,970	128	99
42	Trucking and Warehousing	$18.5 million	$ 93,596	198	99
44	Water Transportation	500 employees	NA	500	499
45	Transportation by Air	1500 employees	NA	1500	499
46	Pipelines, except Natural Gas	1500 employees	NA	1500	499
47	Transportation Services	$ 5 million	$ 73,838	68	99
48	Communication	1500 employees	NA	1500	499
49	Electric, Gas, and Sanitary Services	$ 5 million	$301,546	17	19
50	Wholesale Trade - Durable Goods	100 employees	NA	100	99
51	Wholesale trade - Nondurable Goods	100 employees	NA	100	99
521	Lumber and Other Building Materials	$ 5 million	$225,654	22	19
523	Paint,, Glass, and Wallpaper Stores	$ 5 million	$136,892	37	19
526	Retail Nurseries and Garden Stores	$ 5 million	$ 92,622	54	19

TABLE X-10

CONVERSION OF SBA SIZE DEFINITIONS TO CONFORM TO AVAILABLE DATA

SIC	Industry	Affected Firm Size Class *	Sales per Employee in 20-99 Employee Group	Estimated Number of Employees at Class Limit	Approximated Class Size Limit
527	Mobile Home Dealers	$ 9.5 million	$286,529	33	19
53	General Merchandise Stores	$ 5 million	$138,035	36	19
541	Grocery Stores	$20 million	$118,116	169	99
543	Fruit and Vegetable Markets	$ 5 million	$103,003	49	19
553	Auto and Home Supply Stores	$ 5 million	$137,449	36	19
555	Boat Dealers	$ 5 million	$228,912	22	19
556	Recreational Vehicle Dealers	$ 5 million	$367,035	14	19
571	Furniture and Homefurnishings Stores	$ 5 million	$143,728	35	19
572	Household Appliance Stores	$ 5 million	$188,677	34	19
593	Used Merchandise Stores	$ 5 million	$ 52,924	94	99
596	Nonstore Retailers	$ 5 million	$144,160	35	19
598	Fuel Dealers	$ 5 million	$185,718	27	19
651	Real Estate Operators and Lessors	$ 5 million	$155,042	32	19
655	Subdividers and Developers	$ 5 million	$155,425	32	19
70	Hotels and Other Lodging Places	$ 5 million	$ 44,641	112	99
721	Laundry, Cleaning, and Garment Svcs	$ 5 million	$ 38,848	129	99
734	Services to Buildings	$12 million	$ 23,274	537	499
735	Misc. Equipment Rental & Leasing	$ 5 million	$ 38,848	129	99
736	Personal Supply Services	$ 5 million	$ 32,785	153	99
751	Automotive Rental & Leasing, w/o Drivers	$18.5 million	$172,688	107	99
752	Automobile Parking	$ 5 million	$ 75,807	66	99

TABLE X-10

CONVERSION OF SBA SIZE DEFINITIONS TO CONFORM TO AVAILABLE DATA

SIC	Industry	Affected Firm Size Class *	Sales per Employee in 20-99 Employee Group	Estimated Number of Employees at Class Limit	Approximated Class Size Limit
753	Automotive Repair Shops	$ 5 million	$ 89,691	56	19
754	Automotive Services, except Repair	$ 5 million	$ 33,092	151	99
762	Electrical Repair Shops	$ 5 million	$ 86,830	58	19
763	Watch, Clock, and Jewelry Repair	$ 5 million	NA	NA	19
769	Miscellaneous Repair Shops	$ 5 million	$ 91,007	55	19
794	Commercial Sports	$ 5 million	$176,962	28	19
799	Misc. Amusement & Recreation Svcs	$ 5 million	$ 42,873	117	99
805	Nursing and Personal Care Facilities	$ 5 million	$ 31,102	161	99
806	Hospitals	$ 5 million	$ 50,315	99	99
808	Home Health Care Services	$ 5 million	$ 39,175	128	99
833	Job Training and Related Services	$ 5 million	$ 35,204	142	99
836	Residential Care	$ 5 million	$ 34,361	146	99
842	Botanical and Zoological Gardens	$ 5 million	$ 48,064	104	99

* Dollar figures are for annual receipts.

NA = Not Applicable

Source: Department of Labor, Occupational Safety and Health Administration, Office of Regulatory Analysis

TABLE X-11

ANNUAL COST OF THE FINAL RULE AS A PERCENT OF SALES AND PROFITS FOR COVERED SMALL FIRMS, UNDER WORST CASE SCENARIOS

SIC	Industry	Small Business Definition*	Number of Affected Firms	Average Cost per Firm	Average Sales per Firm	Cost as a Percent of Sales	Average Profit per Firm	Cost as a Percent of Profits
07	Agricultural Services	$5 million	13,670	$24.73	$987,190	0.0025%	$59,231	0.042%
08	Forestry	$5 million	336	$26.21	$2,105,842	0.0012%	$65,281	0.040%
09	Fishing, Hunting, & Trapping	$3 million	161	$27.04	$2,584,497	0.0026%	$129,225	0.052%
13	Oil and Gas Extraction	500 employees	2,710	$31.36	$9,591,457	0.0003%	$489,164	0.006%
15	Gen. Contractors & Op. Builders	$17 million	23,352	$24.77	$5,151,861	0.0005%	$133,948	0.018%
16	Heavy Constr., except Building	$17 million	10,323	$24.56	$4,503,478	0.0005%	$171,132	0.014%
17	Special Trade Contractors	$7 million	69,229	$24.46	$2,124,066	0.0012%	$80,715	0.030%
20	Food and Kindred Products	500 employees	7,458	$29.91	$14,986,974	0.0002%	$299,739	0.010%
21	Tobacco Products	500 employees	34	$35.06	$29,572,735	*	$1,153,337	0.003%
22	Textile Mill Products	500 employees	2,432	$33.25	$8,159,577	0.0004%	$212,149	0.016%
23	Apparel & Other textile Products	500 employees	9,351	$31.31	$3,510,089	0.0009%	$87,752	0.036%
24	Lumber and Wood Products	500 employees	10,560	$27.92	$4,708,398	0.0006%	$169,502	0.016%
25	Furniture and Fixtures	500 employees	4,515	$28.67	$5,096,950	0.0006%	$158,005	0.018%
26	Paper and Allied Products	500 employees	2,724	$33.54	$12,075,394	0.0003%	$458,865	0.007%
27	Printing and Publishing	500 employees	16,857	$31.98	$4,482,306	0.0007%	$183,775	0.017%
28	Chemicals & Allied Products	500 employees	3,668	$37.29	$17,866,821	0.0002%	$750,407	0.005%
29	Petroleum & Coal Products	500 employees	530	$45.57	$28,919,179	0.0002%	$896,495	0.005%
30	Rubber & Misc. Plastics Pdts	500 employees	7,432	$31.24	$7,522,338	0.0004%	$270,804	0.012%
31	Leather and Leather Products	500 employees	695	$30.88	$4,943,160	0.0006%	$88,977	0.035%
32	Stone, Clay, & Glass Products	500 employees	5,293	$36.46	$5,529,515	0.0007%	$270,946	0.013%
33	Primary Metal. Industries	500 employees	2,948	$29.62	$11,867,260	0.0002%	$557,761	0.005%
34	Fabricated Metal Products	500 employees	16,731	$28.41	$5,979,978	0.0005%	$257,139	0.011%

TABLE X-11

ANNUAL COST OF THE FINAL RULE AS A PERCENT OF SALES AND PROFITS FOR COVERED SMALL FIRMS, UNDER WORST CASE SCENARIOS

SIC	Industry	Small Business Definition*	Number of Affected Firms	Average Cost per Firm	Average Sales per Firm	Cost as a Percent of Sales	Average Profit per Firm	Cost as a Percent of Profits
35	Industrial Machinery & Equipment	500 employees	21,451	$28.78	$5,070,462	0.0006%	$207,889	0.014%
36	Electronic and Other Electrical Equipment	500 employees	7,163	$32.43	$8,579,085	0.0004%	$428,954	0.008%
37	Transportation Equipment	500 employees	4,015	$ 26.52	$8,870,271	0.0003%	$354,811	0.007%
38	Instruments & Related Products	500 employees	4,213	$ 32.47	$7,392,197	0.0004%	$406,571	0.008%
39	Misc. Manufacturing Industries	500 employees	5,379	$ 29.47	$4,621,281	0.0006%	$152,502	0.019%
41	Local & Interurban Pass. Transit	$5 million	4,986	$ 27.09	$1,107,785	0.0024%	$65,359	0.041%
42	Trucking and Warehousing	$18.5 million	20,099	$27.34	$2,393,091	0.0011%	$86,151	0.032%
44	Water Transportation	500 employees	1,751	$32.20	$6,533,938	0.0005%	$326,697	0.010%
45	Transportation by Air	1500 employees	1,660	$35.67	$3,558,061	0.0010%	$145,880	0.024%
46	Pipelines, except Natural Gas	1500 employees	21	$101.30	$26,554,857	0.0004%	$1,301,188	0.008%
47	Transportation Services	$5 million	5,506	$36.47	$1,698,837	0.0021%	$54,363	0.067%
48	Communication	1500 employees	6,042	$36.51	$5,716,356	0.0006%	$382,996	0.010%
49	Electric, Gas, & Sanitary Svcs	$5 million	947	$28.00	$2,984,573	0.0009%	$268,612	0.010%
50	Wholesale Trade - Durables	100 employees	62,307	$32.89	$11,930,304	0.0003%	$286,327	0.011%
51	Wholesale Trade - Nondurables	100 employees	34,374	$30.78	$16,844,265	0.0002%	$303,197	0.010%
521	Lumber & Other Bldg Materials	$5 million	2,741	$26.94	$2,603,069	0.0010%	$49,458	0.054%
523	Paint, Glass & Wallpaper Stores	$5 million	577	$31.14	$1,722,688	0.0018%	$15,504	0.201%
526	Retail Nurseries & Garden Stores	$5 million	1,797	$26.58	$1,905,264	0.0020%	$41,916	0.092%
527	Mobile Home Dealers	$9.5 million	557	$28.98	$3,627,901	0.0008%	$105,209	0.027%
53	General Merchandise Stores	$5 million	986	$27.76	$4,174,173	0.0007%	$100,180	0.028%
541	Grocery Stores	$20 million	18,877	$30.99	$2,902,882	0.0011%	$34,835	0.089%
543	Fruit & Vegetable Markets	$5 million	237	$28.46	$2,771,857	0.0010%	$36,034	0.079%
553	Auto & Home Supply Stores	$5 million	3,264	$23.36	$1,453,195	0.0016%	$27,611	0.085%

TABLE X-11

ANNUAL COST OF THE FINAL RULE AS A PERCENT OF SALES AND PROFITS FOR COVERED SMALL FIRMS, UNDER WORST CASE SCENARIOS

SIC	Industry	Small Business Definition*	Number of Affected Firms	Average Cost per Firm	Average Sales per Firm	Cost as a Percent of Sales	Average Profit per Firm	Cost as a Percent of Profits
555	Boat Dealers	$5 million	592	$27.02	$4,343,588	0.0006%	$95,559	0.028%
556	Recreational Vehicle Dealers	$5 million	448	$36.04	$3,801,888	0.0009%	$64,632	0.056%
571	Furniture & Furnishings Stores	$5 million	5,174	$24.38	$1,731,758	0.0014%	$39,830	0.061%
572	Household Appliance Stores	$5 million	892	$25.13	$1,931,969	0.0013%	$44,435	0.057%
593	Used Merchandise Stores	$5 million	1,486	$63.93	$1,151,431	0.0056%	$52,966	0.121%
596	Nonstore Retailers	$5 million	2,234	$28.17	$1,738,348	0.0016%	$34,767	0.081%
598	Fuel Dealers	$5 million	1,156	$29.90	$2,380,413	0.0013%	$19,043	0.157%
651	Real Estate Oprs &Lessors	$5 million	4,854	$19.27	$2,113,760	0.0009%	$325,519	0.006%
655	Subdividers & Developers	$5 million	946	$21.16	$1,811,582	0.0012%	$164,854	0.013%
70	Hotels & Other Lodging Places	$5 million	13,280	$27.33	$1,213,073	0.0023%	$84,915	0.032%
721	Laundry, Cleaning & Garment Svcs	$5 million	8,218	$66.92	$823,024	0.0081%	$31,275	0.214%
734	Services to Buildings	$12 million	12,156	$46.16	$869,064	0.0053%	$32,155	0.144%
735	Misc. Equip. Rental & Leasing	$5 million	3,879	$73.79	$2,917,151	0.0025%	$268,378	0.027%
736	Personal Supply Services	$5 million	6,277	$47.92	$1,334,065	0.0036%	$40,022	0.120%
751	Automotive Rental & Leasing	$18.5 million	998	$35.46	$3,950,718	0.0009%	$225,191	0.016%
752	Automobile Parking	$5 million	438	$58.71	$1,946,436	0.0030%	$93,429	0.063%
753	Automotive Repair Shops	$5 million	12,372	$27.42	$1,405,287	0.0028%	$54,806	0.071%
754	Automotive Svcs, except Repair	$5 million	4,643	$31.54	$873,101	0.0036%	$56,752	0.056%
762	Electrical Repair Shops	$5 million	1,994	$27.68	$1,698,049	0.0026%	$44,149	0.099%
763	Watch, Clock & Jewelry Repair	$5 million	59	$32.89	$2,673,508	0.0012%	$90,899	0.036%
769	Miscellaneous Repair Shops	$5 million	5,231	$26.52	$1,772,231	0.0024%	$104,562	0.040%
794	Commercial Sports	$5 million	347	$25.93	$1,408,876	0.0018%	$50,720	0.051%
799	Misc. Amusement & Rec. Svcs	$5 million	13,777	$26.31	$1,255,992	0.0021%	$52,752	0.050%
805	Nursing & Personal Care Facilities	$5 million	5,202	$38.04	$1,597,604	0.0024%	$68,697	0.055%

TABLE X-11

ANNUAL COST OF THE FINAL RULE AS A PERCENT OF SALES AND PROFITS FOR COVERED SMALL FIRMS, UNDER WORST CASE SCENARIOS

SIC	Industry	Small Business Definition*	Number of Affected Firms	Average Cost per Firm	Average Sales per Firm	Cost as a Percent of Sales	Average Profit per Firm	Cost as a Percent of Profits
806	Hospitals	$5 million	580	$41.62	$3,146,674	0.0013%	$160,480	0.026%
808	Home Health Care Services	$5 million	3,834	$36.50	$1,508,924	0.0024%	$52,812	0.069%
833	Job Training & Related Svcs	$5 million	2,086	$64.80	$1,230,974	0.0053%	$30,774	0.211%
836	Residential Care	$5 million	6,253	$60.64	$1,003,036	0.0060%	$26,079	0.233%
842	Botanical & Zoological Gardens	$5 million	147	$88.76	$1,494,510	0.0059%	$91,165	0.097%
	All Covered Industries		541,988	$31.66				

* Dollar figures are for annual receipts.

Source: Department of Labor, Occupational Safety and Health Administration, Office of Regulatory Analysis

TABLE X-12

ANNUAL COST AS A PERCENT OF SALES AND PROFITS FOR FIRMS WITH 11-19 EMPLOYEES UNDER WORST CASE SCENARIOS

SIC	Industry	Average Cost per Firm	Average Sales per Firm	Cost as a Percent of Sales	Average Profit per Firm	Cost as a Percent of Profits
07	Agricultural Services	$ 25.15	$621,820	0.0040%	$37,309	0.067%
08	Forestry	$ 25.71	$1,393,764	0.0018%	$43,207	0.060%
09	Fishing, Hunting, & Trapping	$ 27.04	$1,038,708	0.0026%	$51,935	0.052%
13	Oil and Gas Extraction	$ 27.34	$2,868,080	0.0010%	$146,272	0.019%
15	Gen Contractors & Op Builders	$ 25.41	$2,580,143	0.0010%	$67,084	0.038%
16	Heavy Constr., except Building	$ 25.50	$2,090,243	0.0012%	$79,429	0.032%
17	Special Trade Contractors	$ 25.23	$1,131,469	0.0022%	$42,996	0.059%
20	Food and Kindred Pdts	$ 26.18	$2,531,479	0.0010%	$50,630	0.052%
22	Textile Mill Products	$ 27.09	$1,515,715	0.0018%	$39,409	0.069%
23	Apparel & Textile Pdts	$ 27.34	$938,592	0.0029%	$23,465	0.117%
24	Lumber and Wood Pdts	$ 25.94	$1,422,378	0.0018%	$51,206	0.051%
25	Furniture and Fixtures	$ 26.30	$1,115,791	0.0024%	$34,590	0.076%
26	Paper and Allied Pdts	$ 26.95	$1,936,363	0.0014%	$73,582	0.037%
27	Printing and Publishing	$ 27.33	$1,172,319	0.0023%	$48,065	0.057%
28	Chemicals & Allied Pdts	$ 27.73	$4,032,271	0.0007%	$169,355	0.016%
29	Petroleum & Coal Pdts	$ 28.84	$6,336,307	0.0005%	$196,426	0.015%
30	Rubber & Misc Plastics Pdts	$ 26.50	$1,679,865	0.0016%	$60,475	0.044%
32	Stone, Clay, & Glass Pdts	$ 26.50	$1,681,495	0.0016%	$82,393	0.032%
33	Primary Metal Industries	$ 25.94	$1,814,577	0.0014%	$85,285	0.030%
34	Fabricated Metal Pdts	$ 26.05	$1,444,760	0.0018%	$62,125	0.042%
35	Industrial Machinery & Equ't	$ 26.51	$1,279,056	0.0021%	$52,441	0.051%

TABLE X-12

ANNUAL COST AS A PERCENT OF SALES AND PROFITS FOR FIRMS WITH 11-19 EMPLOYEES UNDER WORST CASE SCENARIOS

SIC	Industry	Average Cost per Firm	Average Sales per Firm	Cost as a Percent of Sales	Average Profit per Firm	Cost as a Percent of Profits
36	Electronic & Electrical Equ't	$ 27.24	$1,603,741	0.0017%	$80,187	0.034%
37	Transportation Equipment	$ 25.65	$1,568,481	0.0016%	$62,739	0.041%
38	Instruments & Related Pdts	$ 27.70	$1,691,768	0.0016%	$93,047	0.030%
39	Misc. Mfg Industries	$ 26.89	$1,297,254	0.0021%	$42,809	0.063%
41	Local Passenger. Transit	$ 26.11	$483,512	0.0054%	$28,527	0.092%
42	Trucking & Warehousing	$ 26.29	$1,289,953	0.0020%	$46,438	0.057%
44	Water Transportation	$ 27.15	$1,849,451	0.0015%	$92,473	0.029%
47	Transportation Svs	$ 30.57	$932,566	0.0033%	$29,842	0.102%
48	Communication	$ 27.69	$1,590,405	0.0017%	$106,557	0.026%
49	Electric, Gas, & Sanitary Svs	$ 28.00	$2,984,573	0.0009%	$268,612	0.010%
50	Wholesale Trade - Durables	$ 28.01	$5,528,464	0.0005%	$132,683	0.021%
51	Wholesale Trade - Nondurables	$ 27.69	$8,321,447	0.0003%	$149,786	0.018%
521	Lumber & Other Bldg Mat'ls	$ 26.94	$2,603,069	0.0010%	$49,458	0.054%
523	Paint, Glass & Wallpaper Stores	$ 31.14	$1,722,688	0.0018%	$15,504	0.201%
526	Retail Nurseries & Gdn Stores	$ 26.58	$1,314,022	0.0020%	$28,908	0.092%
527	Mobile Home Dealers	$ 28.70	$3,627,901	0.0008%	$105,209	0.027%
53	General Merchandise Stores	$ 27.76	$1,322,364	0.0021%	$31,737	0.087%
541	Grocery Stores	$ 27.50	$1,415,207	0.0019%	$16,982	0.162%
543	Fruit & Vegetable Markets	$ 28.46	$2,771,857	0.0010%	$36,034	0.079%
553	Auto & Home Supply Stores	$ 23.36	$1,453,195	0.0016%	$27,611	0.085%
555	Boat Dealers	$ 27.02	$4,343,588	0.0006%	$95,559	0.028%

TABLE X-12

ANNUAL COST AS A PERCENT OF SALES AND PROFITS FOR FIRMS WITH 11-19 EMPLOYEES UNDER WORST CASE SCENARIOS

SIC	Industry	Average Cost per Firm	Average Sales per Firm	Cost as a Percent of Sales	Average Profit per Firm	Cost as a Percent of Profits
556	Recreational Vehicle Dealers	$36.04	$3,801,888	0.0009%	$64,632	0.056%
571	Furniture & Furnishings Stores	$24.38	$1,731,758	0.0014%	$39,830	0.061%
572	Household Appliance Stores	$25.13	$1,931,969	0.0013%	$44,435	0.057%
593	Used Merchandise Stores	$16.15	$818,933	0.0020%	$37,671	0.043%
596	Nonstore Retailers	$28.17	$1,738,348	0.0016%	$34,767	0.081%
598	Fuel Dealers	$29.90	$2,380,413	0.0013%	$19,043	0.157%
651	Real Estate Oprs & Lessors	$19.27	$2,113,760	0.0009%	$325,519	0.006%
655	Subdividers & Developers	$21.16	$1,811,582	0.0012%	$164,854	0.013%
70	Hotels & Other Lodging Places	$26.54	$613,072	0.0043%	$42,915	0.062%
721	Laundry, Cleaning Svcs	$27.51	$444,393	0.0062%	$16,887	0.163%
734	Services to Buildings	$24.14	$390,494	0.0062%	$14,448	0.167%
735	Misc. Equ't. Rental & Leasing	$34.05	$1,552,492	0.0022%	$142,829	0.024%
736	Personal Supply Services	$32.04	$835,157	0.0038%	$25,055	0.128%
751	Automotive Rental & Leasing	$29.52	$2,284,946	0.0013%	$130,242	0.023%
752	Automobile Parking	$36.38	$1,050,921	0.0035%	$50,444	0.072%
753	Automotive Repair Shops	$27.42	$992,563	0.0028%	$38,710	0.071%
754	Automotive Svs, exc Repair	$28.35	$596,943	0.0048%	$38,801	0.073%
762	Electrical Repair Shops	$27.68	$1,073,521	0.0026%	$27,912	0.099%
763	Watch, Clock, Jewelry Repair	$32.89	$2,673,508	0.0012%	$90,899	0.036%
769	Miscellaneous Repair Shops	$26.52	$1,111,697	0.0024%	$65,590	0.040%
794	Commercial Sports	$25.93	$1,408,876	0.0018%	$50,720	0.051%

TABLE X-12

ANNUAL COST AS A PERCENT OF SALES AND PROFITS FOR FIRMS WITH 11-19 EMPLOYEES UNDER WORST CASE SCENARIOS

SIC	Industry	Average Cost per Firm	Average Sales per Firm	Cost as a Percent of Sales	Average Profit per Firm	Cost as a Percent of Profits
799	Misc Amusement & Rec. Svcs	$26.28	$654,250	0.0040%	$27,478	0.096%
805	Nursing & Personal Care Fac's	$29.68	$577,018	0.0051%	$24,812	0.120%
806	Hospitals	$32.49	$732,676	0.0044%	$37,366	0.087%
808	Home Health Care Svcs	$30.07	$758,133	0.0040%	$26,535	0.113%
833	Job Training & Related Svcs	$42.69	$643,890	0.0066%	$16,097	0.265%
836	Residential Care	$40.83	$388,540	0.0105%	$10,102	0.404%
842	Botanical & Zoological Gdns	$43.84	$722,554	0.0061%	$44,076	0.099%
	All Covered Industries	$29.99				

Source: Department of Labor, Occupational Safety and Health Administration, Office of Regulatory Analysis

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Regulatory Flexibility Analysis

Although a Final Regulatory Flexibility Analysis is not required in this case, OSHA has chosen to include the elements of a final regulatory flexibility analysis in this document. The elements of a Final Regulatory Flexibility Analysis are:

- A succinct statement of the need for, and the objective of, the rule;
- A summary of significant issues raised by the public comments in response to the initial regulatory flexibility analysis, a summary of the assessment of the Agency of such issues, and a statement of any changes made to the proposed rule as a result of such comments;
- A description of and estimate of the number of small entities to which the rule will apply or an explanation of why no such explanation is available;
- A description of the projected reporting, recordkeeping and other compliance requirements of the rule, including an estimate of the classes of small entities that will be subject to the rule's requirements and the types of professional skills necessary for preparation of the record or report;
- A description of the steps the Agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each of the other significant alternatives considered by the agency was rejected.

The Regulatory Flexibility Act states that the Regulatory Flexibility Analysis (RFA) need not contain all of the above elements *in toto* if these elements are presented elsewhere in the documentation and analysis of the regulation. This analysis will follow this approach and refer the reader to other documentation for some of the above elements.

Need for and objectives of the rule. The need for the final rule and its objectives are discussed in the introductory sections of the preamble.

The number of small entities to which the rule will apply. As shown in Table X–11, the final rule will impact 541,988 firms defined as small firms by the SBA.

The compliance requirements of the final rule. The compliance requirements of the final rule are discussed in the summary and explanation section of the preamble, which discusses each requirement in detail.

Steps taken to minimize the impact of the rule on small entities. The final Part 1904 rule minimizes the impact on small entities in two ways. First, all employers who had fewer than 11 workers at all times during the previous year are exempt from keeping Part 1904 records of occupational injuries and illnesses, unless specifically asked to do so by the government. Second, the final rule exempts employers classified in certain industries in the services and retail sectors. These industry-exempt employers are also not required to keep records unless asked to do so by the government. The effect of the size and industry exemptions is that more than 4.5 million of the Nation's 6 million business establishments are exempted from keeping OSHA Part 1904 records on a routine basis.

OSHA considered several alternatives to exempting employers based on size and/or industry classification. A discussion of these alternatives, and why OSHA chose the alternative in the final rule, can be found in the preamble discussion for Subpart B, Scope.

XI. Regulatory Flexibility Certification

Based on OSHA's analysis of small business impacts (Tables X–11 and X–12), OSHA certifies that this final rule will not have a significant impact on a substantial number of small entities. OSHA makes this certification to fulfill its obligations under the Regulatory Flexibility Act (as amended in 1996).

XII. Environmental Impact Assessment

In accordance with the requirements of the National Environmental Policy Act (NEPA) (42 U.S.C. 4321 *et seq.*), Council on Environmental Quality NEPA regulations (40 CFR part 1500 *et seq.*), and the Department of Labor's NEPA regulations (29 CFR part 11), the Assistant Secretary has determined that this final rule will not have a significant impact on the external environment.

XIII. Federalism

This final rule has been reviewed in accordance with Executive Order 13132 (52 FR 41685), regarding Federalism. Because this rulemaking action involves a ''regulation'' issued under section 8 of the OSH Act, and not a ''standard'' issued under section 6 of the Act, the rule does not preempt State law, see 29 U.S.C. § 667 (a). The effect of the final rule on States is discussed above in Section VI, *State Plans.*

XIV. Paperwork Reduction Act of 1995

The final regulation contains information collections which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. Most of the provisions of the final rule contain collection of information requirements, either to keep records or to report information from the records to the government. In addition, the effort employers are required to put forth to learn the requirements are considered information requirements.

In response to OSHA's 1996 proposal, the public submitted 450 written comments . The Agency also held two public meetings where it collected oral comments from 43 individuals and groups during six days of informal meetings.

In summary, OSHA estimates that there are 1,365,985 establishments that will be required to keep records of occupational injuries and illnesses under the provisions. A total of approximately 4,500,000 hours will be needed for employers to comply with the information collection requirements for the first year, and 3,500,000 hours in each subsequent year. This represents an increase of 1,060,000 hours from the previous paperwork burden estimates. OSHA has recently recognized that previous estimates of the burden associated with becoming familiar with the 1904 rule have been understated, and recently corrected those estimates, as noted in OSHA's Final Economic Analysis for the Part 1904 rule.

In accordance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), OSHA has requested OMB approval of the collection of information requirement described above. The information collection provisions will take effect when OMB approves them under the PRA.

XV. Authority

This document was prepared under the direction of Charles N. Jeffress, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, DC 20210.

List of Subjects

29 CFR Part 1904

Health statistics, Occupational safety and health, Reporting and recordkeeping requirements, State plans.

29 CFR Part 1952

Health statistics, Intergovernmental relations, Occupational safety and health, Reporting and recordkeeping requirements, State plans.

Accordingly, pursuant to sections 8(c), 8(g), 20 and 24 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 657, 673), Secretary of Labor's Order No. 1–90 (55 FR 9033), and 5 U.S.C. 553, the Department amends 29 CFR Chapter XVII as set forth below.

Signed in Washington, D.C., this 5th day of January, 2001.

Charles N. Jeffress,

Assistant Secretary of Labor.

1. 29 CFR Part 1904 is revised to read as follows:

Part 1904—Recording and Reporting Occupational Injuries and Illnesses

Sec.

Subpart A—Purpose

1904.0 Purpose

Subpart B—Scope

1904.1 Partial exemption for employers with 10 or fewer employees.
1904.2 Partial exemption for establishments in certain industries.
1904.3 Keeping records for more than one agency.
Non-mandatory Appendix A to Subpart B—Partially Exempt Industries.

Subpart C—Recordkeeping Forms and Recording Criteria

1904.4 Recording criteria.
1904.5 Determination of work-relatedness.
1904.6 Determination of new cases.
1904.7 General recording criteria.
1904.8 Recording criteria for needlestick and sharps injuries.
1904.9 Recording criteria for cases involving medical removal under OSHA standards.
1904.10 Recording criteria for cases involving occupational hearing loss.
1904.11 Recording criteria for work-related tuberculosis cases.
1904.12 Recording criteria for cases involving work-related musculoskeletal disorders.
1904.13–1904.28 [Reserved]
1904.29 Forms.

Subpart D—Other OSHA Injury and Illness Recordkeeping Requirements

1904.30 Multiple business establishments.
1904.31 Covered employees.
1904.32 Annual summary.
1904.33 Retention and updating.
1904.34 Change in business ownership.
1904.35 Employee involvement.
1904.36 Prohibition against discrimination.
1904.37 State recordkeeping regulations.
1904.38 Variances from the recordkeeping rule.

Subpart E—Reporting Fatality, Injury and Illness Information to the Government

1904.39 Reporting fatalities and multiple hospitalization incidents to OSHA.
1904.40 Providing records to government representatives.
1904.41 Annual OSHA Injury and Illness Survey of Ten or More Employers.
1904.42 Requests from the Bureau of Labor Statistics for data.

Subpart F—Transition From the Former Rule

1904.43 Summary and posting of year 2000 data.
1904.44 Retention and updating of old forms.
1904.45 OMB control numbers under the Paperwork Reduction Act

Subpart G—Definitions

1904.46 Definitions.

Authority: 29 U.S.C. 657, 658, 660, 666, 669, 673, Secretary of Labor's Order No. 1–90 (55 FR 9033), and 5 U.S.C. 553.

Subpart A—Purpose

§ 1904.0 Purpose.

The purpose of this rule (Part 1904) is to require employers to record and report work-related fatalities, injuries and illnesses.

Note to § 1904.0: Recording or reporting a work-related injury, illness, or fatality does not mean that the employer or employee was at fault, that an OSHA rule has been violated, or that the employee is eligible for workers' compensation or other benefits.

Subpart B—Scope

Note to Subpart B: All employers covered by the Occupational Safety and Health Act (OSH Act) are covered by these Part 1904 regulations. However, most employers do not have to keep OSHA injury and illness records unless OSHA or the Bureau of Labor Statistics (BLS) informs them in writing that they must keep records. For example, employers with 10 or fewer employees and business establishments in certain industry classifications are partially exempt from keeping OSHA injury and illness records.

§ 1904.1 Partial exemption for employers with 10 or fewer employees.

(a) *Basic requirement.* (1) If your company had ten (10) or fewer employees at all times during the last calendar year, you do not need to keep OSHA injury and illness records unless OSHA or the BLS informs you in writing that you must keep records under § 1904.41 or § 1904.42. However, as required by § 1904.39, all employers covered by the OSH Act must report to OSHA any workplace incident that results in a fatality or the hospitalization of three or more employees.

(2) If your company had more than ten (10) employees at any time during the last calendar year, you must keep OSHA injury and illness records unless your establishment is classified as a partially exempt industry under § 1904.2.

(b) *Implementation.* (1) *Is the partial exemption for size based on the size of my entire company or on the size of an individual business establishment?* The partial exemption for size is based on the number of employees in the entire company.

(2) *How do I determine the size of my company to find out if I qualify for the partial exemption for size?* To determine if you are exempt because of size, you need to determine your company's peak employment during the last calendar year. If you had no more than 10 employees at any time in the last calendar year, your company qualifies for the partial exemption for size.

§ 1904.2 Partial exemption for establishments in certain industries.

(a) *Basic requirement.* (1) If your business establishment is classified in a specific low hazard retail, service, finance, insurance or real estate industry listed in Appendix A to this Subpart B, you do not need to keep OSHA injury and illness records unless the government asks you to keep the records under § 1904.41 or § 1904.42. However, all employers must report to OSHA any workplace incident that results in a fatality or the hospitalization of three or more employees (see § 1904.39).

(2) If one or more of your company's establishments are classified in a non-exempt industry, you must keep OSHA injury and illness records for all of such establishments unless your company is partially exempted because of size under § 1904.1.

(b) *Implementation.* (1) *Does the partial industry classification exemption apply only to business establishments in the retail, services, finance, insurance or real estate industries (SICs 52–89)?* Yes, business establishments classified in agriculture; mining; construction; manufacturing; transportation; communication, electric, gas and sanitary services; or wholesale trade are not eligible for the partial industry classification exemption.

(2) *Is the partial industry classification exemption based on the industry classification of my entire company or on the classification of individual business establishments operated by my company?* The partial industry classification exemption applies to individual business establishments. If a company has several business establishments engaged in different classes of business activities, some of the company's establishments may be required to keep records, while others may be exempt.

(3) *How do I determine the Standard Industrial Classification code for my company or for individual establishments?* You determine your Standard Industrial Classification (SIC) code by using the Standard Industrial Classification Manual, Executive Office of the President, Office of Management and Budget. You may contact your nearest OSHA office or State agency for help in determining your SIC.

§ 1904.3 Keeping records for more than one agency.

If you create records to comply with another government agency's injury and illness recordkeeping requirements, OSHA will consider those records as meeting OSHA's Part 1904 recordkeeping requirements if OSHA accepts the other agency's records under a memorandum of understanding with that agency, or if the other agency's records contain the same information as this Part 1904 requires you to record. You may contact your nearest OSHA office or State agency for help in determining whether your records meet OSHA's requirements.

Non-Mandatory Appendix A to Subpart B—Partially Exempt Industries

Employers are not required to keep OSHA injury and illness records for any establishment classified in the following Standard Industrial Classification (SIC) codes, unless they are asked in writing to do so by OSHA, the Bureau of Labor Statistics (BLS), or a state agency operating under the authority of OSHA or the BLS. All employers, including those partially exempted by reason of company size or industry classification, must report to OSHA any workplace incident that results in a fatality or the hospitalization of three or more employees (see § 1904.39).

SIC code	Industry description	SIC code	Industry description
525	Hardware Stores	725	Shoe Repair and Shoeshine Parlors.
542	Meat and Fish Markets	726	Funeral Service and Crematories.
544	Candy, Nut, and Confectionery Stores	729	Miscellaneous Personal Services.
545	Dairy Products Stores	731	Advertising Services.
546	Retail Bakeries	732	Credit Reporting and Collection Services.
549	Miscellaneous Food Stores	733	Mailing, Reproduction, & Stenographic Services.
551	New and Used Car Dealers	737	Computer and Data Processing Services.
552	Used Car Dealers	738	Miscellaneous Business Services.
554	Gasoline Service Stations	764	Reupholstery and Furniture Repair.
557	Motorcycle Dealers	78	Motion Picture.
56	Apparel and Accessory Stores	791	Dance Studios, Schools, and Halls.
573	Radio, Television, & Computer Stores	792	Producers, Orchestras, Entertainers.
58	Eating and Drinking Places	793	Bowling Centers.
591	Drug Stores and Proprietary Stores	801	Offices & Clinics Of Medical Doctors.
592	Liquor Stores	802	Offices and Clinics Of Dentists.
594	Miscellaneous Shopping Goods Stores	803	Offices Of Osteopathic.
599	Retail Stores, Not Elsewhere Classified	804	Offices Of Other Health Practitioners.
60	Depository Institutions (banks & savings institutions)	807	Medical and Dental Laboratories.
61	Nondepository	809	Health and Allied Services, Not Elsewhere Classified.
62	Security and Commodity Brokers	81	Legal Services.
63	Insurance Carriers	82	Educational Services (schools, colleges, universities and libraries).
64	Insurance Agents, Brokers & Services	832	Individual and Family Services.
653	Real Estate Agents and Managers	835	Child Day Care Services.
654	Title Abstract Offices	839	Social Services, Not Elsewhere Classified.
67	Holding and Other Investment Offices	841	Museums and Art Galleries.
722	Photographic Studios, Portrait	86	Membership Organizations.
723	Beauty Shops	87	Engineering, Accounting, Research, Management, and Related Services.
724	Barber Shops	899	Services, not elsewhere classified.

Subpart C—Recordkeeping Forms and Recording Criteria

Note to Subpart C: This Subpart describes the work-related injuries and illnesses that an employer must enter into the OSHA records and explains the OSHA forms that employers must use to record work-related fatalities, injuries, and illnesses.

§ 1904.4 Recording criteria.

(a) *Basic requirement.* Each employer required by this Part to keep records of fatalities, injuries, and illnesses must record each fatality, injury and illness that:

(1) Is work-related; and

(2) Is a new case; and

(3) Meets one or more of the general recording criteria of § 1904.7 or the application to specific cases of § 1904.8 through § 1904.12.

(b) *Implementation.* (1) *What sections of this rule describe recording criteria for recording work-related injuries and illnesses?* The table below indicates which sections of the rule address each topic.

(i) Determination of work-relatedness. See § 1904.5.

(ii) Determination of a new case. See § 1904.6.

(iii) General recording criteria. See § 1904.7.

(iv) Additional criteria. (Needlestick and sharps injury cases, tuberculosis cases, hearing loss cases, medical removal cases, and musculoskeletal disorder cases). See § 1904.8 through § 1904.12.

(2) *How do I decide whether a particular injury or illness is recordable?* The decision tree for recording work-related injuries and illnesses below shows the steps involved in making this determination.

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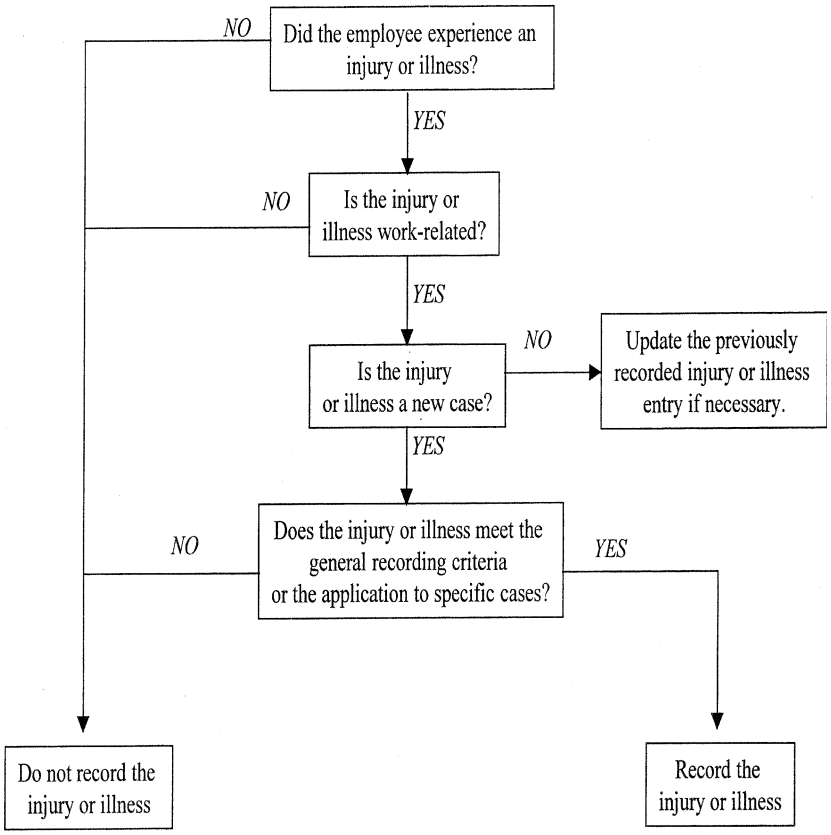

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§ 1904.5 Determination of work-relatedness.

(a) *Basic requirement.* You must consider an injury or illness to be work-related if an event or exposure in the work environment either caused or contributed to the resulting condition or significantly aggravated a pre-existing injury or illness. Work-relatedness is presumed for injuries and illnesses resulting from events or exposures occurring in the work environment, unless an exception in § 1904.5(b)(2) specifically applies.

(b) *Implementation.* (1) What is the ''work environment''? OSHA defines the work environment as ''the establishment and other locations where one or more employees are working or are present as a condition of their employment. The work environment includes not only physical locations, but also the equipment or materials used by the employee during the course of his or her work.''

(2) *Are there situations where an injury or illness occurs in the work environment and is not considered work-related?* Yes, an injury or illness occurring in the work environment that falls under one of the following exceptions is not work-related, and therefore is not recordable.

1904.5(b)(2)	You are not required to record injuries and illnesses if . . .
(i)	At the time of the injury or illness, the employee was present in the work environment as a member of the general public rather than as an employee.
(ii)	The injury or illness involves signs or symptoms that surface at work but result solely from a non-work-related event or exposure that occurs outside the work environment.
(iii)	The injury or illness results solely from voluntary participation in a wellness program or in a medical, fitness, or recreational activity such as blood donation, physical examination, flu shot, exercise class, racquetball, or baseball.
(iv)	The injury or illness is solely the result of an employee eating, drinking, or preparing food or drink for personal consumption (whether bought on the employer's premises or brought in). For example, if the employee is injured by choking on a sandwich while in the employer's establishment, the case would not be considered work-related. **Note:** If the employee is made ill by ingesting food contaminated by workplace contaminants (such as lead), or gets food poisoning from food supplied by the employer, the case would be considered work-related.
(v)	The injury or illness is solely the result of an employee doing personal tasks (unrelated to their employment) at the establishment outside of the employee's assigned working hours.
(vi)	The injury or illness is solely the result of personal grooming, self medication for a non-work-related condition, or is intentionally self-inflicted.
(vii)	The injury or illness is caused by a motor vehicle accident and occurs on a company parking lot or company access road while the employee is commuting to or from work.
(viii)	The illness is the common cold or flu (Note: contagious diseases such as tuberculosis, brucellosis, hepatitis A, or plague are considered work-related if the employee is infected at work).

1904.5(b)(2)	You are not required to record injuries and illnesses if . . .
(ix)	The illness is a mental illness. Mental illness will not be considered work-related unless the employee voluntarily provides the employer with an opinion from a physician or other licensed health care professional with appropriate training and experience (psychiatrist, psychologist, psychiatric nurse practitioner, etc.) stating that the employee has a mental illness that is work-related.

(3) *How do I handle a case if it is not obvious whether the precipitating event or exposure occurred in the work environment or occurred away from work?* In these situations, you must evaluate the employee's work duties and environment to decide whether or not one or more events or exposures in the work environment either caused or contributed to the resulting condition or significantly aggravated a pre-existing condition.

(4) *How do I know if an event or exposure in the work environment ''significantly aggravated'' a preexisting injury or illness?* A preexisting injury or illness has been significantly aggravated, for purposes of OSHA injury and illness recordkeeping, when an event or exposure in the work environment results in any of the following:

(i) Death, provided that the preexisting injury or illness would likely not have resulted in death but for the occupational event or exposure.

(ii) Loss of consciousness, provided that the preexisting injury or illness would likely not have resulted in loss of consciousness but for the occupational event or exposure.

(iii) One or more days away from work, or days of restricted work, or days of job transfer that otherwise would not have occurred but for the occupational event or exposure.

(iv) Medical treatment in a case where no medical treatment was needed for the injury or illness before the workplace event or exposure, or a change in medical treatment was necessitated by the workplace event or exposure.

(5) *Which injuries and illnesses are considered pre-existing conditions?* An injury or illness is a preexisting condition if it resulted solely from a non-work-related event or exposure that occured outside the work environment.

(6) *How do I decide whether an injury or illness is work-related if the employee is on travel status at the time the injury or illness occurs?* Injuries and illnesses that occur while an employee is on travel status are work-related if, at the time of the injury or illness, the employee was engaged in work activities ''in the interest of the employer.'' Examples of such activities include travel to and from customer contacts, conducting job tasks, and entertaining or being entertained to transact, discuss, or promote business (work-related entertainment includes only entertainment activities being engaged in at the direction of the employer).

Injuries or illnesses that occur when the employee is on travel status do not have to be recorded if they meet one of the exceptions listed below.

1904.5 (b)(6)	If the employee has . . .	You may use the following to determine if an injury or illness is work-related
(i)	checked into a hotel or motel for one or more days.	When a traveling employee checks into a hotel, motel, or into a other temporary residence, he or she establishes a ''home away from home.'' You must evaluate the employee's activities after he or she checks into the hotel, motel, or other temporary residence for their work-relatedness in the same manner as you evaluate the activities of a non-traveling employee. When the employee checks into the temporary residence, he or she is considered to have left the work environment. When the employee begins work each day, he or she re-enters the work environment. If the employee has established a ''home away from home'' and is reporting to a fixed worksite each day, you also do not consider injuries or illnesses work-related if they occur while the employee is commuting between the temporary residence and the job location.
(ii)	taken a detour for personal reasons.	Injuries or illnesses are not considered work-related if they occur while the employee is on a personal detour from a reasonably direct route of travel (*e.g.*, has taken a side trip for personal reasons).

(7) *How do I decide if a case is work-related when the employee is working at home?* Injuries and illnesses that occur while an employee is working at home, including work in a home office, will be considered work-related if the injury or illness occurs while the employee is performing work for pay or compensation in the home, and the injury or illness is directly related to the performance of work rather than to the general home environment or setting. For example, if an employee drops a box of work documents and injures his or her foot, the case is considered work-related. If an employee's fingernail is punctured by a needle from a sewing machine used to perform garment work at home, becomes infected and requires medical treatment, the injury is considered work-related. If an employee is injured because he or she trips on the family dog while rushing to answer a work phone call, the case is not considered work-related. If an employee working at home is electrocuted because of faulty home wiring, the injury is not considered work-related.

§ 1904.6 Determination of new cases.

(a) *Basic requirement.* You must consider an injury or illness to be a ''new case'' if:

(1) The employee has not previously experienced a recorded injury or illness of the same type that affects the same part of the body, or

(2) The employee previously experienced a recorded injury or illness of the same type that affected the same part of the body but had recovered completely (all signs and symptoms had disappeared) from the previous injury or illness and an event or exposure in the work environment caused the signs or symptoms to reappear.

(b) *Implementation.* (1) *When an employee experiences the signs or symptoms of a chronic work-related illness, do I need to consider each recurrence of signs or symptoms to be a new case?* No, for occupational illnesses where the signs or symptoms may recur or continue in the absence of an exposure in the workplace, the case must only be recorded once. Examples

may include occupational cancer, asbestosis, byssinosis and silicosis.

(2) *When an employee experiences the signs or symptoms of an injury or illness as a result of an event or exposure in the workplace, such as an episode of occupational asthma, must I treat the episode as a new case?* Yes, because the episode or recurrence was caused by an event or exposure in the workplace, the incident must be treated as a new case.

(3) *May I rely on a physician or other licensed health care professional to determine whether a case is a new case or a recurrence of an old case?* You are not required to seek the advice of a physician or other licensed health care professional. However, if you do seek such advice, you must follow the physician or other licensed health care professional's recommendation about whether the case is a new case or a recurrence. If you receive recommendations from two or more physicians or other licensed health care professionals, you must make a decision as to which recommendation is the most authoritative (best documented, best reasoned, or most authoritative), and record the case based upon that recommendation.

§ 1904.7 General recording criteria.

(a) *Basic requirement.* You must consider an injury or illness to meet the general recording criteria, and therefore to be recordable, if it results in any of the following: death, days away from work, restricted work or transfer to another job, medical treatment beyond first aid, or loss of consciousness. You must also consider a case to meet the general recording criteria if it involves a significant injury or illness diagnosed by a physician or other licensed health care professional, even if it does not result in death, days away from work, restricted work or job transfer, medical treatment beyond first aid, or loss of consciousness.

(b) *Implementation.* (1) *How do I decide if a case meets one or more of the general recording criteria?* A work-related injury or illness must be recorded if it results in one or more of the following:

(i) Death. See § 1904.7(b)(2).

(ii) Days away from work. See § 1904.7(b)(3).

(iii) Restricted work or transfer to another job. See § 1904.7(b)(4).

(iv) Medical treatment beyond first aid. See § 1904.7(b)(5).

(v) Loss of consciousness. See § 1904.7(b)(6).

(vi) A significant injury or illness diagnosed by a physician or other licensed health care professional. See § 1904.7(b)(7).

(2) *How do I record a work-related injury or illness that results in the employee's death?* You must record an injury or illness that results in death by entering a check mark on the OSHA 300 Log in the space for cases resulting in death. You must also report any work-related fatality to OSHA within eight (8) hours, as required by § 1904.39.

(3) *How do I record a work-related injury or illness that results in days away from work?* When an injury or illness involves one or more days away from work, you must record the injury or illness on the OSHA 300 Log with a check mark in the space for cases involving days away and an entry of the number of calendar days away from work in the number of days column. If the employee is out for an extended period of time, you must enter an estimate of the days that the employee will be away, and update the day count when the actual number of days is known.

(i) *Do I count the day on which the injury occurred or the illness began?* No, you begin counting days away on the day after the injury occurred or the illness began.

(ii) *How do I record an injury or illness when a physician or other licensed health care professional recommends that the worker stay at home but the employee comes to work anyway?* You must record these injuries and illnesses on the OSHA 300 Log using the check box for cases with days away from work and enter the number of calendar days away recommended by the physician or other licensed health care professional. If a physician or other licensed health care professional recommends days away, you should encourage your employee to follow that recommendation. However, the days away must be recorded whether the injured or ill employee follows the physician or licensed health care professional's recommendation or not. If you receive recommendations from two or more physicians or other licensed health care professionals, you may make a decision as to which recommendation is the most authoritative, and record the case based upon that recommendation.

(iii) *How do I handle a case when a physician or other licensed health care professional recommends that the worker return to work but the employee stays at home anyway?* In this situation, you must end the count of days away from work on the date the physician or other licensed health care professional recommends that the employee return to work.

(iv) *How do I count weekends, holidays, or other days the employee would not have worked anyway?* You must count the number of calendar days the employee was unable to work as a result of the injury or illness, regardless of whether or not the employee was scheduled to work on those day(s). Weekend days, holidays, vacation days or other days off are included in the total number of days recorded if the employee would not have been able to work on those days because of a work-related injury or illness.

(v) *How do I record a case in which a worker is injured or becomes ill on a Friday and reports to work on a Monday, and was not scheduled to work on the weekend?* You need to record this case only if you receive information from a physician or other licensed health care professional indicating that the employee should not have worked, or should have performed only restricted work, during the weekend. If so, you must record the injury or illness as a case with days away from work or restricted work, and enter the day counts, as appropriate.

(vi) *How do I record a case in which a worker is injured or becomes ill on the day before scheduled time off such as a holiday, a planned vacation, or a temporary plant closing?* You need to record a case of this type only if you receive information from a physician or other licensed health care professional indicating that the employee should not have worked, or should have performed only restricted work, during the scheduled time off. If so, you must record the injury or illness as a case with days away from work or restricted work, and enter the day counts, as appropriate.

(vii) *Is there a limit to the number of days away from work I must count?* Yes, you may ''cap'' the total days away at 180 calendar days. You are not required to keep track of the number of calendar days away from work if the injury or illness resulted in more than 180 calendar days away from work and/or days of job transfer or restriction. In such a case, entering 180 in the total days away column will be considered adequate.

(viii) *May I stop counting days if an employee who is away from work because of an injury or illness retires or leaves my company?* Yes, if the employee leaves your company for some reason unrelated to the injury or illness, such as retirement, a plant closing, or to take another job, you may stop counting days away from work or days of restriction/job transfer. If the employee leaves your company because of the injury or illness, you must estimate the

total number of days away or days of restriction/job transfer and enter the day count on the 300 Log.

(ix) *If a case occurs in one year but results in days away during the next calendar year, do I record the case in both years?* No, you only record the injury or illness once. You must enter the number of calendar days away for the injury or illness on the OSHA 300 Log for the year in which the injury or illness occurred. If the employee is still away from work because of the injury or illness when you prepare the annual summary, estimate the total number of calendar days you expect the employee to be away from work, use this number to calculate the total for the annual summary, and then update the initial log entry later when the day count is known or reaches the 180-day cap.

(4) *How do I record a work-related injury or illness that results in restricted work or job transfer?* When an injury or illness involves restricted work or job transfer but does not involve death or days away from work, you must record the injury or illness on the OSHA 300 Log by placing a check mark in the space for job transfer or restriction and an entry of the number of restricted or transferred days in the restricted workdays column.

(i) *How do I decide if the injury or illness resulted in restricted work?* Restricted work occurs when, as the result of a work-related injury or illness:

(A) You keep the employee from performing one or more of the routine functions of his or her job, or from working the full workday that he or she would otherwise have been scheduled to work; or

(B) A physician or other licensed health care professional recommends that the employee not perform one or more of the routine functions of his or her job, or not work the full workday that he or she would otherwise have been scheduled to work.

(ii) *What is meant by ''routine functions''?* For recordkeeping purposes, an employee's routine functions are those work activities the employee regularly performs at least once per week.

(iii) *Do I have to record restricted work or job transfer if it applies only to the day on which the injury occurred or the illness began?* No, you do not have to record restricted work or job transfers if you, or the physician or other licensed health care professional, impose the restriction or transfer only for the day on which the injury occurred or the illness began.

(iv) *If you or a physician or other licensed health care professional recommends a work restriction, is the injury or illness automatically recordable as a ''restricted work'' case?* No, a recommended work restriction is recordable only if it affects one or more of the employee's routine job functions. To determine whether this is the case, you must evaluate the restriction in light of the routine functions of the injured or ill employee's job. If the restriction from you or the physician or other licensed health care professional keeps the employee from performing one or more of his or her routine job functions, or from working the full workday the injured or ill employee would otherwise have worked, the employee's work has been restricted and you must record the case.

(v) *How do I record a case where the worker works only for a partial work shift because of a work-related injury or illness?* A partial day of work is recorded as a day of job transfer or restriction for recordkeeping purposes, except for the day on which the injury occurred or the illness began.

(vi) *If the injured or ill worker produces fewer goods or services than he or she would have produced prior to the injury or illness but otherwise performs all of the routine functions of his or her work, is the case considered a restricted work case?* No, the case is considered restricted work only if the worker does not perform all of the routine functions of his or her job or does not work the full shift that he or she would otherwise have worked.

(vii) *How do I handle vague restrictions from a physician or other licensed health care professional, such as that the employee engage only in ''light duty'' or ''take it easy for a week''?* If you are not clear about the physician or other licensed health care professional's recommendation, you may ask that person whether the employee can do all of his or her routine job functions and work all of his or her normally assigned work shift. If the answer to both of these questions is ''Yes,'' then the case does not involve a work restriction and does not have to be recorded as such. If the answer to one or both of these questions is ''No,'' the case involves restricted work and must be recorded as a restricted work case. If you are unable to obtain this additional information from the physician or other licensed health care professional who recommended the restriction, record the injury or illness as a case involving restricted work.

(viii) *What do I do if a physician or other licensed health care professional recommends a job restriction meeting OSHA's definition, but the employee does all of his or her routine job functions anyway?* You must record the injury or illness on the OSHA 300 Log as a restricted work case. If a physician or other licensed health care professional recommends a job restriction, you should ensure that the employee complies with that restriction. If you receive recommendations from two or more physicians or other licensed health care professionals, you may make a decision as to which recommendation is the most authoritative, and record the case based upon that recommendation.

(ix) *How do I decide if an injury or illness involved a transfer to another job?* If you assign an injured or ill employee to a job other than his or her regular job for part of the day, the case involves transfer to another job. Note: This does not include the day on which the injury or illness occurred.

(x) *Are transfers to another job recorded in the same way as restricted work cases?* Yes, both job transfer and restricted work cases are recorded in the same box on the OSHA 300 Log. For example, if you assign, or a physician or other licensed health care professional recommends that you assign, an injured or ill worker to his or her routine job duties for part of the day and to another job for the rest of the day, the injury or illness involves a job transfer. You must record an injury or illness that involves a job transfer by placing a check in the box for job transfer.

(xi) *How do I count days of job transfer or restriction?* You count days of job transfer or restriction in the same way you count days away from work, using § 1904.7(b)(3)(i) to (viii), above. The only difference is that, if you permanently assign the injured or ill employee to a job that has been modified or permanently changed in a manner that eliminates the routine functions the employee was restricted from performing, you may stop the day count when the modification or change is made permanent. You must count at least one day of restricted work or job transfer for such cases.

(5) *How do I record an injury or illness that involves medical treatment beyond first aid?* If a work-related injury or illness results in medical treatment beyond first aid, you must record it on the OSHA 300 Log. If the injury or illness did not involve death, one or more days away from work, one or more days of restricted work, or one or more days of job transfer, you enter a check mark in the box for cases where the employee received medical treatment but remained at work and was not transferred or restricted.

(i) *What is the definition of medical treatment?* ''Medical treatment'' means the management and care of a patient to

combat disease or disorder. For the purposes of Part 1904, medical treatment does not include:

(A) Visits to a physician or other licensed health care professional solely for observation or counseling;

(B) The conduct of diagnostic procedures, such as x-rays and blood tests, including the administration of prescription medications used solely for diagnostic purposes (*e.g.*, eye drops to dilate pupils); or

(C) ''First aid'' as defined in paragraph (b)(5)(ii) of this section.

(ii) *What is ''first aid''?* For the purposes of Part 1904, ''first aid'' means the following:

(A) Using a non-prescription medication at nonprescription strength (for medications available in both prescription and non-prescription form, a recommendation by a physician or other licensed health care professional to use a non-prescription medication at prescription strength is considered medical treatment for recordkeeping purposes);

(B) Administering tetanus immunizations (other immunizations, such as Hepatitis B vaccine or rabies vaccine, are considered medical treatment);

(C) Cleaning, flushing or soaking wounds on the surface of the skin;

(D) Using wound coverings such as bandages, Band-Aids™, gauze pads, etc.; or using butterfly bandages or Steri-Strips™ (other wound closing devices such as sutures, staples, etc., are considered medical treatment);

(E) Using hot or cold therapy;

(F) Using any non-rigid means of support, such as elastic bandages, wraps, non-rigid back belts, etc. (devices with rigid stays or other systems designed to immobilize parts of the body are considered medical treatment for recordkeeping purposes);

(G) Using temporary immobilization devices while transporting an accident victim (*e.g.*, splints, slings, neck collars, back boards, etc.).

(H) Drilling of a fingernail or toenail to relieve pressure, or draining fluid from a blister;

(I) Using eye patches;

(J) Removing foreign bodies from the eye using only irrigation or a cotton swab;

(K) Removing splinters or foreign material from areas other than the eye by irrigation, tweezers, cotton swabs or other simple means;

(L) Using finger guards;

(M) Using massages (physical therapy or chiropractic treatment are considered medical treatment for recordkeeping purposes); or

(N) Drinking fluids for relief of heat stress.

(iii) *Are any other procedures included in first aid?* No, this is a complete list of all treatments considered first aid for Part 1904 purposes.

(iv) *Does the professional status of the person providing the treatment have any effect on what is considered first aid or medical treatment?* No, OSHA considers the treatments listed in § 1904.7(b)(5)(ii) of this Part to be first aid regardless of the professional status of the person providing the treatment. Even when these treatments are provided by a physician or other licensed health care professional, they are considered first aid for the purposes of Part 1904. Similarly, OSHA considers treatment beyond first aid to be medical treatment even when it is provided by someone other than a physician or other licensed health care professional.

(v) *What if a physician or other licensed health care professional recommends medical treatment but the employee does not follow the recommendation?* If a physician or other licensed health care professional recommends medical treatment, you should encourage the injured or ill employee to follow that recommendation. However, you must record the case even if the injured or ill employee does not follow the physician or other licensed health care professional's recommendation.

(6) *Is every work-related injury or illness case involving a loss of consciousness recordable?* Yes, you must record a work-related injury or illness if the worker becomes unconscious, regardless of the length of time the employee remains unconscious.

(7) *What is a ''significant'' diagnosed injury or illness that is recordable under the general criteria even if it does not result in death, days away from work, restricted work or job transfer, medical treatment beyond first aid, or loss of consciousness?* Work-related cases involving cancer, chronic irreversible disease, a fractured or cracked bone, or a punctured eardrum must always be recorded under the general criteria at the time of diagnosis by a physician or other licensed health care professional.

Note to § 1904.7: OSHA believes that most significant injuries and illnesses will result in one of the criteria listed in § 1904.7(a): death, days away from work, restricted work or job transfer, medical treatment beyond first aid, or loss of consciousness. However, there are some significant injuries, such as a punctured eardrum or a fractured toe or rib, for which neither medical treatment nor work restrictions may be recommended. In addition, there are some significant progressive diseases, such as byssinosis, silicosis, and some types of cancer, for which medical treatment or work restrictions may not be recommended at the time of diagnosis but are likely to be recommended as the disease progresses. OSHA believes that cancer, chronic irreversible diseases, fractured or cracked bones, and punctured eardrums are generally considered significant injuries and illnesses, and must be recorded at the initial diagnosis even if medical treatment or work restrictions are not recommended, or are postponed, in a particular case.

§ 1904.8 Recording criteria for needlestick and sharps injuries.

(a) *Basic requirement.* You must record all work-related needlestick injuries and cuts from sharp objects that are contaminated with another person's blood or other potentially infectious material (as defined by 29 CFR 1910.1030). You must enter the case on the OSHA 300 Log as an injury. To protect the employee's privacy, you may not enter the employee's name on the OSHA 300 Log (see the requirements for privacy cases in paragraphs 1904.29(b)(6) through 1904.29(b)(9)).

(b) *Implementation.* (1) *What does ''other potentially infectious material'' mean?* The term ''other potentially infectious materials'' is defined in the OSHA Bloodborne Pathogens standard at § 1910.1030(b). These materials include:

(i) Human bodily fluids, tissues and organs, and

(ii) Other materials infected with the HIV or hepatitis B (HBV) virus such as laboratory cultures or tissues from experimental animals.

(2) *Does this mean that I must record all cuts, lacerations, punctures, and scratches?* No, you need to record cuts, lacerations, punctures, and scratches only if they are work-related and involve contamination with another person's blood or other potentially infectious material. If the cut, laceration, or scratch involves a clean object, or a contaminant other than blood or other potentially infectious material, you need to record the case only if it meets one or more of the recording criteria in § 1904.7.

(3) *If I record an injury and the employee is later diagnosed with an infectious bloodborne disease, do I need to update the OSHA 300 Log?* Yes, you must update the classification of the case on the OSHA 300 Log if the case results in death, days away from work, restricted work, or job transfer. You must also update the description to identify the infectious disease and change the classification of the case from an injury to an illness.

(4) *What if one of my employees is splashed or exposed to blood or other*

potentially infectious material without being cut or scratched? Do I need to record this incident? You need to record such an incident on the OSHA 300 Log as an illness if:

(i) It results in the diagnosis of a bloodborne illness, such as HIV, hepatitis B, or hepatitis C; or

(ii) It meets one or more of the recording criteria in § 1904.7.

§ 1904.9 Recording criteria for cases involving medical removal under OSHA standards.

(a) *Basic requirement.* If an employee is medically removed under the medical surveillance requirements of an OSHA standard, you must record the case on the OSHA 300 Log.

(b) *Implementation.* (1) *How do I classify medical removal cases on the OSHA 300 Log?* You must enter each medical removal case on the OSHA 300 Log as either a case involving days away from work or a case involving restricted work activity, depending on how you decide to comply with the medical removal requirement. If the medical removal is the result of a chemical exposure, you must enter the case on the OSHA 300 Log by checking the ''poisoning'' column.

(2) *Do all of OSHA's standards have medical removal provisions?* No, some OSHA standards, such as the standards covering bloodborne pathogens and noise, do not have medical removal provisions. Many OSHA standards that cover specific chemical substances have medical removal provisions. These standards include, but are not limited to, lead, cadmium, methylene chloride, formaldehyde, and benzene.

(3) *Do I have to record a case where I voluntarily removed the employee from exposure before the medical removal criteria in an OSHA standard are met?* No, if the case involves voluntary medical removal before the medical removal levels required by an OSHA standard, you do not need to record the case on the OSHA 300 Log.

§ 1904.10 Recording criteria for cases involving occupational hearing loss.

(a) *Basic requirement.* If an employee's hearing test (audiogram) reveals that a Standard Threshold Shift (STS) has occurred, you must record the case on the OSHA 300 Log by checking the ''hearing loss'' column.

(b) *Implementation.* (1) *What is a Standard Threshold Shift?* A Standard Threshold Shift, or STS, is defined in the occupational noise exposure standard at 29 CFR 1910.95(c)(10)(i) as a change in hearing threshold, relative to the most recent audiogram for that employee, of an average of 10 decibels (dB) or more at 2000, 3000, and 4000 hertz in one or both ears.

(2) *How do I determine whether an STS has occurred?* If the employee has never previously experienced a recordable hearing loss, you must compare the employee's current audiogram with that employee's baseline audiogram. If the employee has previously experienced a recordable hearing loss, you must compare the employee's current audiogram with the employee's revised baseline audiogram (the audiogram reflecting the employee's previous recordable hearing loss case).

(3) *May I adjust the audiogram results to reflect the effects of aging on hearing?* Yes, when comparing audiogram results, you may adjust the results for the employee's age when the audiogram was taken using Tables F–1 or F–2, as appropriate, in Appendix F of 29 CFR 1910.95.

(4) *Do I have to record the hearing loss if I am going to retest the employee's hearing?* No, if you retest the employee's hearing within 30 days of the first test, and the retest does not confirm the STS, you are not required to record the hearing loss case on the OSHA 300 Log. If the retest confirms the STS, you must record the hearing loss illness within seven (7) calendar days of the retest.

(5) *Are there any special rules for determining whether a hearing loss case is work-related?* Yes, hearing loss is presumed to be work-related if the employee is exposed to noise in the workplace at an 8-hour time-weighted average of 85 dBA or greater, or to a total noise dose of 50 percent, as defined in 29 CFR 1910.95. For hearing loss cases where the employee is not exposed to this level of noise, you must use the rules in § 1904.5 to determine if the hearing loss is work-related.

(6) *If a physician or other licensed health care professional determines the hearing loss is not work-related, do I still need to record the case?* If a physician or other licensed health care professional determines that the hearing loss is not work-related or has not been significantly aggravated by occupational noise exposure, you are not required to consider the case work-related or to record the case on the OSHA 300 Log.

§ 1904.11 Recording criteria for work-related tuberculosis cases.

(a) *Basic requirement.* If any of your employees has been occupationally exposed to anyone with a known case of active tuberculosis (TB), and that employee subsequently develops a tuberculosis infection, as evidenced by a positive skin test or diagnosis by a physician or other licensed health care professional, you must record the case on the OSHA 300 Log by checking the ''respiratory condition'' column.

(b) *Implementation.* (1) *Do I have to record, on the Log, a positive TB skin test result obtained at a pre-employment physical?* No, you do not have to record it because the employee was not occupationally exposed to a known case of active tuberculosis in your workplace.

(2) *May I line-out or erase a recorded TB case if I obtain evidence that the case was not caused by occupational exposure?* Yes, you may line-out or erase the case from the Log under the following circumstances:

(i) The worker is living in a household with a person who has been diagnosed with active TB;

(ii) The Public Health Department has identified the worker as a contact of an individual with a case of active TB unrelated to the workplace; or

(iii) A medical investigation shows that the employee's infection was caused by exposure to TB away from work, or proves that the case was not related to the workplace TB exposure.

§ 1904.12 Recording criteria for cases involving work-related musculoskeletal disorders.

(a) *Basic requirement.* If any of your employees experiences a recordable work-related musculoskeletal disorder (MSD), you must record it on the OSHA 300 Log by checking the ''musculoskeletal disorder'' column.

(b) *Implementation.* (1) *What is a ''musculoskeletal disorder'' or MSD?* Musculoskeletal disorders (MSDs) are disorders of the muscles, nerves, tendons, ligaments, joints, cartilage and spinal discs. MSDs do not include disorders caused by slips, trips, falls, motor vehicle accidents, or other similar accidents. Examples of MSDs include: Carpal tunnel syndrome, Rotator cuff syndrome, De Quervain's disease, Trigger finger, Tarsal tunnel syndrome, Sciatica, Epicondylitis, Tendinitis, Raynaud's phenomenon, Carpet layers knee, Herniated spinal disc, and Low back pain.

(2) *How do I decide which musculoskeletal disorders to record?* There are no special criteria for determining which musculoskeletal disorders to record. An MSD case is recorded using the same process you would use for any other injury or illness. If a musculoskeletal disorder is work-related, and is a new case, and meets one or more of the general recording criteria, you must record the musculoskeletal disorder. The following table will guide you to the appropriate

section of the rule for guidance on recording MSD cases.

(i) Determining if the MSD is work-related. See § 1904.5.

(ii) Determining if the MSD is a new case. See § 1904.6.

(iii) Determining if the MSD meets one or more of the general recording criteria:

(A) Days away from work, see § 1904.7(b)(3).

(B) Restricted work or transfer to another job, or see § 1904.7(b)(4).

(C) Medical treatment beyond first aid. See § 1904.7(b)(5).

(3) *If a work-related MSD case involves only subjective symptoms like pain or tingling, do I have to record it as a musculoskeletal disorder?* The symptoms of an MSD are treated the same as symptoms for any other injury or illness. If an employee has pain, tingling, burning, numbness or any other subjective symptom of an MSD, and the symptoms are work-related, and the case is a new case that meets the recording criteria, you must record the case on the OSHA 300 Log as a musculoskeletal disorder.

§§ 1904.13–1904.28 [Reserved]

§ 1904.29 Forms

(a) *Basic requirement.* You must use OSHA 300, 300–A, and 301 forms, or equivalent forms, for recordable injuries and illnesses. The OSHA 300 form is called the Log of Work-Related Injuries and Illnesses, the 300–A is the Summary of Work-Related Injuries and Illnesses, and the OSHA 301 form is called the Injury and Illness Incident Report.

(b) *Implementation.* (1) *What do I need to do to complete the OSHA 300 Log?* You must enter information about your business at the top of the OSHA 300 Log, enter a one or two line description for each recordable injury or illness, and summarize this information on the OSHA 300–A at the end of the year.

(2) *What do I need to do to complete the OSHA 301 Incident Report?* You must complete an OSHA 301 Incident Report form, or an equivalent form, for each recordable injury or illness entered on the OSHA 300 Log.

(3) *How quickly must each injury or illness be recorded?* You must enter each recordable injury or illness on the OSHA 300 Log and 301 Incident Report within seven (7) calendar days of receiving information that a recordable injury or illness has occurred.

(4) *What is an equivalent form?* An equivalent form is one that has the same information, is as readable and understandable, and is completed using the same instructions as the OSHA form it replaces. Many employers use an insurance form instead of the OSHA 301 Incident Report, or supplement an insurance form by adding any additional information required by OSHA.

(5) *May I keep my records on a computer?* Yes, if the computer can produce equivalent forms when they are needed, as described under §§ 1904.35 and 1904.40, you may keep your records using the computer system.

(6) *Are there situations where I do not put the employee's name on the forms for privacy reasons?* Yes, if you have a ''privacy concern case,'' you may not enter the employee's name on the OSHA 300 Log. Instead, enter ''privacy case'' in the space normally used for the employee's name. This will protect the privacy of the injured or ill employee when another employee, a former employee, or an authorized employee representative is provided access to the OSHA 300 Log under § 1904.35(b)(2). You must keep a separate, confidential list of the case numbers and employee names for your privacy concern cases so you can update the cases and provide the information to the government if asked to do so.

(7) *How do I determine if an injury or illness is a privacy concern case?* You must consider the following injuries or illnesses to be privacy concern cases:

(i) An injury or illness to an intimate body part or the reproductive system;

(ii) An injury or illness resulting from a sexual assault;

(iii) Mental illnesses;

(iv) HIV infection, hepatitis, or tuberculosis;

(v) Needlestick injuries and cuts from sharp objects that are contaminated with another person's blood or other potentially infectious material (see § 1904.8 for definitions); and

(vi) Other illnesses, if the employee independently and voluntarily requests that his or her name not be entered on the log. Musculoskeletal disorders (MSDs) are not considered privacy concern cases.

(8) *May I classify any other types of injuries and illnesses as privacy concern cases?* No, this is a complete list of all injuries and illnesses considered privacy concern cases for Part 1904 purposes.

(9) *If I have removed the employee's name, but still believe that the employee may be identified from the information on the forms, is there anything else that I can do to further protect the employee's privacy?* Yes, if you have a reasonable basis to believe that information describing the privacy concern case may be personally identifiable even though the employee's name has been omitted, you may use discretion in describing the injury or illness on both the OSHA 300 and 301 forms. You must enter enough information to identify the cause of the incident and the general severity of the injury or illness, but you do not need to include details of an intimate or private nature. For example, a sexual assault case could be described as ''injury from assault,'' or an injury to a reproductive organ could be described as ''lower abdominal injury.''

(10) *What must I do to protect employee privacy if I wish to provide access to the OSHA Forms 300 and 301 to persons other than government representatives, employees, former employees or authorized representatives?* If you decide to voluntarily disclose the Forms to persons other than government representatives, employees, former employees or authorized representatives (as required by §§ 1904.35 and 1904.40), you must remove or hide the employees' names and other personally identifying information, except for the following cases. You may disclose the Forms with personally identifying information only:

(i) to an auditor or consultant hired by the employer to evaluate the safety and health program;

(ii) to the extent necessary for processing a claim for workers' compensation or other insurance benefits; or

(iii) to a public health authority or law enforcement agency for uses and disclosures for which consent, an authorization, or opportunity to agree or object is not required under Department of Health and Human Services Standards for Privacy of Individually Identifiable Health Information, 45 CFR 164.512.

Subpart D—Other OSHA Injury and Illness Recordkeeping Requirements

§ 1904.30 Multiple business establishments.

(a) *Basic requirement.* You must keep a separate OSHA 300 Log for each establishment that is expected to be in operation for one year or longer.

(b) *Implementation.* (1) *Do I need to keep OSHA injury and illness records for short-term establishments (i.e., establishments that will exist for less than a year)?* Yes, however, you do not have to keep a separate OSHA 300 Log for each such establishment. You may keep one OSHA 300 Log that covers all of your short-term establishments. You may also include the short-term establishments' recordable injuries and illnesses on an OSHA 300 Log that

covers short-term establishments for individual company divisions or geographic regions.

(2) *May I keep the records for all of my establishments at my headquarters location or at some other central location?* Yes, you may keep the records for an establishment at your headquarters or other central location if you can:

(i) Transmit information about the injuries and illnesses from the establishment to the central location within seven (7) calendar days of receiving information that a recordable injury or illness has occurred; and

(ii) Produce and send the records from the central location to the establishment within the time frames required by § 1904.35 and § 1904.40 when you are required to provide records to a government representative, employees, former employees or employee representatives.

(3) *Some of my employees work at several different locations or do not work at any of my establishments at all. How do I record cases for these employees?* You must link each of your employees with one of your establishments, for recordkeeping purposes. You must record the injury and illness on the OSHA 300 Log of the injured or ill employee's establishment, or on an OSHA 300 Log that covers that employee's short-term establishment.

(4) *How do I record an injury or illness when an employee of one of my establishments is injured or becomes ill while visiting or working at another of my establishments, or while working away from any of my establishments?* If the injury or illness occurs at one of your establishments, you must record the injury or illness on the OSHA 300 Log of the establishment at which the injury or illness occurred. If the employee is injured or becomes ill and is not at one of your establishments, you must record the case on the OSHA 300 Log at the establishment at which the employee normally works.

§ 1904.31 Covered employees.

(a) *Basic requirement.* You must record on the OSHA 300 Log the recordable injuries and illnesses of all employees on your payroll, whether they are labor, executive, hourly, salary, part-time, seasonal, or migrant workers. You also must record the recordable injuries and illnesses that occur to employees who are not on your payroll if you supervise these employees on a day-to-day basis. If your business is organized as a sole proprietorship or partnership, the owner or partners are not considered employees for recordkeeping purposes.

(b) *Implementation.* (1) *If a self-employed person is injured or becomes ill while doing work at my business, do I need to record the injury or illness?* No, self-employed individuals are not covered by the OSH Act or this regulation.

(2) *If I obtain employees from a temporary help service, employee leasing service, or personnel supply service, do I have to record an injury or illness occurring to one of those employees?* You must record these injuries and illnesses if you supervise these employees on a day-to-day basis.

(3) *If an employee in my establishment is a contractor's employee, must I record an injury or illness occurring to that employee?* If the contractor's employee is under the day-to-day supervision of the contractor, the contractor is responsible for recording the injury or illness. If you supervise the contractor employee's work on a day-to-day basis, you must record the injury or illness.

(4) *Must the personnel supply service, temporary help service, employee leasing service, or contractor also record the injuries or illnesses occurring to temporary, leased or contract employees that I supervise on a day-to-day basis?* No, you and the temporary help service, employee leasing service, personnel supply service, or contractor should coordinate your efforts to make sure that each injury and illness is recorded only once: either on your OSHA 300 Log (if you provide day-to-day supervision) or on the other employer's OSHA 300 Log (if that company provides day-to-day supervision).

§ 1904.32 Annual summary.

(a) *Basic requirement.* At the end of each calendar year, you must:

(1) Review the OSHA 300 Log to verify that the entries are complete and accurate, and correct any deficiencies identified;

(2) Create an annual summary of injuries and illnesses recorded on the OSHA 300 Log;

(3) Certify the summary; and

(4) Post the annual summary.

(b) *Implementation.* (1) *How extensively do I have to review the OSHA 300 Log entries at the end of the year?* You must review the entries as extensively as necessary to make sure that they are complete and correct.

(2) *How do I complete the annual summary?* You must:

(i) Total the columns on the OSHA 300 Log (if you had no recordable cases, enter zeros for each column total); and

(ii) Enter the calendar year covered, the company's name, establishment name, establishment address, annual average number of employees covered by the OSHA 300 Log, and the total hours worked by all employees covered by the OSHA 300 Log.

(iii) If you are using an equivalent form other than the OSHA 300-A summary form, as permitted under § 1904.6(b)(4), the summary you use must also include the employee access and employer penalty statements found on the OSHA 300-A Summary form.

(3) *How do I certify the annual summary?* A company executive must certify that he or she has examined the OSHA 300 Log and that he or she reasonably believes, based on his or her knowledge of the process by which the information was recorded, that the annual summary is correct and complete.

(4) *Who is considered a company executive?* The company executive who certifies the log must be one of the following persons:

(i) An owner of the company (only if the company is a sole proprietorship or partnership);

(ii) An officer of the corporation;

(iii) The highest ranking company official working at the establishment; or

(iv) The immediate supervisor of the highest ranking company official working at the establishment.

(5) *How do I post the annual summary?* You must post a copy of the annual summary in each establishment in a conspicuous place or places where notices to employees are customarily posted. You must ensure that the posted annual summary is not altered, defaced or covered by other material.

(6) *When do I have to post the annual summary?* You must post the summary no later than February 1 of the year following the year covered by the records and keep the posting in place until April 30.

§ 1904.33 Retention and updating.

(a) *Basic requirement.* You must save the OSHA 300 Log, the privacy case list (if one exists), the annual summary, and the OSHA 301 Incident Report forms for five (5) years following the end of the calendar year that these records cover.

(b) *Implementation.* (1) *Do I have to update the OSHA 300 Log during the five-year storage period?* Yes, during the storage period, you must update your stored OSHA 300 Logs to include newly discovered recordable injuries or illnesses and to show any changes that have occurred in the classification of previously recorded injuries and illnesses. If the description or outcome of a case changes, you must remove or line out the original entry and enter the new information.

(2) *Do I have to update the annual summary?* No, you are not required to update the annual summary, but you may do so if you wish.

(3) *Do I have to update the OSHA 301 Incident Reports?* No, you are not required to update the OSHA 301 Incident Reports, but you may do so if you wish.

§ 1904.34 Change in business ownership.

If your business changes ownership, you are responsible for recording and reporting work-related injuries and illnesses only for that period of the year during which you owned the establishment. You must transfer the Part 1904 records to the new owner. The new owner must save all records of the establishment kept by the prior owner, as required by § 1904.33 of this Part, but need not update or correct the records of the prior owner.

§ 1904.35 Employee involvement.

(a) *Basic requirement.* Your employees and their representatives must be involved in the recordkeeping system in several ways.

(1) You must inform each employee of how he or she is to report an injury or illness to you.

(2) You must provide limited access to your injury and illness records for your employees and their representatives.

(b) *Implementation.* (1) *What must I do to make sure that employees report work-related injuries and illnesses to me?*

(i) You must set up a way for employees to report work-related injuries and illnesses promptly; and

(ii) You must tell each employee how to report work-related injuries and illnesses to you.

(2) *Do I have to give my employees and their representatives access to the OSHA injury and illness records?* Yes, your employees, former employees, their personal representatives, and their authorized employee representatives have the right to access the OSHA injury and illness records, with some limitations, as discussed below.

(i) *Who is an authorized employee representative?* An authorized employee representative is an authorized collective bargaining agent of employees.

(ii) *Who is a ''personal representative'' of an employee or former employee?* A personal representative is:

(A) Any person that the employee or former employee designates as such, in writing; or

(B) The legal representative of a deceased or legally incapacitated employee or former employee.

(iii) *If an employee or representative asks for access to the OSHA 300 Log, when do I have to provide it?* When an employee, former employee, personal representative, or authorized employee representative asks for copies of your current or stored OSHA 300 Log(s) for an establishment the employee or former employee has worked in, you must give the requester a copy of the relevant OSHA 300 Log(s) by the end of the next business day.

(iv) *May I remove the names of the employees or any other information from the OSHA 300 Log before I give copies to an employee, former employee, or employee representative?* No, you must leave the names on the 300 Log. However, to protect the privacy of injured and ill employees, you may not record the employee's name on the OSHA 300 Log for certain ''privacy concern cases,'' as specified in paragraphs 1904.29(b)(6) through 1904.29(b)(9).

(v) *If an employee or representative asks for access to the OSHA 301 Incident Report, when do I have to provide it?*

(A) When an employee, former employee, or personal representative asks for a copy of the OSHA 301 Incident Report describing an injury or illness to that employee or former employee, you must give the requester a copy of the OSHA 301 Incident Report containing that information by the end of the next business day.

(B) When an authorized employee representative asks for a copies of the OSHA 301 Incident Reports for an establishment where the agent represents employees under a collective bargaining agreement, you must give copies of those forms to the authorized employee representative within 7 calendar days. You are only required to give the authorized employee representative information from the OSHA 301 Incident Report section titled ''Tell us about the case.'' You must remove all other information from the copy of the OSHA 301 Incident Report or the equivalent substitute form that you give to the authorized employee representative.

(vi) *May I charge for the copies?* No, you may not charge for these copies the first time they are provided. However, if one of the designated persons asks for additional copies, you may assess a reasonable charge for retrieving and copying the records.

§ 1904.36 Prohibition against discrimination.

Section 11(c) of the Act prohibits you from discriminating against an employee for reporting a work-related fatality, injury or illness. That provision of the Act also protects the employee who files a safety and health complaint, asks for access to the Part 1904 records, or otherwise exercises any rights afforded by the OSH Act.

§ 1904.37 State recordkeeping regulations.

(a) *Basic requirement.* Some States operate their own OSHA programs, under the authority of a State Plan approved by OSHA. States operating OSHA-approved State Plans must have occupational injury and illness recording and reporting requirements that are substantially identical to the requirements in this Part (see 29 CFR 1902.3(k), 29 CFR 1952.4 and 29 CFR 1956.10(i)).

(b) *Implementation.* (1) State-Plan States must have the same requirements as Federal OSHA for determining which injuries and illnesses are recordable and how they are recorded.

(2) For other Part 1904 provisions (for example, industry exemptions, reporting of fatalities and hospitalizations, record retention, or employee involvement), State-Plan State requirements may be more stringent than or supplemental to the Federal requirements, but because of the unique nature of the national recordkeeping program, States must consult with and obtain approval of any such requirements.

(3) Although State and local government employees are not covered Federally, all State-Plan States must provide coverage, and must develop injury and illness statistics, for these workers. State Plan recording and reporting requirements for State and local government entities may differ from those for the private sector but must meet the requirements of paragraphs 1904.37(b)(1) and (b)(2).

(4) A State-Plan State may not issue a variance to a private sector employer and must recognize all variances issued by Federal OSHA.

(5) A State Plan State may only grant an injury and illness recording and reporting variance to a State or local government employer within the State after obtaining approval to grant the variance from Federal OSHA.

§ 1904.38 Variances from the recordkeeping rule.

(a) *Basic requirement.* If you wish to keep records in a different manner from the manner prescribed by the Part 1904 regulations, you may submit a variance petition to the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, Washington, DC 20210. You can obtain

a variance only if you can show that your alternative recordkeeping system:

(1) Collects the same information as this Part requires;

(2) Meets the purposes of the Act; and

(3) Does not interfere with the administration of the Act.

(b) *Implementation.* (1) *What do I need to include in my variance petition?* You must include the following items in your petition:

(i) Your name and address;

(ii) A list of the State(s) where the variance would be used;

(iii) The address(es) of the business establishment(s) involved;

(iv) A description of why you are seeking a variance;

(v) A description of the different recordkeeping procedures you propose to use;

(vi) A description of how your proposed procedures will collect the same information as would be collected by this Part and achieve the purpose of the Act; and

(vii) A statement that you have informed your employees of the petition by giving them or their authorized representative a copy of the petition and by posting a statement summarizing the petition in the same way as notices are posted under § 1903.2(a).

(2) *How will the Assistant Secretary handle my variance petition?* The Assistant Secretary will take the following steps to process your variance petition.

(i) The Assistant Secretary will offer your employees and their authorized representatives an opportunity to submit written data, views, and arguments about your variance petition.

(ii) The Assistant Secretary may allow the public to comment on your variance petition by publishing the petition in the **Federal Register**. If the petition is published, the notice will establish a public comment period and may include a schedule for a public meeting on the petition.

(iii) After reviewing your variance petition and any comments from your employees and the public, the Assistant Secretary will decide whether or not your proposed recordkeeping procedures will meet the purposes of the Act, will not otherwise interfere with the Act, and will provide the same information as the Part 1904 regulations provide. If your procedures meet these criteria, the Assistant Secretary may grant the variance subject to such conditions as he or she finds appropriate.

(iv) If the Assistant Secretary grants your variance petition, OSHA will publish a notice in the **Federal Register** to announce the variance. The notice will include the practices the variance allows you to use, any conditions that apply, and the reasons for allowing the variance.

(3) *If I apply for a variance, may I use my proposed recordkeeping procedures while the Assistant Secretary is processing the variance petition?* No, alternative recordkeeping practices are only allowed after the variance is approved. You must comply with the Part 1904 regulations while the Assistant Secretary is reviewing your variance petition.

(4) *If I have already been cited by OSHA for not following the Part 1904 regulations, will my variance petition have any effect on the citation and penalty?* No, in addition, the Assistant Secretary may elect not to review your variance petition if it includes an element for which you have been cited and the citation is still under review by a court, an Administrative Law Judge (ALJ), or the OSH Review Commission.

(5) *If I receive a variance, may the Assistant Secretary revoke the variance at a later date?* Yes, the Assistant Secretary may revoke your variance if he or she has good cause. The procedures revoking a variance will follow the same process as OSHA uses for reviewing variance petitions, as outlined in paragraph 1904.38(b)(2). Except in cases of willfulness or where necessary for public safety, the Assistant Secretary will:

(i) Notify you in writing of the facts or conduct that may warrant revocation of your variance; and

(ii) Provide you, your employees, and authorized employee representatives with an opportunity to participate in the revocation procedures.

Subpart E—Reporting Fatality, Injury and Illness Information to the Government

§ 1904.39 Reporting fatalities and multiple hospitalization incidents to OSHA.

(a) *Basic requirement.* Within eight (8) hours after the death of any employee from a work-related incident or the in-patient hospitalization of three or more employees as a result of a work-related incident, you must orally report the fatality/multiple hospitalization by telephone or in person to the Area Office of the Occupational Safety and Health Administration (OSHA), U.S. Department of Labor, that is nearest to the site of the incident. You may also use the OSHA toll-free central telephone number, 1–800–321–OSHA (1–800–321–6742).

(b) *Implementation.* (1) *If the Area Office is closed, may I report the incident by leaving a message on OSHA's answering machine, faxing the area office, or sending an e-mail?* No, if you can't talk to a person at the Area Office, you must report the fatality or multiple hospitalization incident using the 800 number.

(2) *What information do I need to give to OSHA about the incident?* You must give OSHA the following information for each fatality or multiple hospitalization incident:

(i) The establishment name;

(ii) The location of the incident;

(iii) The time of the incident;

(iv) The number of fatalities or hospitalized employees;

(v) The names of any injured employees;

(vi) Your contact person and his or her phone number; and

(vii) A brief description of the incident.

(3) *Do I have to report every fatality or multiple hospitalization incident resulting from a motor vehicle accident?* No, you do not have to report all of these incidents. If the motor vehicle accident occurs on a public street or highway, and does not occur in a construction work zone, you do not have to report the incident to OSHA. However, these injuries must be recorded on your OSHA injury and illness records, if you are required to keep such records.

(4) *Do I have to report a fatality or multiple hospitalization incident that occurs on a commercial or public transportation system?* No, you do not have to call OSHA to report a fatality or multiple hospitalization incident if it involves a commercial airplane, train, subway or bus accident. However, these injuries must be recorded on your OSHA injury and illness records, if you are required to keep such records.

(5) *Do I have to report a fatality caused by a heart attack at work?* Yes, your local OSHA Area Office director will decide whether to investigate the incident, depending on the circumstances of the heart attack.

(6) *Do I have to report a fatality or hospitalization that occurs long after the incident?* No, you must only report each fatality or multiple hospitalization incident that occurs within thirty (30) days of an incident.

(7) *What if I don't learn about an incident right away?* If you do not learn of a reportable incident at the time it occurs and the incident would otherwise be reportable under paragraphs (a) and (b) of this section, you must make the report within eight (8) hours of the time the incident is reported to you or to any of your agent(s) or employee(s).

§ 1904.40 Providing records to government representatives.

(a) *Basic requirement.* When an authorized government representative asks for the records you keep under Part 1904, you must provide copies of the records within four (4) business hours.

(b) *Implementation.* (1) *What government representatives have the right to get copies of my Part 1904 records?* The government representatives authorized to receive the records are:

(i) A representative of the Secretary of Labor conducting an inspection or investigation under the Act;

(ii) A representative of the Secretary of Health and Human Services (including the National Institute for Occupational Safety and Health—NIOSH) conducting an investigation under section 20(b) of the Act, or

(iii) A representative of a State agency responsible for administering a State plan approved under section 18 of the Act.

(2) *Do I have to produce the records within four (4) hours if my records are kept at a location in a different time zone?* OSHA will consider your response to be timely if you give the records to the government representative within four (4) business hours of the request. If you maintain the records at a location in a different time zone, you may use the business hours of the establishment at which the records are located when calculating the deadline.

§ 1904.41 Annual OSHA injury and illness survey of ten or more employers.

(a) *Basic requirement.* If you receive OSHA's annual survey form, you must fill it out and send it to OSHA or OSHA's designee, as stated on the survey form. You must report the following information for the year described on the form:

(1) the number of workers you employed;

(2) the number of hours worked by your employees; and

(3) the requested information from the records that you keep under Part 1904.

(b) *Implementation.* (1) *Does every employer have to send data to OSHA?* No, each year, OSHA sends injury and illness survey forms to employers in certain industries. In any year, some employers will receive an OSHA survey form and others will not. You do not have to send injury and illness data to OSHA unless you receive a survey form.

(2) *How quickly do I need to respond to an OSHA survey form?* You must send the survey reports to OSHA, or OSHA's designee, by mail or other means described in the survey form, within 30 calendar days, or by the date stated in the survey form, whichever is later.

(3) *Do I have to respond to an OSHA survey form if I am normally exempt from keeping OSHA injury and illness records?* Yes, even if you are exempt from keeping injury and illness records under § 1904.1 to § 1904.3, OSHA may inform you in writing that it will be collecting injury and illness information from you in the following year. If you receive such a letter, you must keep the injury and illness records required by § 1904.5 to § 1904.15 and make a survey report for the year covered by the survey.

(4) *Do I have to answer the OSHA survey form if I am located in a State-Plan State?* Yes, all employers who receive survey forms must respond to the survey, even those in State-Plan States.

(5) *Does this section affect OSHA's authority to inspect my workplace?* No, nothing in this section affects OSHA's statutory authority to investigate conditions related to occupational safety and health.

§ 1904.42 Requests from the Bureau of Labor Statistics for data.

(a) *Basic requirement.* If you receive a Survey of Occupational Injuries and Illnesses Form from the Bureau of Labor Statistics (BLS), or a BLS designee, you must promptly complete the form and return it following the instructions contained on the survey form.

(b) *Implementation.* (1) *Does every employer have to send data to the BLS?* No, each year, the BLS sends injury and illness survey forms to randomly selected employers and uses the information to create the Nation's occupational injury and illness statistics. In any year, some employers will receive a BLS survey form and others will not. You do not have to send injury and illness data to the BLS unless you receive a survey form.

(2) *If I get a survey form from the BLS, what do I have to do?* If you receive a Survey of Occupational Injuries and Illnesses Form from the Bureau of Labor Statistics (BLS), or a BLS designee, you must promptly complete the form and return it, following the instructions contained on the survey form.

(3) *Do I have to respond to a BLS survey form if I am normally exempt from keeping OSHA injury and illness records?* Yes, even if you are exempt from keeping injury and illness records under § 1904.1 to § 1904.3, the BLS may inform you in writing that it will be collecting injury and illness information from you in the coming year. If you receive such a letter, you must keep the injury and illness records required by § 1904.5 to § 1904.15 and make a survey report for the year covered by the survey.

(4) *Do I have to answer the BLS survey form if I am located in a State-Plan State?* Yes, all employers who receive a survey form must respond to the survey, even those in State-Plan States.

Subpart F—Transition From the Former Rule

§ 1904.43 Summary and posting of the 2001 data.

(a) *Basic requirement.* If you were required to keep OSHA 200 Logs in 2001, you must post a 2000 annual summary from the OSHA 200 Log of occupational injuries and illnesses for each establishment.

(b) *Implementation.* (1) *What do I have to include in the summary?*

(i) You must include a copy of the totals from the 2001 OSHA 200 Log and the following information from that form:

(A) The calendar year covered;

(B) Your company name;

(C) The name and address of the establishment; and

(D) The certification signature, title and date.

(ii) If no injuries or illnesses occurred at your establishment in 2001, you must enter zeros on the totals line and post the 2001 summary.

(2) *When am I required to summarize and post the 2001 information?*

(i) You must complete the summary by February 1, 2002; and

(ii) You must post a copy of the summary in each establishment in a conspicuous place or places where notices to employees are customarily posted. You must ensure that the summary is not altered, defaced or covered by other material.

(3) You must post the 2001 summary from February 1, 2002 to March 1, 2002.

§ 1904.44 Retention and updating of old forms.

You must save your copies of the OSHA 200 and 101 forms for five years following the year to which they relate and continue to provide access to the data as though these forms were the OSHA 300 and 301 forms. You are not required to update your old 200 and 101 forms.

§ 1904.45 OMB control numbers under the Paperwork Reduction Act

The following sections each contain a collection of information requirement which has been approved by the Office of Management and Budget under the control number listed

29 CFR citation	OMB Control No.
1904.4–35	1218–0176
1904.39–41	1218–0176
1904.42	1220–0045
1904.43–44	1218–0176

Subpart G—Definitions

§ 1904.46 Definitions

The Act. The Act means the Occupational Safety and Health Act of 1970 (29 U.S.C. 651 *et seq.*). The definitions contained in section 3 of the Act (29 U.S.C. 652) and related interpretations apply to such terms when used in this Part 1904.

Establishment. An establishment is a single physical location where business is conducted or where services or industrial operations are performed. For activities where employees do not work at a single physical location, such as construction; transportation; communications, electric, gas and sanitary services; and similar operations, the establishment is represented by main or branch offices, terminals, stations, etc. that either supervise such activities or are the base from which personnel carry out these activities.

(1) *Can one business location include two or more establishments?* Normally, one business location has only one establishment. Under limited conditions, the employer may consider two or more separate businesses that share a single location to be separate establishments. An employer may divide one location into two or more establishments only when:

(i) Each of the establishments represents a distinctly separate business;

(ii) Each business is engaged in a different economic activity;

(iii) No one industry description in the Standard Industrial Classification Manual (1987) applies to the joint activities of the establishments; and

(iv) Separate reports are routinely prepared for each establishment on the number of employees, their wages and salaries, sales or receipts, and other business information. For example, if an employer operates a construction company at the same location as a lumber yard, the employer may consider each business to be a separate establishment.

(2) *Can an establishment include more than one physical location?* Yes, but only under certain conditions. An employer may combine two or more physical locations into a single establishment only when:

(i) The employer operates the locations as a single business operation under common management;

(ii) The locations are all located in close proximity to each other; and

(iii) The employer keeps one set of business records for the locations, such as records on the number of employees, their wages and salaries, sales or receipts, and other kinds of business information. For example, one manufacturing establishment might include the main plant, a warehouse a few blocks away, and an administrative services building across the street.

(3) *If an employee telecommutes from home, is his or her home considered a separate establishment?* No, for employees who telecommute from home, the employee's home is not a business establishment and a separate 300 Log is not required. Employees who telecommute must be linked to one of your establishments under § 1904.30(b)(3).

Injury or illness. An injury or illness is an abnormal condition or disorder. Injuries include cases such as, but not limited to, a cut, fracture, sprain, or amputation. Illnesses include both acute and chronic illnesses, such as, but not limited to, a skin disease, respiratory disorder, or poisoning. (Note: Injuries and illnesses are recordable only if they are new, work-related cases that meet one or more of the Part 1904 recording criteria.)

Physician or Other Licensed Health Care Professional. A physician or other licensed health care professional is an individual whose legally permitted scope of practice (*i.e.*, license, registration, or certification) allows him or her to independently perform, or be delegated the responsibility to perform, the activities described by this regulation.

You. ''You'' means an employer as defined in Section 3 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 652).

PART 1952—[AMENDED]

2. The authority citation for Part 1952 is revised to read as follows:

Authority: 29 U.S.C. 667; 29 CFR part 1902, Secretary of Labor's Order No. 1–90 (55 FR 9033) and 6–96 (62 FR 111).

3. Section 1952.4 is revised to read as follows:

§ 1952.4 Injury and illness recording and reporting requirements.

(a) Injury and illness recording and reporting requirements promulgated by State-Plan States must be substantially identical to those in 29 CFR part 1904 ''Recording and Reporting Occupational Injuries and Illnesses.'' State-Plan States must promulgate recording and reporting requirements that are the same as the Federal requirements for determining which injuries and illnesses will be entered into the records and how they are entered. All other injury and illness recording and reporting requirements that are promulgated by State-Plan States may be more stringent than, or supplemental to, the Federal requirements, but, because of the unique nature of the national recordkeeping program, States must consult with OSHA and obtain approval of such additional or more stringent reporting and recording requirements to ensure that they will not interfere with uniform reporting objectives. State-Plan States must extend the scope of their regulation to State and local government employers.

(b) A State may not grant a variance to the injury and illness recording and reporting requirements for private sector employers. Such variances may only be granted by Federal OSHA to assure nationally consistent workplace injury and illness statistics. A State may only grant a variance to the injury and illness recording and reporting requirements for State or local government entities in that State after obtaining approval from Federal OSHA.

(c) A State must recognize any variance issued by Federal OSHA.

(d) A State may, but is not required, to participate in the Annual OSHA Injury/Illness Survey as authorized by 29 CFR 1904.41. A participating State may either adopt requirements identical to 1904.41 in its recording and reporting regulation as an enforceable State requirement, or may defer to the Federal regulation for enforcement. Nothing in any State plan shall affect the duties of employers to comply with 1904.41, when surveyed, as provided by section 18(c)(7) of the Act.

[FR Doc. 01–725 Filed 1–18–01; 8:45 am]

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Part V

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 120

Hazard Analysis and Critical Control Point (HAACP); Procedures for the Safe and Sanitary Processing and Importing of Juice; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 120

[Docket No. 97N–0511]

RIN 0910–AA43

Hazard Analysis and Critical Control Point (HAACP); Procedures for the Safe and Sanitary Processing and Importing of Juice

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or the agency) is adopting final regulations to ensure the safe and sanitary processing of fruit and vegetable juices. The regulations mandate the application of Hazard Analysis and Critical Control Point (HACCP) principles to the processing of these foods. HACCP is a preventive system of hazard control. FDA is taking this action because there have been a number of food hazards associated with juice products and because a system of preventive control measures is the most effective and efficient way to ensure that these products are safe.

DATES: Effective Dates: This rule is effective January 22, 2002.

Compliance Date: For small businesses as defined in 21 CFR 120.1(b)(1), the final rule will be binding January 21, 2003. For very small businesses as defined in 21 CFR 120.1(b)(2), the final rule will be binding January 20, 2004.

FOR FURTHER INFORMATION CONTACT: Shellee Anderson, Center for Food Safety and Applied Nutrition (HFS–366), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5023.

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I. Background

A. Notice of Intent

In the **Federal Register** of August 28, 1997 (62 FR 45593)(Ref. 1), FDA published a notice of intent (hereinafter referred to as the notice of intent) that announced a comprehensive program to address the incidence of foodborne illness related to consumption of fresh juice and ultimately to address the safety of all juice products. In the notice of intent, the agency invited comment on the appropriateness of its strategy to: (1) Initiate rulemaking on a mandatory HACCP program for some or all juice products; (2) propose that the labels or the labeling of juice products not specifically processed to prevent, reduce, or eliminate pathogens bear a warning statement informing consumers of the risk of illness associated with consumption of the product; and (3) initiate several educational programs to minimize the hazards associated with consumption of fresh juices. The agency stated that it would address comments received within 15 days of publication of the notice of intent as part of any rule proposed by the agency. FDA also stated that it would consider all comments to the notice of intent received after 15 days in any final rulemaking. FDA reviewed all of the comments received within 15 days of publication and found that they provided no information that would cause the agency to conclude that the HACCP proposal was inappropriate. Comments received 15 days after publication of the notice of intent are discussed in this final rule.

B. The Proposal

In the **Federal Register** of April 24, 1998 (63 FR 20450) (Ref. 2), FDA published a proposed rule to establish requirements relating to the processing of juice and juice products (hereinafter referred to as the HACCP proposal).[1] The proposal would have required the application of HACCP principles by processors and importers to ensure juice safety to the maximum extent practicable. FDA proposed these regulations because there had been a number of food hazards, including some directly affecting children, associated with juice products. The agency tentatively concluded that the most effective way to ensure the safety of juice products is to process the products under a system of preventive control measures based on HACCP principles. Interested persons were given until July 8, 1998, to comment on the HACCP proposal. The agency subsequently extended the comment period to August 7, 1998 (63 FR 37057; July 8, 1998) (Ref. 3).

In addition to publishing the HACCP proposal, FDA published in the same issue of the **Federal Register** (63 FR 20486) (Ref. 4) a proposed rule (the juice labeling proposal) to require warning labels on juice that has not been processed to prevent, reduce to acceptable levels, or eliminate pathogens that may be present. As fully discussed in the juice labeling proposal, FDA proposed that untreated juice products bear a warning statement informing at risk consumers of the hazard posed by untreated juices to allow them to make informed decisions on whether to purchase and consume such products. The labeling proposal was finalized on July 8, 1998 (63 FR 37030) (Ref. 5).

FDA issued in the **Federal Register** of May 1, 1998 (63 FR 24254) (Ref. 6) a single Preliminary Regulatory Impact Analysis (PRIA) that addressed both the

[1] As defined in § 120.1 (21 CFR 120.1) ''juice'' refers both to beverages that are composed exclusively of an aqueous liquid or liquids extracted from one or more fruits or vegetables and to the juice ingredient in those beverages that contain other ingredients in addition to juice. In this document, the term ''juice product'' refers both to beverages that contain only juice and to the juice ingredient of beverages that are composed of juice and other ingredients.

In the remainder of this document, products not processed to prevent, reduce, or eliminate hazards will be referred to as ''untreated juice products.'' In addition, processing to ''prevent, reduce, or eliminate'' hazards will be referred to as processing to ''control'' hazards.

juice labeling proposal and the juice HACCP proposal. Interested parties were given until May 26, 1998, to comment on aspects of the PRIA relating to the juice labeling proposal and until July 8, 1998, to comment on aspects of the PRIA relating to the juice HACCP proposal.

C. Additional Opportunities for Public Participation

Under the juice labeling rule (§ 101.17(g) (21 CFR 101.17(g))), juice and juice products that have not been specifically processed to attain a 5-log reduction in the pertinent pathogen must bear a warning label. Similarly, under the juice HACCP proposal (proposed § 120.24), covered processors must attain a 5-log reduction in the pertinent pathogen in their HACCP systems. Accordingly, in November 1998, FDA held two technical workshops on how processors could attain a 5-log (*i.e.*, 10^5) reduction in the pertinent pathogen in citrus juices (63 FR 57594; October 28, 1998) (Ref. 7). The transcripts from the two workshops were placed on display in the docket for the juice HACCP proposal and on the FDA/CFSAN website http://www.fda.gov/). On December 17, 1998 (63 FR 69579) (Ref. 8), the comment period for the juice HACCP proposal was reopened until January 19, 1999, to allow public comment on data and other information that were presented at or developed as a result of these workshops. In addition, FDA expressly sought comments on the following four specific topics related to the application of the 5-log pathogen reduction standard: (1) Appropriate baselines for the calculation of the 5-log pathogen reduction; (2) feasible interventions or practices for the cultivation and harvest of fruits and vegetables, and acquisition of supplies and materials that may contribute to achieving a 5-log pathogen reduction; (3) feasible interventions for the production process that may contribute to achieving a 5-log pathogen reduction; and (4) acceptable methods for measuring and validating 5-log reductions.

On July 15 and 16, 1999, FDA held a workshop on food safety controls for the apple cider[2] industry (64 FR 34125; June 25, 1999) (Ref. 9). The workshop dealt with issues related to the implementation of the agency's regulations requiring a warning statement for certain juice products. Specifically, the workshop addressed pathogen reduction interventions that may be effective for apple cider production and the methods used to measure and validate such interventions. Results of research conducted by Federal, State, private, and academic institutions were presented.

In the **Federal Register** of November 23, 1999 (64 FR 65669) (Ref. 10), FDA announced the availability of new data and information regarding the safe processing of citrus juice and juice products, and reopened the comment period for the juice HACCP proposal until January 24, 2000, in order to receive comment on the new data and other information. In that same notice, in order to develop the most complete administrative record possible, FDA requested additional data and information relating to four separate areas: Internalization and survival of pathogens in produce used to produce juice, especially citrus fruit; application and measurement of the 5-log reduction standard; current methods used by juice processors to monitor the application of heat treatment to juice; and certain economic matters related to juice regulation. The notice discussed in detail the particular issues in each of the four areas in which the agency was seeking comments (64 FR 65669 at 65670 through 65671). Two of these areas (internalization and survival of pathogens and application and measurement of the 5-log reduction standard) were also to be the subject of the December 8 to 9, 1999, public meeting of the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) (discussed in more detail below), and the comment period extension was established so as to permit comments on the identified issues in light of any information or recommendations coming out of that meeting of the NACMCF.

D. NACMCF Public Meeting

NACMCF is an advisory committee chartered under the U.S. Department of Agriculture (USDA) and has members from USDA (Food Safety and Inspection Service), the Department of Health and Human Services (U.S. Food and Drug Administration and the Centers for Disease Control and Prevention (CDC)), the Department of Commerce (National Marine Fisheries Service), the Department of Defense (Office of the Army Surgeon General), academia, industry and State agencies. The NACMCF provides guidance and recommendations to the Secretary of Agriculture and the Secretary of Health and Human Services regarding the microbiological safety of foods.

The NACMCF held a public meeting on December 8 to 9, 1999 (64 FR 63281; November 19, 1999) (Refs. 11 and 12) to discuss recent research and other information related to performance criteria for fresh citrus juices. FDA sought advice from the NACMCF on two issues. In addition, the meeting agenda provided an opportunity for public comment.

First, FDA asked the NACMCF about the potential internalization and survival of pathogens in citrus fruits and citrus juices. The NACMCF members generally agreed that it is theoretically possible for microorganisms to enter the interior of apparently sound, intact citrus fruit under certain conditions (*e.g.*, temperature difference between fruit and wash water), and that human pathogens appear to be able to survive, at least under defined laboratory conditions, in the fruit itself (Ref. 12). However, the NACMCF members concluded, based on the current information, that the potential for microorganisms to enter and survive in intact fruit is not likely to result in a significant public health risk. In particular, the Committee members concluded, based upon the limited data available, including data presented by the industry, that although it is theoretically possible, it is unlikely that pathogens will enter and grow in sound, intact fruit under actual current industry processing practices.

Second, the agency asked the NACMCF about the application and measurement of the 5-log pathogen reduction standard to citrus fruit. In response, the NACMCF outlined the following five basic consensus decisions related to the application and measurement of the 5-log reduction standard to citrus juices:

1. The 5-log reduction need not start with the extracted juice but may begin with the exterior decontamination of citrus fruit. However, processors should not start a cumulative 5-log reduction until after the fruit is cleaned (*i.e.,* washed) and culled (*i.e.*, damaged or dropped fruit is removed so that the remaining fruit is USDA choice level or higher quality).

2. One possible method to minimize potential microbial infiltration into the fruit would be by controlling fruit and wash water temperatures, as well as excluding fruit that is split, punctured, or otherwise not intact. Laboratory studies indicate that microbial infiltration of fruit occurred when warm fruit was washed or submerged into cold water (Refs. 13 and 14).

3. The entire 5-log process must occur under one firm's control and in one processing facility, *i.e.*, all steps from

[2] Although the terms ''apple cider'' and ''apple juice'' may have different meanings throughout the United States, these terms are used interchangeably throughout this final rule.

fruit receiving to final juice packaging (and all points included in the 5-log reduction process) must occur at one facility. If processors transport fruit or juice to another facility for extraction, blending, or final packaging, the 5-log reduction must be accomplished in the second facility.

4. If the expressed juice is aseptically packaged in a single-use sanitary non-reusable tote (sterile bag in box type package form) and the bulk packed juice will be repackaged at another facility, a 5-log reduction process must be performed on that juice prior to final fill and packaging. If the juice is used directly from the tote (*e.g.*, used to dispense juice and juice beverages at retail), the 5-log reduction process need not be repeated. Because juice in tanker trucks is not juice in a final package form, juice shipped in bulk tankers must undergo a 5-log reduction process after transport and prior to final fill and packaging.

5. As part of a HACCP verification program, firms should conduct microbial testing on the final product if the 5-log reduction process relies in part on fruit surface treatment. This testing would not be batch-by-batch testing for lot acceptance prior to shipping, but would be used to verify the 5-log reduction process. The testing should use generic *E. coli* as a means to assess the control of the process and should be conducted as specified in the HACCP plan, utilizing an appropriate sampling plan. However, if results indicate (*i.e.*, the presence of generic *E. coli*) that the 5-log reduction has not been achieved, processors should consider testing the juice for specific pathogens of concern, such as *Salmonella* or any other microorganisms of concern, according to an appropriate sampling plan and processors should take suitable corrective actions. If the 5-log reduction is applied after the juice is expressed, microbiological testing would not be required as part of a HACCP verification program.

II. Response to the Comments

FDA received approximately 85 responses, each containing one or more comments, to the notice of intent. FDA addressed some of these comments in the juice HACCP proposal. FDA subsequently received approximately 800 responses, each containing one or more comments, to the juice HACCP proposal. Comments received in response to the notice of intent and to the juice HACCP proposal came from industry, trade organizations, consumers, consumer interest groups, academia, and State government agencies. Comments concerning labeling issues are discussed to the extent that they fall within the scope of issues presented by the juice HACCP proposal. Some of the comments supported the proposal. Other comments opposed, or suggested modifications of various provisions of, the proposal. The agency discusses below the significant comments bearing on the proposed HACCP regulation and, when applicable, any revisions to the proposed regulation made in response to these comments. Responses to the notice of intent that bear on the juice HACCP proposal and that were not addressed in that proposal also are addressed in this document. For simplicity, the agency's discussion does not identify comments as to whether they were received in response to the notice of intent or in response to the juice HACCP proposal.

A. Alternatives to HACCP Considered by the Agency

In developing a strategy to address the hazards associated with juice, FDA considered the following alternatives to HACCP: (1) Increased inspections, (2) current good manufacturing practices (CGMP's), (3) mandatory pasteurization, (4) labeling as a long-term solution, (5) education, and (6) an approach that would draw a distinction between untreated apple cider and all other juices. The agency discussed each alternative in the HACCP proposed rule (63 FR 20450 at 20454) and its reasons for proposing the use of HACCP systems rather than the alternatives (Ref. 2). FDA received a number of comments questioning the agency's rejection of certain alternatives. The agency's responses to those comments are set forth in this section (section II.A). To provide a meaningful context for the discussion of the alternatives, FDA is providing the following discussion of HACCP.

HACCP is a focused, efficient, preventive system that minimizes the chance that foods contaminated with hazardous materials or microorganisms will be consumed. The strength of HACCP lies in its ability to enable the processor to identify, systematically and scientifically, the primary food safety hazards of concern for the specific products, the specific processes, and the specific manufacturing facilities in question, and then to implement on a focused, consistent basis, steps (critical control points (CCP's)) in food production, processing, or preparation that are critical to prevent, reduce to acceptable levels, or eliminate hazards from the particular food being processed. Flexibility in how to address identified hazards is inherent in HACCP systems. Even when producing comparable products, no two processors use the same source of incoming materials or the same processing technique, or manufacture in identical facilities. Each of these factors (and their many combinations) presents potential opportunities for contamination of the food. HACCP focuses the processor on understanding his own process and the hazards that may be introduced during that process, and identifying specific controls to prevent, reduce, or eliminate the identified hazards.

The flexibility of the HACCP approach is a critically important attribute. This flexibility allows manufacturers to adjust CCP's, adjust techniques used to address CCP's when changes occur in the system (*e.g.*, use of new ingredients), and readily incorporate new scientific developments (*e.g.*, use of new control techniques, new preventive technologies, identification of new hazards). Another important strength of HACCP is the development of a plan written by the processor detailing the control measures to be used at CCP's. By developing a written plan, juice processors gain a working knowledge of their processing system, its effect on the food, and where in the system potential contamination may occur. Both the processor and the agency are able to derive the full benefits of a HACCP system. The hazard analysis and HACCP plan allow both the processor and the agency to verify and validate the operation of the system. HACCP's flexibility also permits processors to select the appropriate control measures in the context of how the whole system functions, allowing processors to use the most appropriate and economical methods to control food hazards that are reasonably likely to occur in their operation. The ability to choose among various control methods encourages research on and development of new and innovative technologies to better address individual situations. Because of its flexibility, HACCP is particularly advantageous to small businesses and seasonal processors.

HACCP provides the processor with a record of identified food hazards. It allows quick identification of a breakdown in the processing system and thus, prevents products with food hazards from entering the marketplace and causing illness. Moreover, review of records over a longer period of time (days or weeks) may reveal a trend toward a breakdown in the system, such as a critical processing temperature that is slowly drifting down. HACCP records allow evaluation of whether changes in the processing system require changes

in CCP's or their critical limits (CL's), thus ensuring that the HACCP system is up-to-date and adequate to control all food hazards that are reasonably likely to occur. This recordkeeping also allows regulatory investigators to readily review the long term performance of a firm's processing system, rather than relying on a time-limited inspection, which provides only a snapshot of how well the firm is doing in producing and distributing safe product on any given day.

HACCP is ideally suited to respond to emerging problems because a HACCP system is a dynamic system that must be validated periodically to ensure that all hazards reasonably likely to occur are identified and controlled via CCP's. Validation of both the hazard analysis and the HACCP plan entails a thorough review to ensure that all hazards that are reasonably likely to occur are addressed in the HACCP system.

Because of its preventive yet flexible nature, HACCP is recognized by food safety professionals as the single most effective means to assure the safety of foods. It has been endorsed by the National Academy of Sciences (Ref. 15), the Codex Alimentarius Commission (an international food standard-setting organization) (Ref. 16), and the NACMCF (Ref. 17). Increasingly, use of HACCP systems is an indication to importing countries that food safety systems that provide a standardized level of public health protection are in place and being used by producers in exporting countries.

1. Increased Inspection

(Comment 1) Several comments suggested that the increased FDA inspection approach would be preferable to HACCP.

The agency disagrees. FDA's responsibility is to implement and enforce the Federal Food, Drug, and Cosmetic Act (the act), *i.e.*, to oversee the manufacture of safe food. Increased inspection by FDA is a resource-intensive activity that puts the responsibility and burden for ensuring food safety on the agency rather than on the juice processors. Inspections can, of course, provide food processors with valuable information about improving the safety of their products. However, safety cannot be effectively inspected into foods. Rather, food processing systems themselves must be designed and implemented in a manner that results in the production of safe food. Part 120 (21 CFR part 120) provides a flexible standard that both the juice industry and the agency will use to determine the adequacy of a process. HACCP has been shown to be an approach that effectively ensures the production of food that is safe and wholesome (Ref. 17). Importantly, the HACCP approach clearly delineates the processor's responsibility to make safe products and FDA's responsibility to monitor conformance with the act through inspections and record review.

(Comment 2) One comment advocated a short-term solution of increased inspections for adherence to sanitation standard operating procedures (SSOP's) and CGMP's with zero tolerance for noncompliance. Another comment stated that the juice industry would welcome increased inspections as it implements new safety measures.

The agency has been actively monitoring the juice industry, especially the fresh juice industry, in response to recent outbreaks. In addition, FDA has conducted inspections to determine compliance with the label warning statement required by § 101.17(g). The agency will continue this additional oversight of the juice industry during implementation of part 120 until it has assurance that the industry is in compliance.

(Comment 3) One comment suggested that cider operations be inspected and graded for cleanliness by the States, like restaurants.

The agency disagrees with the comment. Although sanitation (*i.e.*, cleanliness) is important in cider and all other food production operations, it is only a starting point for ensuring that safe food is produced and distributed to consumers. This limitation exists regardless of the regulatory agency inspecting for sanitation.

(Comment 4) Several comments suggested that industry-funded inspections could be used to ensure safe juice.

FDA disagrees with these comments. As discussed above, inspections are not an adequate substitute for HACCP. Moreover, the agency does not have the authority to require or accept funds from the industry for inspections of juice processors.

2. Current Good Manufacturing Practices

(Comment 5) Comments maintained that a survey of several small citrus producers and juice bars showed that SSOP's and CGMP's are sufficient to produce safe juice. One comment stated that no additional regulations are needed for dairies that process juice because dairies follow sanitation and other procedures outlined by the National Conference on Interstate Milk Shipments (NCIMS) and the application of these principles affects other products made in these facilities.

The agency disagrees that CGMP's and SSOP's alone are adequate to control microbial hazards in juice although it does believe that CGMP's play an important role in juice safety. The survey referenced by the comment, was conducted by the Florida Department of Agriculture & Consumer Services and found that 17 out of 383 samples analyzed (4.4 percent) were positive for generic *E. coli* and did not indicate what, if any, other microorganisms were present. While generic *E. coli* are not pathogens, their presence is indicative of fecal contamination and may be indicative of the presence of pathogens such as *E. coli* O157:H7. (The significance of fecal contamination is discussed in more detail in the response to comment 143.) Therefore, it is unclear how the comments concluded that CGMP's and SSOP's provide adequate control of potential food hazards to assure the safety of the food by relying on the survey data.

The NCIMS procedures (*i.e.*, the Pasteurized Milk Ordinance (PMO) (Ref.18)) were developed to assure the safety of milk. While there may be some fundamental principles, such as basic sanitation procedures, that apply to both the production of milk and juice, the products are vulnerable to different hazards. Moreover, States administer the PMO, and the agency has no information indicating consistency in the application of the PMO to juice inspections in dairies. Thus, investigators in some States may use the PMO as a guide in conducting dairy juice operations and others may not. Therefore, the agency does not believe that application of NCIMS procedures in some dairies that process juice negates the need for juice-specific HACCP regulations.

(Comment 6) Several comments argued that the examples of nonmicrobial hazards (*e.g.*, tin, lead, nitrates, patulin, glass, or plastic) cited in the juice HACCP proposal are CGMP violations and would not be included in a processor's HACCP plan.

The agency does not agree with the comments. Whether or not a nonmicrobial food hazard jeopardizes the safety of a juice product is determined by the processor during the hazard analysis of his process. If potential nonmicrobial food hazards are not reasonably likely to occur, then the HACCP plan does not need to address these hazards with CCP's. Thus, FDA does not believe that it is reasonable to make a global statement that CGMP's in part 110 (21 CFR part 110) are adequate

to control nonmicrobial hazards in all systems, because that determination must be made by each individual processor through a hazard analysis of the individual system.

(Comment 7) Several comments noted that the risks posed by the nonmicrobial hazards identified by FDA cannot be quantified for economic purposes, that microbial hazards alone are not an adequate basis on which to mandate HACCP, and that CGMP's are adequate.

FDA disagrees with these comments. There are nonmicrobial food hazards that may be reasonably likely to occur in juice. Some non-microbial hazards, such as glass, tin, and copper, present acute risks (Ref. 6), and result in acute illnesses or injuries that generate medical and hospital costs, as well as lost productivity costs.

The adverse health effects of other nonmicrobial hazards are chronic (long-term) in nature. For example, long-term exposure to the mycotoxin, patulin, has been shown to be toxic in safety assessments conducted in the United States (Refs. 19 and 20) and by international organizations (Refs. 21 and 22). Patulin is produced by several species of mold that can grow on apples, particularly if bruised or otherwise damaged, and has been found to occur at high levels in some apple juice products. The long-term toxic effects in young children are of particular concern because children consume larger quantities of apple juice relative to body weight than other age groups. A compilation of data from three surveys showed that nearly one-fifth of the samples of apple juice contained levels of patulin in excess of 50 microgram/liter (μg/L) (Ref. 23), the level recently established by FDA in draft guidance as the maximum level that should be present in foods (Ref. 24).

The agency recognizes that quantifying the economic effects of chronic non-microbial hazards is difficult. Given the difficulties in quantification, FDA chose to not include nonmicrobial hazards with chronic health risks in the PRIA, thereby underestimating the benefits of the proposal. Nevertheless, hazards with chronic health risks exist and the potential effects on health are real. Thus, hazards with chronic health risks must be considered, along with nonmicrobial hazards with acute health consequences and microbial hazards, during the hazard analysis and a determination made as to whether the potential hazard is reasonably likely to occur (comment 63 discusses how a hazard analysis must be conducted) and thus, must be included in the HACCP plan.

(Comment 8) Several comments maintained that the enforcement of CGMP's or sanitation standards would ensure the safety of all juices.

The agency disagrees with the comments. Outbreaks of foodborne disease have been associated with juice despite the fact that the processors appear to have been actively implementing CGMP's. Increased compliance with the CGMP regulations in part 110, including all sanitation provisions, is certainly desirable. However, CGMP's are general in nature and apply to all types of facilities that process all types of food products from highly processed foods to raw foods that are merely packaged and labeled. CGMP's were not designed specifically to address individual production facilities (for juice or any other commodity) or the unique attributes associated with specific foodborne hazards. HACCP systems, as discussed in section II.A of this document, provide focused, product- and process-specific prevention and control of potential hazards. HACCP augments the controls established through CGMP's by: (1) Determining the food hazards that are reasonably likely to occur in a specific facility and process and thus, warrant extra consideration beyond application of routine food safety measures, (2) identifying a specific CGMP or additional control measure that must be undertaken to prevent this food hazard that is reasonably likely to occur from reaching the consumer, and (3) developing a verifiable procedure for assuring that each control measure was applied and was effective. This focused consideration of hazards and their prevention provides a higher degree of safety assurance than application of CGMP's.

3. Mandatory Pasteurization

(Comment 9) Several comments requested that the agency mandate pasteurization or use of a universal thermal process (thermal kill) to ensure juice safety. The comments maintained that mandatory pasteurization is a reasonable, science-based solution that would ensure safe juice, is consistent with FDA's mission to protect the public health, and would assure consumers and regulators that the microbial hazards associated with juice are being prevented in the most effective manner. Conversely, a number of comments opposed mandatory pasteurization. They argued that nutritional value is lost from heat treatment; some consumers prefer unpasteurized juice; pasteurized juice may become contaminated after treatment and still put consumers at risk; and the apple cider and fresh juice industry would be destroyed.

Based upon the available information, FDA does not believe that it is necessary or appropriate to mandate pasteurization or other thermal treatment of juice. The agency is aware of the reasons why processors pasteurize or elect not to pasteurize their juice products. Pasteurization, a heat treatment sufficient to destroy pathogens, is an effective and proven technology that will attain the 5-log reduction in pathogens and, thus ensure microbiologically safe juice. Pasteurization also results in a longer shelf-life of refrigerated juices. With proper post-processing handling, pasteurization assures consumers and regulators that the potential microbial hazards associated with juice are prevented. However, pasteurization is not the only method for addressing potential microbial contamination. This was discussed extensively in the juice HACCP proposal (63 FR 20450 at 20454) (Ref. 2) and again in the juice labeling final rule (63 FR 37030 at 37041) (Ref. 5). This approach is supported by the NACMCF recommendation that FDA establish safety performance criteria for appropriate target organisms rather than mandating a specific intervention technology (Ref. 25). Mandating a specific intervention technology such as pasteurization would limit the development of new, potentially less costly technologies that may be as effective as pasteurization. New nonthermal technologies (*e.g.*, UV irradiation and pulsed light, as approved by FDA; high pressure) may be able to achieve the required pathogen reduction. The use of non-thermal technologies will provide consumers with a greater selection of safe products to purchase. Furthermore, mandatory pasteurization would not control non-microbial hazards in juice. Therefore, FDA is declining to mandate pasteurization for juice.

(Comment 10) One comment stated that pasteurization should be mandatory for apple cider to eliminate a major source of health risks.

FDA disagrees with the comment. Under § 120.24, apple cider processors must treat their juice to achieve a 5-log reduction in the pertinent pathogen. At the present time, the agency is not aware of any technology that can accomplish the 5-log reduction in apple juice products except by treating the extracted juice with a ''kill step.'' However the ''kill step'' does not necessarily have to be pasteurization. This approach allows for innovation in

the development of new processes to achieve the 5-log pathogen reduction.

4. Labeling

(Comment 11) Two comments suggested that FDA require either pasteurization or a permanent warning label statement for producers who do not pasteurize. One comment stated that FDA should require HACCP with a CCP of either a 5-log performance standard for pathogen reduction or a warning label.

FDA disagrees with the comments. Under § 120.24, juice processors must achieve the 5-log reduction in their juice. As discussed in both the HACCP proposal and in this final rule, it is possible for firms to manufacture juice to achieve this reduction by means other than pasteurization. The alternative presented in the comments, labeling, has some limitations as a public health measure. The effectiveness of labeling untreated juice to alert consumers to possible harmful effects from its consumption relies on consumers' reading, comprehending, and acting on the information in the labeling. Although labeling can provide consumers with the information to make food safety related choices, education is an important factor in a consumer's choice. Therefore, there are limitations to the effectiveness of labeling.

The agency mandated the use of warning label statements on juice largely as an interim step to establishing the HACCP regulation. For most juice products, the warning label is a short term solution. While FDA is reluctant to rely on labeling as the sole safety measure, the agency recognizes that in certain circumstances, labeling may, on balance, provide the most reasonable approach to protect the public health. FDA believes that HAACP, as required in this final rule, is a reasonable approach because, in contrast to some other food safety problems, the facts show that, for juice, processor control of pathogens is reasonably achievable. Moreover, a warning label does not substitute for adequate processing of juice, is not an appropriate substitute for the 5-log performance standard, and would not be considered a CCP for juice under part 120.

For juice produced by retailers (as defined in the rule), however, the warning statement is a long term solution. The agency discussed its reasons for exempting retail establishments from part 120 in the juice HACCP proposal (63 FR 20450 at 20464) (Ref. 2), and these reasons are further discussed in section III.B.2.b of this document. The agency intends to work closely with the States to provide recommendations for implementing measures that will assure safe juice at retail. Therefore, the agency concludes that its current regulations and programs are balanced and appropriate for juice and juice products.

(Comment 12) Several comments asked that FDA make the warning label statement a permanent option because, if it is adequate to ensure consumer safety with products exempt from HACCP, it should be adequate for all juice products.

FDA disagrees with the comments. As noted in the previous response, while the warning label statement may be effective, particularly with consumers aware of juice safety problems, it has limitations as a public health measure. The warning label statement simply informs consumers that the juice bearing the statement has not been treated to control pathogens and that the consumption of untreated juice may pose a risk of illness. As noted, the effectiveness of any warning label relies on consumer education and action. FDA is not changing the warning label statement requirements in this rulemaking.

5. Education

(Comment 13) Several comments maintained that increasing industry education is all that is needed to ensure the safety of all juices.

The agency disagrees. While FDA supports and encourages processor education as a way to improve the safety of the food supply, such measures alone, without being teamed with implementation of an effective food safety control program, such as HACCP, and government oversight, will not ensure consumer protection from hazards that may be present in juice. Training and education is only one step in the effective implementation of any food safety system, including HACCP. Effectively, this final rule requires the industry to improve their education in food safety in order to implement effective HACCP systems. Implementation of an effective HACCP system demonstrates a processor's understanding of HACCP principles and the ability to translate theory into production of safer food. Therefore, the agency concludes that increased industry education alone would not be sufficient to ensure the safety of all juices.

6. Alternative Approach

(Comment 14) Many comments supported the alternative approach outlined in the proposed rule (63 FR 20450 at 20456) (Ref. 2) that would: (1) Require producers of apple cider to choose between HACCP with a performance standard and labeling and (2) require processors of all other juices to choose between HACCP, a performance standard, and labeling.

The agency has evaluated the alternative approaches and concludes that HACCP with a performance standard is the most effective and efficient approach to ensure safe juice. FDA notes that no data or other information were submitted to persuade the agency that the alternative approach described in the proposal would provide adequate public health assurance as would be provided by the HACCP regulation set forth below. Although more outbreaks have been traced to the consumption of apple juice than other juices, a fact reflected in the proposed alternative approach, the agency concludes that, because microbial, chemical, and physical hazards may occur in all juices, and outbreaks have been associated with a variety of juices, there is a need to regulate all juices in the same general manner. Furthermore, the performance standard and the label warning statement only address microbial hazards. In contrast, HACCP systems address physical and chemical, as well as microbiological, hazards, thus providing greater assurance that juice is safe. Therefore, the agency is requiring that all juice processors with the exception of those specifically exempted by § 120.3(j)(2) use HACCP systems as set forth in part 120.

B. Response to the Decision to Propose HACCP

FDA proposed to require HACCP for juice products because it had tentatively concluded that HACCP was an appropriate system of preventive controls necessary to produce safe juice products. The evidence presented in the proposal demonstrated that juice has been a vehicle for pathogens that have caused a number of foodborne illness outbreaks. While pathogens can be controlled through heat treatment, the data (Ref. 2) clearly demonstrate that there are potential nonmicrobiological hazards associated with juice that cannot be controlled through heat treatment. For these reasons, FDA tentatively concluded that a HACCP program that addresses all potential hazards (*i.e.*, microbiological, chemical, and physical), allows each juice manufacturer to evaluate its own process, and to institute appropriate controls for all hazards identified as reasonably likely to occur in that manufacturer's process should be established.

(Comment 15) Several comments advocated HACCP limited to pathogen control.

The agency disagrees with the comments. While pathogen control is a significant part of any HACCP system for juice, there are potential chemical and physical hazards that can occur in juice, with significant public health implications, and these hazards may be most effectively controlled through application of HACCP (Ref. 2). HACCP provides a way to focus on specific CCP's addressing specific hazards, both microbial and non-microbial (*e.g.*, tin, lead, nitrates, patulin, glass, or plastic) that are relevant to juice processing operations and products. These hazards may be appropriately identified in the hazard analysis as hazards that are reasonably likely to occur and controlled through a HACCP plan.

There are a number of potential hazards for juice that are nonmicrobial in nature. For example, juice products have become contaminated with cleaning solution. If this contamination is a hazard that is reasonably likely to occur in a particular process (*e.g.*, there is a repeated history of its occurrence), the processor must establish controls in its HACCP plan to prevent the contamination rather than address the contamination in their SSOP's.

Similarly, some juice products have been recalled due to the presence of glass. Glass shards in juice represent a severe and acute public health threat. Processors who package in glass must consider whether glass in their final product is reasonably likely to occur in the absence of control. If so, processors must establish controls for glass in their HACCP plans.

Excess detinning represents another potential nonmicrobial hazard for juice. Certain juices are purposely packaged to allow some detinning of the can in order to protect the color quality of the product. However, detinning can be accelerated by unusually high nitrate content in the product or by elevated temperatures during storage or shipping (Refs. 26). Excessive detinning has resulted in consumer illness (Refs. 26 and 27). Thus, processors of juice products that employ detinning as a means of color protection must determine whether it is necessary to establish specific control measures, *i.e.*, a CCP, because excessive detinning is reasonably likely to occur.

Potential hazards may also be caused by the nature of incoming materials. Patulin in apple juice products is one such example. Patulin is a mycotoxin produced by several species of mold that can grow on apples, particularly if bruised or otherwise damaged. A compilation of data from three surveys showed that 19 percent of samples of apple juice contained levels of patulin in excess of 50 μg/L (Ref. 23). FDA has recently issued guidance describing 50 parts per billion (ppb) as a recommended level for patulin (Refs. 19 and 24). For apple juice processors, patulin may represent a hazard that is reasonably likely to occur when juice is made from bruised or damaged fruit, as even moderate bruising can result in mold growth on apples. Moreover, patulin may be a chronic potential hazard and therefore particular attention must be given to the frequency of occurrence. Therefore, a prudent processor must determine whether the frequency of occurrence of this potential hazard in juice is unacceptable without controls. If patulin is reasonably likely to occur at unacceptably high levels, processors must include it as a hazard in their HACCP plans. Patulin is not the sole mycotoxin that may be a hazard in juice. There is evidence that other mycotoxins, such as ochratoxin in grapes and *Alternaria* toxins in fruit and vegetable products (Ref. 28), may be emerging public health problems in juices and at least warrant monitoring of future developments.

Lead contamination has also been associated with juices. In 1996, infant apple prune and prune juices were recalled for unacceptable levels of lead (Refs. 29 and 30). More recently, unacceptable levels of lead have been found in babyfood containing carrots and in carrots in frozen mixed vegetables as a result of lead contamination in the soil (Refs. 31 and 32). Juice made from produce with high lead levels will also be high in lead. A German survey of lead in foods found that 12 percent of fruit juices contained elevated levels of lead and over 5 percent of fruits had elevated levels of lead (Ref. 33). It is well recognized that lead has no known ''no-effect level'' and consumption of lead-contaminated food is a recognized health problem, particularly for children in their developmental stages. Responsible processors should exercise control to ensure that their juice products do not contain lead at harmful levels. Again, HACCP provides both the necessary control and flexibility to address the problem of lead contamination. If a processor is importing juice from a geographic region known to have a problem with lead contamination in foods, that processor should identify lead as a hazard in their HACCP plan. However, if a juice processor determines through its hazard analysis that, given their source, incoming materials are not reasonably likely to be contaminated with lead, that processor would not need to identify lead as a hazard in its HACCP plan. Importantly, processors who are currently implementing HACCP to address microbial hazards only already have the infrastructure in place to analyze their processing system and can then determine if there are chemical or physical hazards that are reasonably likely to occur. Therefore, with minimal effort, these processors can readily expand the scope of their HACCP system to include consideration of all potential hazards.

Based upon the foregoing, the agency concludes that chemical and physical hazards, as well as pathogens, may pose public health risks in juice products. These hazards, when they are reasonably likely to occur, require specific preventive controls. HACCP is the most appropriate system to control both microbial and nonmicrobial hazards that are reasonably likely to occur in juice products.

(Comment 16) Several comments suggested that quality assurance systems devised specifically for juices would be appropriate alternatives to mandatory HACCP with a performance standard. The comments contended that the quality assurance systems developed by and for the citrus industry in conjunction with the University of Florida (Ref. 34) are adequate to ensure the safety of citrus juices and that the Apple Hill Quality Assurance Program (Ref. 35) is adequate to ensure the safety of apple juice. Some comments asserted that these programs are just as effective as HACCP, while being less expensive to implement.

FDA encourages the efforts by industry, universities, State and local government agencies, and others to develop programs to ensure the safety and quality of the food supply and is aware of several such programs. The agency has reviewed the quality assurance programs mentioned by the comments and finds that the HACCP system in part 120 provides a greater level of public health assurance. If a processor can implement a quality assurance program that also meets the requirements of part 120, then FDA does not object to the processor using that program for its HACCP system. However, quality and safety are not necessarily synonymous. Quality programs focus on the combination of attributes or characteristics of a product that have significance in determining the degree of acceptability of that product by consumers. Safety programs focus on hazards and public health assurance. Quality assurance systems may not address all public health

hazards just as safety programs may not address all quality issues.

(Comment 17) Several comments requested that FDA exempt from the HACCP regulation processors who pasteurize their product, make shelf-stable product, or meet the 5-log performance standard because the aim of the rule should be pathogen control. The comments said that HACCP is regulatory overkill and it is unfair to impose HACCP on the 98 percent who pasteurize in order to control the real risk from the 2 percent who do not. The comments noted that illness outbreak evidence only supports the need for interventions to control pathogens in unpasteurized juice because there have been no reported outbreaks of illness from consumption of pasteurized juice.

The agency agrees that, when used with appropriate times and temperatures, thermal pasteurization [3] is a proven and effective method for controlling pathogens. However, the effectiveness of pasteurization is dependent on implementation of an integrated system that validates and verifies the efficacy of the pasteurization process. It is likely that processors who make concentrated, shelf-stable, or pasteurized juices have already incorporated HACCP principles, aimed at control of pathogens, into their processing operations (Ref. 36). Processors already attaining the 5-log reduction performance standard are likely to have established process parameters (*i.e.*, critical limits), are monitoring the process, and are keeping records of their monitoring. Therefore, it should require minimal effort for processors that make concentrated, shelf-stable, or pasteurized juices to satisfy the requirements of part 120 relating to pathogen control. Moreover, as discussed in section L of this document ''Process Controls,'' in recognition of the effectiveness of thermal treatments for pathogen control, FDA is providing in part 120 an alternative method for processors making shelf-stable juices or certain juice concentrates to comply with the 5-log reduction in the pertinent pathogen. The agency believes that the alternative method is reasonable because the processes for shelf-stable juices and concentrates are so rigorous that they exceed the minimum requirements for control of microbiological hazards. A copy of the thermal process in a processor's hazard analysis will provide evidence that the process is adequate.

Importantly, pathogen control is not the only problem with juice safety. As discussed in the juice HACCP proposal (63 FR 20450 at 20451) (Ref. 2) and in the response to comment 15, there are also established chemical and physical risks with juice. A juice product can only be considered safe if all hazards (*i.e.*, microbial, chemical, and physical) are considered and, if these hazards are reasonably likely to occur, are controlled. Therefore, FDA concludes that processors of thermally processed juice must comply completely with this HACCP regulation, but can do so with minimal added effort.

(Comment 18) Some comments contended that the HACCP proposal goes way beyond establishing necessary measures to ensure juice safety and is neither reasonable nor economically feasible for an industry characterized by small producers, family businesses, seasonal production, and very little prior experience in food safety management. Comments also noted that there is a low level of compliance with seafood HACCP among small producers and the success of juice HACCP will depend upon small processors complying with costly regulations. Conversely, several comments argued that HACCP is the appropriate food safety system for small producers because it can be implemented without being overly burdensome and forcing them out of business.

The flexibility of HACCP allows the processor to control hazards identified in the hazard analysis in a manner that best fits an individual operation, large or small. In addition, if small producers actually have very little prior experience or knowledge in food safety management, as some comments asserted, then HACCP training and consultation are very much needed by this group and will provide specific food safety goals customized to their individual operations.

Thus, features of the agency's regulatory strategy will accommodate small processors. First, FDA intends to provide a juice HACCP hazards and controls guidance that will assist processors. Second, this final rule has a staggered compliance schedule (§ 120.1(b)(1) and (b)(2)), which provides small and very small juice processors additional time to implement fully the final rule.

The agency's HACCP strategy for the seafood industry, which is dominated by small processors, has been to acknowledge that the implementation of HACCP can be an educational process, especially with regard to science-based analysis, and thus to allow for the progression in mastering the HACCP system that accompanies that process. The progress in implementing HACCP systems that the seafood industry is making suggests that other segments of the food industry, including those populated by small businesses, can also benefit from a HACCP program, even if complete understanding of what constitutes full implementation of a HACCP system is not immediate.

(Comment 19) Several comments stated that HACCP presents an undue burden to the pasteurized juice industry with no consumer benefits. The comments stated that the chemical hazards cited by FDA are not reasonably likely to occur and that there has never been a foodborne illness outbreak associated with pasteurized juice.

The agency does not agree. The preamble to the proposed rule described incidents of illness associated with chemical contaminants in juice (63 FR 20450 at 20451) (Ref. 2). Chemical hazards can occur in juice regardless of pasteurization. Moreover, for some juices, the risk of chemical contamination can be high, depending on the quality of the incoming produce and the chosen processing steps. In fact, in two recent incidents, juice was recalled by the processor in one case due to the presence of dairy and egg allergens (Refs. 37 and 38), and in the other, due to the presence of cleaning solution (Refs. 39, 40, and 41). As discussed earlier in comment 15, the risk of patulin contamination in apple juice is high if the processor uses bruised apples.

The agency does not agree that HACCP for the pasteurized juice industry does not convey benefits to consumers. While the classic definition of pasteurization is a heat-treatment to destroy pathogens, the agency has no assurance that all juice processors who believe they are pasteurizing their products actually have all the controls in place to assure that every particle of the juice is receiving sufficient heat to destroy pathogens. Moreover, pasteurization alone does not assure the safety of juice products. Proper handling of the product after pasteurization is required to prevent post-process contamination. A HACCP system based on CGMP's provides assurance to the processor, as well as to the agency and the consumer, that pasteurized products are safe.

The agency is required, by Executive Order and law, to consider both the costs and benefits to consumers and industry. This analysis can be found in the PRIA, and the Regulatory Flexibility

[3] FDA has not defined what pasteurization means in terms of juice and juice products because of the unique characteristics of the many various types of juice and juice products. The scientific literature provides data on adequate pasteurization times and temperatures. Prudent processors using pasteurization rely on this research data for their particular types of juices.

Analysis in sections V and VI of this final rule. Based on FDA's analysis, the benefits (*i.e.*, prevention of illness) of this final rule outweigh the costs to industry.

A few comments expressed concern that HACCP regulations may be enforced at the expense of CGMP's.

The agency does not agree with the comments. In fact, FDA expects that the opposite will be true. A HACCP system cannot be operating properly if a processor is not following CGMP's because CGMP's provide the foundation for an adequate and appropriate HACCP system. Therefore, to evaluate the effectiveness of a HACCP system, processors and agency inspectors must also evaluate processors' adherence to CGMP's.

(Comment 20) One comment stated that HACCP as set forth in the proposal places the responsibility for product safety on the government rather than the processor.

FDA does not agree with this comment. Each juice processor is responsible for developing a system of preventive controls by adapting the HACCP principles in new part 120 to its specific operation and needs. Under HACCP, the manufacturer is responsible for knowing and understanding its manufacturing process, identifying points where contamination can occur, and implementing control measures in order to produce safe food. To accomplish this, the processor must: (1) Have an individual who is trained in HACCP conduct a hazard analysis, determine where controls are needed, and validate the adequacy of any HACCP plan that is developed; (2) put those controls in place and verify that they are working through monitoring and recordkeeping; and (3) revalidate the HACCP plan at least annually or any time there is a significant change in the process or whenever scientific information demonstrates a new risk that processors have not previously considered in their hazard analysis. FDA's responsibility is to conduct oversight to ensure that HACCP is properly implemented and is effective.

(Comment 21) Several comments stated that HACCP's cost is not justified because most foodborne illness occurs as a result of problems that originate after juice leaves the processor and HACCP will not remedy these problems. One comment cited a source that estimated that food manufacturers are involved in less than 10 percent of foodborne disease outbreaks of known origin (Ref. 42).

FDA maintains that all steps in juice production and handling are potential points of contamination in the absence of adequate controls, not just post-process handling. Processors must consider prevention of post-process contamination to the extent feasible. For example, post-process piping must prevent contamination from occurring prior to packaging. HACCP systems are implemented to assure the safety of food when it leaves the processor's control and under normal handling conditions after that. The agency points out that the CAST report cited by the comment includes all foods (not just juice) and all food sources (processors, food service, institutions) and is limited to microbial contamination of foods. The majority of juice outbreaks have not been caused by post-process contamination but rather by contaminated incoming product or contamination during processing (Ref. 43). Thus, the performance standard (5-log reduction in pathogen level) established by this rulemaking is set to ensure that the final product is not contaminated with illness-causing bacteria that may have been present on incoming fruit. In addition, processors must use CGMP's, SSOP's, and HACCP to ensure that product is not contaminated with pathogens while in the processing facility.

(Comment 22) Several comments stated that hazards in juice are adequately dealt with under State laws (*i.e.*, Connecticut, Florida, Illinois, Maryland, Massachusetts, Michigan, New Jersey, New Hampshire, Wisconsin).

The agency applauds State efforts to ensure the safety of juice produced and sold in their States. However, while there may be some State laws that govern the manufacture of juices, these laws are generally not as comprehensive as this HACCP rule. In addition, not all juice producing States have applicable State laws. This HACCP final rule provides a uniform minimum level of public health protection across the country for juices. FDA believes that this final rule will enhance State efforts and help extend the food safety efforts of some States to all States.

C. Significance of Illness Data

The preamble to the proposed regulation described occurrences of juice-related foodborne illness in the United States. It is well recognized that foodborne illnesses are significantly underreported to public health authorities (Ref. 44). Consequently, precise data on the numbers and causes of foodborne illness do not exist. The primary purpose of these regulations is to ensure that juice is safe through the use of preventive controls that are systematically and routinely applied in juice processing, and applied in a way that can be verified as effective by company management as well as regulatory authorities.

(Comment 23) Many comments questioned the validity of FDA's risk assessment on juice. They stated that it was not scientific and sound, not probabilistic, didn't include pasteurized juice, and contains inaccuracies. However, comments did not specifically identify the inaccuracies.

FDA maintains that its ''Preliminary Investigation into the Morbidity and Mortality Associated with the Consumption of Fruit and Vegetable Juices'' is sound. As outlined in the juice labeling final rule (63 FR 37030 at 37031) (Ref. 5), the agency performed a detailed evaluation of the potential hazards posed by untreated juices. This evaluation is part of the record of the HACCP proposal and was included as an appendix to the PRIA (63 FR 24292; May 1, 1998) (Ref. 6). The evaluation was based on available scientific information, included pasteurized juice, and examined both heat-treatable microbial hazards and non-heat-treatable hazards. Non-heat-treatable hazards are discussed in section VII and the evidence is summarized in table 7 of FDA's Investigation. The conclusion that the most significant juice-borne hazards are associated with non-heat-treated juice was based on this investigation.

(Comment 24) One comment stated that all outbreaks in cider have been traced to using dropped apples or unsanitary processing conditions and that eliminating these circumstances will stop outbreaks in cider.

FDA disagrees with the comment because the causes of cider-related outbreaks are not limited to using drops or processing in an insanitary facility. In fact, from a structural standpoint, apples are susceptible to contamination because they have an open blossom end, and thus, the interior of the fruit can be contaminated while the exterior appears clean and blemish free (Ref. 45). This potential for contamination is confirmed by data that show that cider, even when it is made from tree-picked fruit and processed under CGMP's, can contain pathogens and provide an environment conducive to the survival of pathogens of public health significance (Ref. 13).

(Comment 25) Several comments maintained that the risk from juice is low and does not warrant a HACCP regulation.

The agency does not agree with the comments. There are documented cases of lifethreatening foodborne illness associated with the consumption of various juice products contaminated with pathogens such as *E. coli* O157:H7,

Salmonella species, *Cryptosporidium*, and *Vibrio cholerae*. Some of the illnesses associated with juices have been very severe (*e.g.*, cases of long-term reactive arthritis and severe chronic illness) (Ref. 2). In one case, consumption of contaminated juice resulted in the death of a child and in another case, consumption of contaminated juice contributed to the death of an elderly man. These reported outbreaks likely represent only a fraction of the outbreaks and sporadic cases that actually occur (Ref. 44).

Chemical and physical hazards have also been associated with juices. Examples of these hazards were included in the proposal (63 FR 20450 at 20451) (Ref. 2) and are discussed in detail in the response to comment 15.

The evidence demonstrates that hazards can be present in juice. The comments did not provide the agency with additional data that either contradict FDA's hazard evaluation (Ref. 6) or that can be used to reevaluate the health risks associated with consumption of juice products. Therefore, FDA believes that the public health risk associated with consumption of juices is sufficiently high to justify mandating use of HACCP systems.

(Comment 26) Many comments argued that HACCP is no longer necessary for juice because of the safety improvements made by the juice industry since the 1996 outbreak of *E. coli* O157:H7 in apple juice. They stated that these improvements are evidenced by the fact that there has not been an outbreak associated with juice since 1997.

FDA disagrees with the comments. There have been documented outbreaks of juice-associated foodborne illness since 1997. The agency acknowledges the recent steps taken by the industry to address microbial contamination of juice. Nevertheless, while there were no reported outbreaks attributed to juice in the United States in 1997 and 1998, there were several outbreaks in 1999 and 2000. These outbreaks are discussed below.

In early 1999 in south Florida, there were 16 reported cases from *Salmonella typhi* linked to the consumption of frozen mamey, a product often used to make juice beverages (Ref. 46).

During June 1999, there was an outbreak of *Salmonella* serotype Muenchen infection associated with consumption of unpasteurized orange juice (Ref. 47). As of April 2000, a total of 423 cases, including one that contributed to a death, from S. Muenchen infection had been reported. Nine additional *Salmonella* serotypes were identified from orange juice collected from the implicated firm.

In October 1999, there was an outbreak of *E. coli* O157:H7 in commercially-processed unpasteurized apple cider in Oklahoma with 9 illnesses (7 children) and 6 hospitalizations (4 cases of hemolytic uremic syndrome (HUS)) (Ref. 48).

While no illnesses were reported in October 1998, the State of Florida found *Salmonella* Manhattan in an unpasteurized juice blend containing strawberry, apple, and papaya juice (Ref. 49).

In November 1999, the same firm involved in the June 1999 outbreak initiated and subsequently expanded a recall because their routine testing found *Salmonella* in samples of unpasteurized orange juice (Ref. 50). The product had been distributed to restaurants and other food service establishments in eight U.S. States and one Canadian Province and to one retail store in Oregon. No known illnesses were associated with this incident.

In April 2000, there was an outbreak of *Salmonella* Enteritidis associated with unpasteurized orange juice (Ref. 51). As of May 2000, 143 cases traced to this orange juice had been identified in Arizona, California, Colorado, Minnesota, Nevada, Washington, and Wyoming.

Also in April 2000, 24 people who attended a conference in Atlanta, Georgia, were reported ill with viral gastroenteritis (Ref. 52). Fresh-squeezed unpasteurized fruit smoothies were implicated in this outbreak. CDC detected Norwalk-like virus in three patient stools.

Thus, the potential for juice-related illness still exists, although the number of illness outbreaks linked to juice may vary from year to year. In addition, the agency has no information indicating that all members of the juice industry have implemented adequate safety improvements to address the potential for microbial contamination and other potential hazards in their products. The fact that outbreaks continue to occur is evidence to the contrary.

(Comment 27) One comment asserted that most problems associated with citrus juices were a result of insanitary processing conditions at small or very small businesses or contamination by asymptomatic food handlers, and HACCP would not prevent problems in either situation.

The agency disagrees with this comment. FDA often finds in their investigations into outbreaks that the exact cause of the outbreak is unknown. The agency may find various possible causes that include those mentioned by the comment. However, as discussed throughout this preamble, insanitary conditions and workers' health are not the only source of food hazards in juice. For example, if juice is made from contaminated fruit and the 5-log reduction is not accomplished, an outbreak could occur. HACCP systems do provide greater assurance than CGMP's and SSOP's alone that juice is safe. HACCP recordkeeping provisions allow processors and regulators to detect process deviations and stop distribution of or recall product before it results in an outbreak.

(Comment 28) Several comments stated that the rules should cover apple products only, asserting this is where problems have occurred.

The agency disagrees that only apple juice should be covered by part 120, and all other juices should be exempt. There have been illness outbreaks from other types of juice, *e.g.*, orange juice. Some of these were cited in the proposal (63 FR 20450) (Ref. 2). As discussed in comment 27, additional outbreaks since publication of the proposal have occurred. Therefore, FDA concludes that because there are documented foodborne illness risks associated with juices other than apple juice, all types of juice must be covered under part 120.

(Comment 29) Many comments argued that juice regulations should not be more stringent than regulations for other foods that are more hazardous, such as seafood or meat and poultry. Many comments noted that seafood HACCP has no performance standard but is a much higher risk food than juice.

The agency disagrees that juice is being regulated more stringently than warranted. HACCP for juice mirrors FDA's HACCP regulations for seafood and USDA's regulations for meat and poultry. In contrast to most seafood and meat and poultry, juice is generally consumed as sold. The record of this proceeding demonstrates that microbial contamination of juice is a substantial public health risk and that a performance standard is achievable as a practical matter. Thus, to ensure the safety of juice products, FDA is establishing a mandatory HACCP program that includes a performance standard to prevent, reduce, or eliminate levels of pathogens known to cause foodborne illness. The performance standard ensures that controls within the HACCP system are working effectively to reduce the risk of illness and that the final product is safe.

(Comment 30) One comment maintained that the physical hazards related to juice are a result of metal cans

and glass, both of which are not used by the fresh juice industry.

FDA recognizes that juices that are minimally processed usually are packaged in plastic to provide for expansion of the product. Whether or not packaging materials are included in a processor's HACCP plan will be determined in the processor's hazard analysis. If the hazard analysis shows that a particular operation has no physical hazards, such as metal or glass, that are reasonably likely to occur, no control measures are required for such hazards. Even if there are no physical hazards in fresh juice that require controls, the risk of microbial contamination of fresh juice is well-documented and a HACCP approach is needed to address these risks.

(Comment 31) One comment stated that the *Bacillus cereus* incident cited by FDA is not significant and any final rule should clearly state that sporeformers are not a problem that needs to be considered in a treatment system for juice.

The agency has considered the issues surrounding hazards from spore forming bacteria. Regulations in parts 113 and 114 (21 CFR parts 113 and 114) already address the hazard from *Clostridium botulinum* in low acid canned foods and acidified foods. Spore forming bacteria have not been associated with public health problems in juice that has been properly handled (*e.g.*, refrigerated) after leaving the processing plant. Therefore, FDA does not anticipate that processors' hazard analyses will establish that spore forming bacteria are a hazard that is reasonably likely to occur.

D. Comparison of the Proposal and This Final Regulation

The comments received generated some clarifications of and changes in provisions of the proposed regulation. These are discussed in detail in the comments noted after each item. Among the most significant clarifications and changes are the following:

- Clarification that the regulation covers intrastate, as well as interstate juice (discussed in comments 33 and 74)
- Adoption of the most recent NACMCF definition of ''food hazard'' (comment 39)
- Elimination of the proposed exemption from the regulation for retail establishments that produce juice on their premises and sell 40,000 or less gallons of juice per year (comment 47)
- Addition of a definition of ''retail establishment'' (comment 48)
- Clarification of how a hazard analysis is conducted (comments 63 to 70)
- Clarification of application of the 5-log pathogen reduction performance standard (comments 115 and 131 to 139)
- Creation of an exemption for shelf-stable juice processors and concentrated juice processors from the requirement for a pathogen reduction critical control point, under specific conditions (comment 140)
- Establishment of a process verification sampling and testing procedure for citrus juices that use surface treatment as part of the 5-log pathogen reduction process (comment 142 to 143)

III. The Final Regulation

A. Applicability

The agency proposed in § 120.1(a) that any juice sold as such or used as an ingredient in beverages be processed in accordance with the requirements of part 120 (63 FR 20450 at 20462) (Ref. 2). As proposed, juice is the aqueous liquid expressed or extracted from one or more fruits or vegetables, purees of the edible portions of one or more fruits or vegetables, or any concentrates of such liquid or puree.

(Comment 32) One comment requested that FDA define juice as the aqueous liquid expressed or otherwise extracted from food and that this definition should be synonymous with juice definitions in other regulations, *i.e.*, food standards. One comment noted that food products (*e.g.*, fruit cocktail) other than beverages contain fruit juice.

FDA advises that the purpose of § 120.1(a) is to define the scope of what is covered under part 120 rather than to provide a general definition for the term ''juice.'' Part 120 only covers products sold as juice or used as an ingredient in beverages. The agency recognizes that products other than beverages, *e.g.*, canned fruit cocktail, may contain fruit or vegetable juice. However, the foodborne illness outbreaks prompting the juice HACCP proposal were associated with juices and juice products that were beverages rather than juice ingredients contained in non-beverage products. Therefore, FDA is not defining ''juice'' in the general sense requested by the comment.

(Comment 33) Several comments requested that FDA clarify whether the juice HACCP regulation covers only interstate commerce.

FDA intends that this final rule cover both ''interstate juice'' (*i.e.*, juice that is shipped in interstate commerce or that is made using one or more components that were shipped in interstate commerce) and ''intrastate juice'' (*i.e.*, juice that is made entirely from components grown within a single State and then sold to the ultimate consumer within the same State).

As noted in the proposal, FDA is relying upon both its authority under the act, 21 U.S.C. 321 *et seq.*, and the Public Health Service Act, 42 U.S.C. 241, 242l, 264. FDA's authority to regulate ''interstate juice'' is discussed in detail below in comment 74. Under section 361 of the Public Health Service Act (42 U.S.C. 264), the Surgeon General is authorized to issue and enforce regulations to prevent the introduction, transmission, or spread of communicable diseases from one State to another State. (This authority has been delegated to the Commissioner of Food and Drugs, 5 CFR 5.10(a)(4).) Activities that are wholly intrastate in character, such as the production and final sale to consumers of a regulated article within one State, are subject to regulation under section 361 of the PHS Act *State of Louisiana* v. *Mathews*, 427 F. Supp. 174, 176 (E.D. La. 1977). The record in this rulemaking amply demonstrates that juice can function as a vehicle for transmitting foodborne illness caused by pathogens such as *Salmonella* and *E. coli* O157:H7. Similarly, the record (Ref. 53) demonstrates that consumers (particularly out-of-State tourists and other travelers) are likely to purchase and/or consume ''intrastate'' juice. These consumers subsequently take the juice back to their home State where the juice is consumed or carry a communicable disease back to their home State, thereby creating the risk that foodborne illness may occur in the home State as a result of such consumption.

The agency believes that its intent to regulate both ''interstate'' and ''intrastate'' juice was evident from § 120.1(a) of the proposal, which stated that the requirements of part 120 would apply to ''any juice'' without qualification as to its ''interstate'' or ''intrastate'' character. However, to clarify further the products to which this final rule applies, FDA is adding a sentence to § 120.1(a) as follows: ''The requirements of this part shall apply to any juice regardless of whether the juice, or any of its ingredients, is or has been shipped in interstate commerce (as defined in section 201(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321(b)).''

(Comment 34) Some comments requested that FDA exempt citrus juices from the HACCP regulation because these juices contain organic acids that stop microbial growth, the pH of citrus juices is too low for pathogen growth, and peel oil contains an antimicrobial agent. One comment included data

indicating that *Listeria* and *E. coli* O157:H7 cannot survive in lemon and lime juices under normal storage conditions and requested that these two juices be exempted from the HACCP rule.

The agency disagrees that citrus juices should be exempt from the requirements of part 120. Although the organic acids, pH, and peel oil in citrus juice may inhibit (*i.e.*, prevent or slow down) the growth of pathogens, such organisms can still be present in citrus juice and may cause illness if consumed. Fruits and vegetables differ in their inherent chemical composition; even within varieties of particular fruits or vegetables, there can be some variation in composition depending on growing conditions. However, the comments provided no data to show how the chemical composition of a citrus juice (pH or antimicrobial compounds in peel oil) will ensure the safety of fresh citrus juice. In fact, because the amount of peel oil in juice will vary from process to process, the agency disagrees that the antimicrobial effects of citrus peel oil can adequately control pathogens in juice. Similarly, the organic acid in citrus juice (*i.e.*, citric acid) has not been shown to provide any additional protection against pathogen contamination and survival compared to the acid found in apple juice (Refs. 54, 55, and 56).

A 1997 study of *E. coli* O157:H7 behavior in apple juice and orange juice, particularly under refrigerated conditions, demonstrated that even in the relatively acidic environment of these juices, this organism can survive (Ref. 57). In the study, juice was inoculated with *E. coli* O157:H7. After a 24-day period at refrigeration temperatures, there was only a small decline in numbers of *E. coli* O157:H7. The fact that *E. coli* O157:H7 can survive in orange juice and that human illnesses from other pathogens, such as *S. Muenchen* and other *Salmonella* species, have been traced to orange juice demonstrates that, if contaminated, orange juice has the potential to cause human illness.

Lemon and lime juices are more acidic than other types of citrus juice. The strong acidity of these juices does have an antimicrobial effect as the comment's data demonstrated. However, the resistance of oocysts to the strong acidity of these juices is not known. In addition, there can be differences in acidity between varieties of lemons and limes, and thus, differences in their inherent antimicrobial effects. These juices may be diluted and sweetened to make them palatable as beverages, thus changing antimicrobial parameters. In addition, there may be chemical and physical hazards that are reasonably likely to occur in these types of juices that pH and acids cannot control. Therefore, FDA concludes that the chemical composition of lemon and lime juices does not justify exempting these juices from this rule. If processors can demonstrate that the inherent antimicrobial qualities of a juice are adequate to accomplish the 5-log reduction in the pertinent pathogen under refrigerated conditions (or freezing conditions, if the product is frozen) prior to the product leaving the processing facility, then the antimicrobial parameters, along with the necessary time to accomplish the 5-log reduction, could constitute CCP's. FDA notes, however, that under the final rule, processors must establish critical limits and monitor each of the CCP's as part of their HACCP systems.

(Comment 35) Some comments maintained that there is less inherent risk from citrus juices because citrus processing limits contact time of peel and juice. The comments included data from citrus processors that separate the peel from the juice with only a small fraction of peel contacting the juice.

The agency disagrees that there is less risk from citrus juices such that these juices should not be subject to part 120. The significance of peel/juice contact as a source of pathogens in the juice depends on several factors, including the microbial load on the peel and the amount of contact of the peel with the juice. If the small fraction of peel, as described by the comments, is contaminated and comes into contact with the juice, that contact is significant. As discussed in the proposed rule (63 FR 20450) (Ref. 2) and also in the response to comment 26, there have been outbreaks of food borne illness associated with orange juice.

(Comment 36) A few comments requested that FDA exempt apple cider from the HACCP regulation because the agency found no pathogen contamination in the 1997 cider survey, which, according to the comment, indicates that there is no real risk from pathogens in cider.

FDA's 1997 survey involved inspection of fresh unpasteurized apple cider operations at 237 processors in 32 States (Ref. 45) during which the agency collected samples at various processing steps. These samples were analyzed for *E. coli* O157:H7, *Salmonella, Staphylococcus aureus,* fecal coliforms, and generic *E. coli.* Although the survey did not detect any pathogens in finished juice products, one firm's apples tested positive for *Salmonella,* demonstrating that pathogens can occur on incoming apples. (The analytical method used for *Salmonella* has since been improved to better detect low levels of this pathogen in acidic foods, such as apple juice.) Results also showed that samples of wash water from several firms tested positive for generic *E. coli* and fecal coliforms; overall, generic *E. coli* was found in 15 percent of the finished product samples. The presence of fecal coliforms and generic *E. coli* are widely recognized as indicators of fecal contamination (Ref. 58). Further, the survey concluded that it is likely that any microbial hazards that are introduced at the beginning of processing will be carried through to the finished product; no microbial reduction will occur during the process (Ref. 45).

The agency disagrees that these results indicate there is no real risk from pathogens in cider. Contrary to the comments' contention, the cider survey results affirm that risk factors such as fecal coliforms, an indicator of the possible presence of pathogens, as well as pathogenic bacteria, such as *Salmonella,* are present in cider processing operations and could give rise to microbiological safety hazards in finished cider products.

Finally, illness outbreaks associated with apple cider continue to occur. In particular, in October 1999 in Oklahoma, there was an outbreak related to *E. coli* O157:H7 in a commercially produced, unpasteurized apple cider, that resulted in nine reported illnesses. The agency, therefore, is not granting the requested exemption.

(Comment 37) Several comments requested that FDA clarify whether concentrates are covered under the rule.

The agency advises that under the final rule, a juice concentrate satisfies the definition of ''juice'' in § 120.1, and thus, producers of concentrates are required to comply with part 120.

(Comment 38) One comment requested that FDA clarify whether processors of beverages that include juice as an ingredient but do not produce the juice itself are covered under the juice HACCP regulation. One comment stated that dairies using concentrates that are processed to meet the 5-log requirement or untreated juices that are further pasteurized should not be subject to the HACCP regulation.

The agency advises that any juice processing activity, including juice ingredient processing, must comply with the provisions of part 120. Dairies making juice, regardless of whether they use concentrates, must comply with part

120. However, dairies producing a non-juice beverage that contains a juice ingredient (*e.g.*, a dairy-based beverage containing orange juice) are not required to comply with part 120 in terms of the process for producing that non-juice beverage. Processors of juice used as a beverage ingredient must comply with the provisions of part 120.

B. Definitions

1. Food Hazard

FDA proposed in § 120.3(e) (finalized as § 120.3(g)) that ''food hazard'' means any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.

(Comment 39) One comment requested that FDA adopt the most recent NACMCF definition of a food hazard to clarify the mechanism by which a hazard analysis is conducted.

The agency agrees with this comment. The NACMCF currently defines ''hazard'' as a ''biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control'' (Ref. 17). The definition differs from, but is not inconsistent with, the definitions for food hazards used in the seafood HACCP and meat and poultry HACCP regulations. Adopting the most recent NACMCF recommendations to the extent feasible will allow the HACCP regulation to remain current with the science of HACCP.

In the first step of a hazard analysis, processors must identify all the hazards that could potentially occur in the juice. Potential hazards are those microbial, chemical, and physical agents that are reasonably likely to cause illness or injury regardless of the likelihood of their occurrence. FDA intends to publish a juice HACCP hazards and controls guidance to assist processors in this step of the hazard analysis.

Second, processors must determine whether the potential hazards identified are ''reasonably likely to occur'' in their particular process. Under § 120.7(b), a hazard is ''reasonably likely to occur'' if a prudent processor would establish controls because experience, illness data, scientific reports, or other information provide a basis to conclude that there is a reasonable possibility that, in the absence of those controls, the food hazard will occur in the particular type of product being processed.

In the NACMCF's view, if a hazard has a severe, acute public health impact (*e.g.*, illness caused by a pathogen, injury caused by ingestion of glass), that hazard presents a significant risk even at an extremely low frequency of occurrence and must be appropriately identified as a hazard that is ''reasonably likely to occur'' (Ref. 17). FDA concurs in this view. On the other hand, chronic hazards would need to occur at a higher frequency to be identified as a hazard that is ''reasonably likely to occur.'' In the case of chronic hazards, it must be understood that the illness or injury need not be caused by any specific occurrence of the hazard but may occur with exposure to the hazard over time. Each hazard identified in the hazard analysis as ''reasonably likely to occur'' requires the identification of at least one CCP, the critical step or steps in the process that must be controlled to prevent, reduce to acceptable levels, or eliminate the hazard.

Because hazards can be either acute or chronic (*i.e.*, having short-term or long-term effects, respectively) and the purpose of HACCP is to focus on public health hazards that are ''reasonably likely to occur,'' FDA finds that the NACMCF definition better describes what must be considered in a hazard analysis. Therefore, the agency is modifying § 120.3(g) to state that a ''food hazard'' means any biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control.

2. Processing

The agency proposed in § 120.3(h)(1) (finalized as § 120.3(j)(1)) to define ''processing'' as activities that are directly related to the production of juice products. However, for purposes of proposed part 120, certain activities were proposed to be exempted by § 120.3(h)(2) (finalized as § 120.3(j)(2)). These are: (1) Harvesting, picking, or transporting raw agricultural ingredients of juice products, without otherwise engaging in processing; (2) the operation of a retail establishment; and (3) the operation of a retail establishment that is a very small business and that makes juice on its premises, provided that the establishment's total sales of juice and juice products do not exceed 40,000 gallons per year, and that sells the juice (a) directly to consumers or (b) directly to consumers and other retail establishments.

a. Harvesting, Picking, and Transporting Raw Agricultural Products.

(Comment 40) Several comments objected to the definition of processing in proposed § 120.3(h)(2)(i) (finalized as 120.3(j)(2)(i)) excluding harvesting, picking, and transporting raw agricultural ingredients of juice products because this will leave a big gap in the farm to table system and contamination is very likely to occur in this gap. One comment advocated mandatory HACCP that either begins at the farm including harvesting, picking, and transport or includes a ''kill step.''

The agency has concluded that it would be unduly burdensome to require that harvesting, picking, and transportation be included as part of a processor's HACCP system or to require a kill step. Under HACCP, processors are responsible for evaluating their production system for hazards and establishing CCP's. This includes the quality of incoming raw materials. FDA encourages farmers and processors to evaluate and modify their agricultural practices in accordance with FDA's ''Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables'' (Ref. 59). This guidance document is based upon certain basic principles and practices associated with minimizing microbial food safety hazards from the field through distribution of fresh fruits and vegetables. Farmers should take all steps to ensure their products are safe for the intended food use, but safe juice can be produced without these activities at the farm level coming under the processor's HACCP system. Processors can control hazards that may be present on incoming produce by: (1) Rejecting produce at receipt that does not meet processor specifications; (2) removing contaminated produce during initial processing; (3) cleaning and sanitizing produce; (4) using, as a minimum standard, the 5-log reduction in the pertinent pathogen as set forth in § 120.24; and (5) using any other effective method.

The agency does not believe it is appropriate to mandate a ''kill step'' in the absence of HACCP at the farm. It is the processor's decision, based on its hazard analysis whether or not the first CCP in its HACCP system is at the point of receipt of raw materials, to control hazards that may have occurred earlier. The hazard analysis must be based on experience, illness data, scientific reports, or other information that provide a basis to conclude that there is a reasonable possibility that, in the absence of HACCP controls, the food hazard will occur in the particular type of product being processed. The performance standard establishes the minimum level of microbial pathogen reduction the process must be able to provide to produce safe juice and this may be met by a ''kill step'' or any other appropriate method. The 5-log reduction in the pertinent pathogen is adequate to ensure that the juice is safe when done under a HACCP system with a foundation of CGMP's and SSOP's.

(Comment 41) One comment suggested that the definition of processing should at least mention FDA's ''Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables'' (GAP's).

FDA has considered the comment's suggestion and believes that reference to the GAP's in part 120 would be useful. However, the agency finds that it is more appropriate to discuss the GAP's in terms of the application of part 120. Therefore, FDA is modifying § 120.1(a) to state that raw agricultural ingredients are not subject to the requirements of this part and that processors should apply existing agency guidance to minimize microbial food safety hazards for fresh fruits and vegetables in handling raw agricultural products.

b. Retail.

(Comment 42) Several comments were opposed to excluding retail establishments from the definition of processing in proposed § 120.3(h)(2)(ii) (finalized as § 120.3(j)(2)(ii)). The comments expressed concern because outbreaks associated with products processed in retail establishments will be equally devastating to the industry as a whole. One comment stated that relying on the Food Code and State regulators is inadequate because: (1) The adoption of Food Code provisions is voluntary and varies widely on a State-by-State basis and (2) State regulators do not have the resources to inspect retail establishments on a regular basis.

The agency recognizes that retail is an important segment of the juice industry and that retailers may also mishandle products. FDA is concerned that juice sold at retail be safe. However, retail establishments pose a unique situation for the implementation of HACCP. Retail establishments, in general, deal with a greater variety of products and processes at relatively lower volumes than non-retail producers. For example, cider retailers at farmers' markets will generally sell other products, including fresh produce, as well as apple cider. Therefore, because retail establishments handle lower volumes of a variety of products, HACCP systems at retail are significantly different from HACCP systems in processing plants. Because of the wide variety of products and processes used by retail establishments, the relatively low volumes of juices produced, the normally small area of product distribution, and the large number of retail establishments, FDA has chosen to focus its regulatory resources on manufacturers that produce larger quantities of widely distributed products.

Even though retail establishments are not included in this rulemaking, prudent retailers should take steps to ensure the safety of their products. FDA traditionally provides guidance to the retail industry through the Food Code and works with the States to implement Food Code provisions. The States should be aware that the Food Code is responsive to many of the concerns raised in the comment. FDA encourages juice retailers to implement Food Code provisions. Also, FDA provides training and other forms of technical assistance to States and local Governments who inspect retail food establishments through the agency's retail Federal/State cooperative program. The agency will continue to provide this support through the Federal/State cooperative mechanism. FDA recognizes that not all States have adopted the Food Code.

Finally, more than 25 States have adopted the Food Code as law with most other States in the process of adopting the Code. However, retail establishments pose an inspection burden well beyond the capacity of FDA. There are not sufficient resources to adequately inspect the many retail establishments in the United States.

Although retail establishments are not covered in this final rule, they are subject to § 101.17(g), which requires that packaged untreated juice products carry a statement informing consumers that the product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems.

(Comment 43) One comment suggested that, rather than exempting all retail establishments from the definition for processors, only retailers who produce in batches of less than 32 ounces at a time or who sell product in glass containers that can be washed and reused might be exempted because the less fruit and vegetables that go into a batch, the lower the risk.

The agency agrees with the concept that the smaller the batch, the lower the microbial risk. Larger establishments produce larger quantities of juice that are often widely distributed. Retail establishments produce much smaller quantities of juice that are more likely (but not always) consumed locally. Thus, the public health impact of a foodborne illness outbreak associated with larger firms is likely to be greater. However, the special considerations discussed in the response to the previous comment still exist for retail firms, regardless of batch size. Therefore, FDA concludes that it is appropriate that part 120 excludes operators of retail establishments from the definition of processor.

(Comment 44) One comment requested that FDA establish national standards for juice processors in the Food Code if the agency excludes retail establishments from the definition for processing. Conversely, several comments stated that the provisions of the Food Code adequately ensure juice safety at retail. A few comments stated that the guidelines developed by the Fresh Citrus Juice Task Force in combination with Food Code provisions are adequate to ensure the safety of citrus juice without mandatory HACCP for retailers.

FDA agrees with the comments that maintain that the Food Code describes appropriate controls that can be applied to reduce juice hazards at retail. The agency has traditionally relied on the Food Code to provide guidance to retail establishments. As noted in the response to comment 42, FDA will work with the States through its Federal/State mechanism. The agency urges retailers to implement State and industry guidance in their establishments to ensure the safety of juice.

(Comment 45) One comment suggested that all juice, like milk, should be pastuerized and FDA should not permit the sale of untreated juice since raw milk sales are not allowed.

The agency agrees. Under § 120.24(a), processors must include in their HACCP plans control measures that will produce, at a minimum, a 5-log reduction in the pertinent pathogen. Thus, all juice subject to part 120 will be treated to control microorganisms.

(Comment 46) One comment requested information on which processors will not be covered under either the juice labeling rule or the juice HACCP rule and which processors, if any, have a permanent labeling option.

The agency advises that § 101.17(g) requires that any packaged juice in interstate commerce that has not been specifically processed to prevent, reduce, or eliminate the presence of pathogens must bear the warning statement. Under this final rule, a juice retailer as defined in § 120.3(l) is not required to establish a HACCP system; however, any juice produced by that retailer that includes an interstate ingredient or is shipped in interstate commerce must bear the warning label statement. Such a retailer may avoid the labeling requirements by treating its product to achieve a 5-log reduction in the pertinent microorganism.

c. 40,000 gallon exemption.

(Comment 47) Most of the comments on the 40,000 gallon exemption from both large and small processors requested that FDA withdraw the exemption in proposed § 120.3(h)(2)(iii)

(the definition of ''processing''). The comments stated that small processors are just as likely to produce contaminated juice as larger processors and that company size should not dictate compliance with regulations when public safety is at stake. The comments also noted that this exemption does not maximize public health protection.

The comments have persuaded the agency to exclude from this final rule the exemption proposed for very small retail businesses who sell less than 40,000 gallons of juice annually either to consumers directly or to other retailers. FDA agrees that company size should not dictate compliance with food safety rules. The agency also agrees with comments that stated that this exemption does not protect the public health. Although large processing firms can be responsible for more widespread outbreaks than the firms in the proposed exemption because of their broader product distribution, those smaller businesses can make juice that may cause an outbreak. Further, other regulations addressing public health concerns (*e.g.*, seafood HACCP in part 123 (21 CFR part 123) mandatory pasteurization of milk and milk products in 21 CFR 1240.61) do not contain such exemptions. Therefore, the agency is removing the exemption from this final rule. FDA notes that those producers who would have been covered by the 40,000 gallon exemption and who are strictly engaged in retail sales would not be required to comply with this final rule consistent with § 120.3(j)(2)(ii). Juice produced by these retailers would be required to bear the label warning statement as described in the response to comment 46.

3. Retail Establishment

(Comment 48) Several comments requested that FDA define ''retail establishment'' for clarity. One comment requested that FDA revise proposed § 120.3(h) so that retailers who sell to other retailers are covered by the definition for processors.

FDA agrees with the comment that recommended establishing a definition of ''retail establishment.'' The FDA Food Code has a definition of '' food establishment'', which, given the purpose and scope of the Food Code, is essentially a definition of a retail establishment. In establishing a definition for ''retail establishment'' in this final rule, FDA is relying on this Food Code definition. The Food Code definition of '' food establishment'' has been in existence for many years, and is recognized by the States. The Food Code definition includes establishments in which juice is produced and sold directly to consumers in stores, from roadside stands, at farmers' markets, and in food service operations (such as juice bars and restaurants).

FDA also agrees with the comment that requested that juice retailers who sell to other retailers be subject to the HACCP regulation. FDA believes that this approach will contribute to public health protection. Accordingly, under this final rule, only a retail establishment that limits its juice business to direct consumer sales would qualify for exemption from the requirements of this HACCP regulation, and would be subject to regulation by the State in which it operates. Thus, the ''retail establishment'' definition in this regulation is consistent with the Food Code, and also describes establishments that are included and excluded specifically for the purpose of this regulation. For example, a retail establishment, central kitchen, or processing facility that provides juice to more than one retail operation (e.g., juice production operation that provides juice to outlets of a chain supermarket) would not be considered a retail establishment that is exempt from this regulation. However, a retail establishment that produces juice for sale directly to consumers at that location and at other locations under the same ownership would be considered a retail establishment exempt from this regulation. Therefore, the agency is adding a § 120.3(l) to define a ''retail establishment'' as an operation that provides juice directly to consumers, and does not include an establishment that sells or distributes juice to other business entities as well as directly to consumers. ''Provides'' includes storing, preparing, packaging, serving, and vending. (Because the agency is establishing an additional definition in § 120.3, it is recodifying the other terms in § 120.3 so that they continue to appear in alphabetical order.)

4. Verification and Validation

(Comment 49) Several comments requested that the terms ''validation'' and ''verification'' be defined and be used consistent with NACMCF principles.

FDA agrees with the comments. The agency intends that the terms ''validation'' and ''verification'' be used consistent with NACMCF principles throughout this final rule. The NACMCF has established definitions for these terms that the agency finds useful (Ref. 17). According to the NACMCF definition, validation is a subset of verification (Ref. 17). Therefore, in this final rule the agency is amending § 120.3(p) and (q) to include the NACMCF definitions of both validation and verification as follows:

Validation means that element of verification focused on collecting and evaluating scientific and technical information to determine whether the HACCP plan, when properly implemented, will effectively control the identified hazards;

Verification means those activities, other than monitoring, that establish the validity of the HACCP plan and that the system is operating according to the plan.

C. Prerequisite Program Standard Operating Procedures

The HACCP proposal discussed two types of prerequisite program standard operating procedures (SOP's). FDA proposed to require the first type, SSOP's, in § 120.6. SSOP's cover sanitary conditions and practices before, during, and after processing. The agency requested comment (63 FR 20450 at 20466) (Ref. 2) on a second prerequisite program to provide control over materials as they enter the plant. However, the agency did not propose to require incoming material SOP's in part 120.

(Comment 50) One comment asked that if FDA requires prerequisite program SOP's, the agency should be more specific about what is to be included in the prerequisite program SOP's. It stated that some SOP's ensure wholesomeness and quality and should not be a part of HACCP.

The agency advises that it is requiring that processors implement SSOP's in part 120 at this time and not any other type of SOP. The SSOP's in § 120.6 do include specific standards that must be maintained. The SSOP's as described in § 120.6(a) address insanitary conditions and are not directed to ensure wholesomeness and quality although they may have a beneficial effect on these attributes.

1. SSOP's

(Comment 51) Several comments stated that SSOP's are covered under CGMP's and should not also be covered in HACCP and neither SSOP's nor CGMP's should be a written requirement for HACCP. One comment stated that SSOP's should not be written for the same reasons that SSOP's are not written for seafood HACCP. One comment stated that prerequisite program SSOP's should not be mandated and that CGMP's provide an adequate basis for HACCP. However, other comments maintained that SSOP's and CGMP's should be a part of written HACCP programs.

It is important to understand the difference between CGMP's, SSOP's, and HACCP. The agency has established CGMP's in part 110. These regulations provide general guidance on such matters as facility design, materials, personnel practices, and cleaning and sanitation procedures. In § 120.5, FDA requires that part 110 apply in determining whether the facilities, methods, practices, and controls used to process food are safe, and whether the food has been processed under sanitary conditions. Processors do not need to make a record of these activities for FDA review. However, the agency will continue to include in its inspections determinations of processor compliance with CGMP's. All appropriate CGMP's must be implemented, whether they are incorporated into a processor's HACCP system or not, because they reflect norms of good processing.

SSOP's are specific sanitation CGMP's that FDA has found are key to the successful implementation of a HACCP system. Not all CGMP's deal with sanitation issues (e.g., contamination with aflatoxin or other natural toxins in § 110.80(a)(3)). As required by § 120.6(a), SSOP's emphasize sanitation conditions and practices before, during, and after processing. Because of the importance of sanitation to a facility, processors must monitor SSOP conditions and practices during processing to at least ensure compliance with part 110. If sanitation conditions and practices are not met, processors must take corrective actions (§ 120.6((b)). Insanitary conditions can directly result in food hazards, especially microbiological hazards. Inadequate sanitation has a direct effect on whether the HACCP plan can adequately control food hazards. For example, insanitary conditions can cause post process contamination.

Both CGMP's and SSOP's have a broad scope. As noted in section II.A, HACCP is a system to identify specific points in a particular manufacturers process where risks exist and critical controls are needed to control the identified risks. CGMP's and SSOP's both play an important role in HACCP in that they form the foundation upon which the HACCP system is built.

FDA stated in the proposal (63 FR 20450 at 20467) (Ref. 2) that the records bearing on the monitoring of relevant sanitation conditions and practices and the agency's access to such records are essential if SSOP's are to be part of an effective regulatory strategy. Although the agency elected not to require written SSOP's under the seafood HACCP regulation, it required that seafood processors establish SSOP's and maintain records monitoring and documenting corrective actions. Juice is significantly different than seafood in that juice is generally consumed as sold whereas seafood is generally cooked, thus sanitation takes on increased importance. Because of the significance of sanitary conditions, the agency concludes that juice processors must maintain SSOP records in the same manner as that required for other HACCP records.

(Comment 52) One comment requested that FDA require that the quality and safety of water used in juice processing plants be verified.

The agency agrees that water used in juice processing plants must be safe and of an adequate sanitary quality for its intended use. This is consistent with the CGMP requirements in § 110.37(a). Section 120.6(a)(1) of this final rule requires that juice processors have SSOP's that address the safety of the water that comes into contact with food or food contact surfaces or that is used in the manufacture of ice. Processors must examine the source of the water used in their facilities and determine the necessary provisions to ensure the water's safety. The processor's particular obligations may vary, depending on the source of the water. Water from community water supplies is tested for many substances and the processor can obtain the results of that testing from the local water authority. In the case of well water, processors must know that the water they use is safe because such water could present potential hazards. Thus, processors using well water need to test the water. Moreover, if substances in the water are hazards that are reasonably likely to occur, one or more CCP's must be established and included in the HACCP plan.

(Comment 53) One comment requested that FDA require processors to monitor for water and cleaning solution contamination.

FDA believes that, given the regulation as proposed, the requested revision is unnecessary. Section 120.6(a)(1) already requires processors to have and implement SSOP's relating to water quality and § 120.6(a)(5) requires processors to have and implement SSOP's relating to the protection of food from cleaning compounds. Processors must monitor their SSOP's and take corrective actions for sanitation conditions and practices where the specified conditions are not met (§ 120.6(b)). In addition, processors must maintain records that document monitoring and any corrective actions taken (§ 120.6(c)). If either water or cleaning solution contamination is a hazard that is reasonably likely to occur, one or more control measures must be included in the HACCP plan for each hazard identified.

(Comment 54) One comment requested that FDA clarify whether § 120.6(a)(5) permits certain amounts of ''no rinse'' sanitizers to come into contact with product.

The agency advises that ''no rinse'' sanitizers used according to product directions do not present a contamination problem and, with appropriate use, their presence would not be considered a violation of § 120.6(a)(5).

(Comment 55) One comment requested that FDA set an ''acceptable level of infestation'' for insect control and require that processors use insect light traps as monitoring devices. Another comment requested that FDA revise § 120.6(a)(8) to read as follows: ''Exclusion of pests from the food plant and prevention of contamination from pests within the plant, as well as in packaging and raw materials delivered to the plant.''

FDA disagrees that it should establish an ''acceptable level of infestation'' for insects or that it should revise § 120.6(a)(8) as the comment requested. Exclusion of pests from the food plant is included as a necessary part of SSOP's in § 120.6(a)(8). The comment's requested modification is already implied in § 120.6(a)(8). Pests are recognized sources of microbial contamination, as well as filth, in foods. The agency believes that generally no unusual pest control requirements are necessary for juice processing operations beyond the general requirements for pest control in all food processing facilities, as laid out in part 110. However, if, during its hazard analysis, a processor identifies pests or contamination from pests as a food hazard that is reasonably likely to occur in its particular system, the processor will need to establish a control measure, critical limits, and a means of monitoring.

(Comment 56) One comment requested that FDA add the following to § 120.6(b): ''The requirements under this section shall apply both to the processor's own premises and the premises of any supplier of raw materials and packaging, as far as this is relevant.'' The comment concluded that this is necessary because packaging and raw materials are particular sources of contamination in most food processing plants.

FDA agrees that incoming materials can be a possible source of contamination in juice processing plants but points out that the focus of this

regulation is the production of safe juice by juice processors. Nevertheless, processors are urged to take steps to control hazards before the hazards enter the processing facility. Under part 120, processors must control food hazards in the juice products they make. If a processor's hazard analysis indicates that a hazard is reasonably likely to occur in incoming materials, then an appropriate control (such as a supplier agreement concerning that hazard) must be a part of the processor's HACCP plan, and the processor must monitor the CCP and verify supplier performance. Thus, FDA concludes that raw materials and packaging are already covered adequately and is not modifying § 120.6(b) as the comment requested.

(Comment 57) One comment stated that corrective actions should not be required for CGMP's and SSOP's.

FDA advises that there are no corrective actions specifically required for CGMP's in these HACCP regulations. However, part 120 sets forth monitoring and corrective action requirements for SSOP's. Insanitary conditions create an environment in which products may become contaminated with pathogens or other substances. If a product becomes contaminated because of insanitary conditions, it is important that corrections be made as quickly as possible so as not to subject subsequently processed product to conditions that could introduce food hazards. Therefore, processors need to monitor the performance of SSOP's to ensure that the SSOP's are functioning as designed, and that any problems that arise are corrected. The comment did not provide data to persuade the agency to conclude otherwise.

(*Comment 58*) One comment suggested that FDA only require SSOP's in a HACCP plan if their control is essential to eliminate or control a public health risk, as determined in the hazard analysis. The comment contended that a distinction must be made between failure to meet sanitation requirements and failure to meet a food safety/HACCP requirement. The comment further stated that singling out items to be included in SSOP's implies that the other sanitation requirements in part 110 are not that important, and this is not the case. It stated that if FDA establishes SSOP's that, at the very least, no recordkeeping requirements should be associated with SSOP's.

FDA advises that processors are not required to include sanitation controls in their HACCP plans. Section 120.6(d) allows processors the option of including sanitation controls in the HACCP plan, but they are under no obligation to do so as long as the sanitation controls are being implemented through the SSOP. Insanitary facilities or equipment, poor food handling, improper personal hygiene, and similar insanitary conditions create an environment in which products may become contaminated with pathogens and other substances. A processor may determine that a task normally covered by SSOP's may be of such importance that it must be included in the HACCP plan because it controls a hazard that is reasonably likely to occur. Similarly, an SSOP task may simply be more efficiently or effectively performed under the HACCP plan rather than SSOP controls, and thus, a processor may choose to incorporate the SSOP task into the HACCP system. However, HACCP controls generally focus on discrete steps or ''points'' in a processing system, while sanitation and sanitation controls generally have broader, plantwide applicability. Thus, sanitation does not always lend itself well to HACCP controls. Therefore, the agency is not modifying § 120.6(d) as requested.

FDA disagrees that singling out items to be included in SSOP's implies that the other provisions of part 110 are not important. Rather, the items listed in § 120.6(a) are to assist processors in identifying and implementing key sanitation activities. Sanitation controls, such as controls preventing use of contaminated water in juice making, have a direct impact on the presence or absence of pathogens during processing, which in turn, directly affects the effectiveness of the HACCP plan. No matter how reliable the process is, insanitary conditions can cause the product to become contaminated with pathogens. It is because of the critical role that sanitation plays in the production of safe juice that FDA is requiring SSOP's, identifying specific items to be included, and requiring recordkeeping. However, processors must comply with all provisions of part 110 in addition to having SSOP's as required under § 120.5.

2. Other SOP's

(*Comment 59*) Several comments requested that FDA require written, monitored, and verified SOP's for incoming materials. One comment contended that reasonable procedures for these SOP's should include no use of dropped apples, no contact with water that could contain pathogens, no manure as fertilizer, steam cleaning of crates in contact with fruit between lots, and regular inspections of source farms and orchards. Another comment suggested that incoming material SOP's be required only for producers that do not pasteurize their product.

The agency is not convinced of the need for mandatory incoming material SOP's because these activities may be adequately controlled under the CGMP's in part 110. However, FDA does recognize the value of incoming material SOP's, and it encourages processors to establish and monitor incoming material conditions and practices and to take corrective actions when needed. Processors must evaluate the need for controls at all points in their process, including incoming materials. If incoming materials are reasonably likely to present a hazard, then the hazard must be controlled by one or more CCP's in the HACCP plan, even if a processor has an incoming material SOP.

Many of the controls mentioned in the comments are addressed in FDA's ''Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables.'' As noted earlier, FDA encourages farmers and processors to evaluate and modify their agricultural practices in accordance with GAP guidance. Processors may include GAP's in any SOP's for incoming materials that they may establish.

Finally, because all processors, regardless of whether or not they pasteurize, must meet the performance standard required under § 120.24, as well as the other requirements of part 120, there is no need to differentiate between processors for the purposes of requiring incoming material SOP's, and thus, to require more SSOP's from a processor that does not pasteurize.

(*Comment 60*) One comment requested that FDA hold a public meeting for input on incoming material SOP's.

The agency does not believe that such a public meeting is necessary. There have been many opportunities for interested parties to comment on all issues related to HACCP, including incoming material SOP's (see section I.B of this final rule). FDA requested public input in the HACCP proposed rule (63 FR 20450 at 20466) (Ref. 2) and in this final rule has considered all significant comments received. In addition, some issues surrounding incoming materials for citrus juices were discussed at the public NACMCF meeting in December, 1999 (Ref. 12). Finally, FDA intends to issue a juice HACCP hazards and controls guidance, which will provide another opportunity for public input on the incoming materials issue.

(*Comment 61*) One comment suggested that the GAP's for fresh produce can be used in conjunction

with SOP's to ensure the safety of incoming material.

FDA agrees that the use of GAP's in combination with SOP's may enhance the safety of incoming materials. FDA's GAP's for fresh produce provide valuable guidance for use in the production and post harvest handling of raw agricultural commodities. As noted, the agency also intends to publish a juice HACCP hazards and controls guidance that will provide additional guidance on ensuring the safety of incoming materials.

(*Comment 62*) One comment stated that HACCP should include a requirement for incoming materials testing to prevent another outbreak like the one in 1996.

The agency disagrees that it should require incoming materials testing in part 120, although it encourages processors to test incoming materials as appropriate. Testing may be used as a control measure for a hazard that is reasonably likely to occur and it may also be used to gather information on a product or supplier for use in the hazard analysis. However, testing may not be useful in all cases. Microbial contamination of fresh produce is usually at low levels and is not uniformly distributed throughout a lot. Thus, while detecting a pathogen, such as *E. coli* O157:H7, would allow a processor to avoid using contaminated produce, failure to detect pathogens by testing does not provide assurance that the hazard is not present in incoming materials. The 5-log reduction in the pertinent pathogen as implemented in a HACCP system provides the assurance that microbial hazards are under control throughout the process. Therefore, the agency is not requiring the testing of incoming materials.

D. Hazard Analysis

The agency proposed in § 120.7 that processors develop a written hazard analysis to determine whether there are hazards that are reasonably likely to occur for each type of juice produced by a processor and to identify the control measures that the processor can apply to control those hazards.

(*Comment 63*) One comment requested that FDA clarify how a hazard analysis is conducted. The comment suggested that FDA emphasize the NACMCF recommendations, including consideration of both likelihood of occurrence and severity of hazards. The comment expressed concern that without considering both the likelihood of occurrence and severity of hazards, HACCP plans would not be consistent with international practice and World Trade Organization (WTO) obligations, which state that scientific determinations of risk are needed to form a sound basis for food safety standards.

The agency agrees that the approach outlined by the NACMCF will best assist processors in conducting a hazard analysis. First, processors will benefit from using the five preliminary steps set forth by the NACMCF, which are to assemble a HACCP team, describe the food and its distribution, identify the intended use and consumers of the food, develop a flow diagram that describes the process, and verify the flow diagram (Ref. 17). Although the agency is not specifically requiring that processors use these preliminary steps, these steps will aid processors in focusing on their specific product and process.

According to the NACMCF, processors must accomplish three objectives in the hazard analysis: (1) Identify hazards that are reasonably likely to occur and their associated control measures; (2) identify needed modifications to a process or product so that product safety is further assured or improved; and (3) provide a basis for determining CCP's in the HACCP plan (Ref. 17). FDA agrees with these objectives.

The first NACMCF objective is accomplished in three steps. First, processors must list all the potential hazards that could be present in the juice. During this step, the processor's HACCP expert or team reviews the ingredients used in the product, the activities conducted at each step in the process and the equipment used, the final product and its method of storage and distribution, and the intended use and consumers of the product. A list of categories of potential food hazards is found in § 120.7(c). Based on this review, the processor's HACCP team develops a list of potential biological, chemical, or physical food hazards that may be introduced, increased, or controlled at each step in the production process. A hazard analysis must be conducted for each type of juice product manufactured by the processor because different hazards may be associated with different juice products. (For example, patulin need only be considered in apple juice products.)

The processor must then identify those food hazards that are reasonably likely to occur. According to NACMCF, this step takes into account both the consequences of exposure (i.e., severity) and the probability of occurrence (i.e., frequency) of the health impact of the potential hazards in question (Ref. 17). FDA agrees with the NACMCF approach. Accordingly, when applying the phrase ''reasonably likely to occur,'' a processor must consider both severity and frequency of potential hazards. The NACMCF stated that consideration of the likelihood of the hazard's occurrence is usually based upon a combination of experience, epidemiological data, and information in the technical literature (Ref. 17). The NACMCF also stated that consideration should be given to the effects of short term, as well as long-term, exposure to the potential hazards. Because this process takes into consideration both frequency and severity, a potential hazard may be identified as reasonably likely to occur even though it occurs infrequently because the public health consequences when it does occur are so severe, *e.g.,* HUS in small children from *E. coli* O157:H7 in juice. This approach also provides greater harmony for international trade because it is the same approach recommended by the Codex Alimentarius Commission, which is a recognized standard setting body by the WTO. Hazards that are not reasonably likely to occur do not require further consideration within a HACCP plan but are controlled under CGMP's.

Identification of control measures is a third step in the first NACMCF objective in developing a hazard analysis. For example, juice processors must identify the process they will use to achieve the 5-log reduction in the pertinent pathogen. This may be pasteurization, surface treatments for citrus, or other effective methods. Therefore, § 120.7 requires that processors identify the measures that they will apply to control the hazards that have been identified as reasonably likely to occur. These control measures must be included in the HACCP plan as well as the hazard analysis.

Under the second NACMCF objective, processors must review their current process to determine deficiencies in controlling food hazards and then identify the changes that must be made to ensure that food hazards are controlled. For example, some juice beverages may be thinner or thicker than others, a characteristic that may affect how fast the product flows through the pasteurizer; in this stage of the hazard analysis, the processor must review its process to determine whether the product is flowing through the pasteurizer at a rate sufficient to ensure that all particles of the juice receive the appropriate treatment in terms of both time and temperature to achieve, at a minimum, the 5-log reduction in the pertinent pathogen.

The third NACMCF objective requires that processors use the hazard analysis to provide a basis for determining CCP's in the HACCP plan. For example, some

processors may run different juice beverages on the same line during the same day with only a water flush between products. If one juice product contains a potential allergen, such as a soy ingredient, then a possible control measure is that this product be run last in the day with a thorough cleaning of the system before the next day's startup.

To clarify the necessary steps in developing a hazard analysis, as the comment requested, the agency is codifying them in § 120.7(a). (Because the agency is adding these steps to § 120.7, it is recodifying the other paragraphs in § 120.7 for clarity.)

(*Comment 64*) A few comments objected to the requirement of a written hazard analysis because the seafood HACCP regulation does not require a written hazard analysis. However, some comments supported such a requirement.

FDA acknowledges that a written hazard analysis is not required by the seafood HACCP regulation and believes that, at the time that the regulation was established, this was appropriate. Although the seafood HACCP regulation does not require a written hazard analysis for agency record review, seafood processors are strongly urged to have a written hazard analysis to resolve differences between the processor and the agency about whether a HACCP plan is needed and about the selection of hazards, CCP's, and CL's.

Since the issuance of the seafood HACCP regulation, the HACCP concept and how best to implement HACCP has evolved in step with industry's increasing experience with HACCP; part of that evolution is the idea that the hazard analysis should be written. Processors will have a better HACCP system if they document the hazard analysis process. A thorough hazard analysis is the key to preparing an effective HACCP plan. According to the NACMCF, if the hazard analysis is not done correctly and the hazards warranting control are not properly identified, the plan will not be effective regardless of how well it is followed (Ref. 17).

Another aspect of HACCP implementation that affects the need for a written hazard analysis is the availability of specially trained investigators. At the time the seafood HACCP program was established, FDA had sufficient resources to hire and specifically train investigators in seafood HACCP, as well as to provide assistance to the industry in implementing HACCP. With expansion of HACCP into other commodity areas, the agency does not have the resources to develop cadres of investigators with expertise in a single commodity, such as juice. With a written hazard analysis, investigators can more easily determine whether processors have adequately considered all juice hazards and have adequately identified those hazards that are reasonably likely to occur.

Even though a written hazard analysis is not required by the seafood HACCP regulation, that regulation, as well as USDA's meat and poultry HACCP regulations, require a systematic and comprehensive hazard analysis. In addition, USDA's meat and poultry HACCP regulations require a written hazard analysis. Thus, the only difference in the juice final rule and the seafood HACCP regulation is that the analysis is written, not that it is or is not required. FDA believes that the additional step of recording the hazard analysis poses no significant burden, economic or otherwise, to juice processors and, on the contrary, has advantages for the processor. A written hazard analysis provides processors with a ready record of the decisions made in conducting a safety analysis of their process, which they may use in evaluating potential changes to the system and for discussions with regulatory officials. Further, written hazard analyses are useful to processors in that they help provide the rationale for the establishment of critical limits and other plan components. Having the basis for these decisions available will be helpful when processors experience changes in personnel, especially those associated with the HACCP process, and in responding to unanticipated CL deviations.

A written hazard analysis need not be a highly detailed document, but it must reflect consideration of all the potential hazards that could occur in a processor's system for a product and the processor's decisions about whether these hazards are reasonably likely to occur. The hazard analysis may be as simple as a checklist of potential hazards and the reason why certain decisions were made. A written hazard analysis clearly and rationally demonstrates that processors have considered all potential hazards, identified those hazards that are reasonably likely to occur and are associated with their product and process, and identified CCP's and CL's in their HACCP plan.

(Comment 65) Several comments stated that HACCP should only cover hazards that are reasonably likely to occur and that have been documented.

FDA agrees that processors need only control in their HACCP plan those hazards that are reasonably likely to occur and that have been documented. The hazard analysis is where processors differentiate between unlikely hazards and hazards that are reasonably likely to occur in the absence of controls. This determination is made for each type of juice processed in a particular facility. Data such as experience, illness data, scientific reports, or other information may be used as documentation as to whether the hazard is reasonably likely to occur in juice and, if so, how the hazard is best controlled.

(Comment 66) One comment requested that the agency revise proposed § 120.7(a) to state generally that all physical, chemical, and microbiological hazards be considered, instead of providing a numbered list of potential hazards to be considered in the hazard analysis.

FDA disagrees that all physical, chemical, and microbiological hazards must be considered, but only those that can be introduced both within and outside the particular processing environment, including hazards that can occur before, during, and after harvest. The agency points out that the provision now codified as § 120.7(c), simply provides guidance in the form of a minimum list of potential physical, chemical, and microbiological hazards that processors should consider. The list is not intended to be all-encompassing, and is not so constructed. FDA believes that this guidance is useful because it provides detail about the types of potential hazards that fall into the more general categories of physical, chemical, and microbiological hazards. For these reasons, FDA declines to revise § 120.7(c) as requested.

(Comment 67) Several comments argued that unapproved pesticide residues, unapproved food and color additives, and food allergens are not appropriate for inclusion in HACCP because, categorically, they are not a significant threat to public health and are already covered by other regulations. One of the comments supported its claim of inappropriateness by pointing out that FDA failed to give any examples of problems caused by unlawful pesticide residues or unapproved food and color additives. Therefore, it stated, these are not problems that should be covered by HACCP, but addressed under CGMP's.

FDA disagrees that certain types of potential hazards, such as those mentioned in § 120.7(c), need not be considered in a hazard analysis. For example, pesticide residues above tolerance may be potential hazards. However, it is unlikely that pesticide residues above tolerance will need to be identified during a hazard analysis as hazards that must be included in the

HACCP plan because they occur infrequently and the public health impact of infrequent exposure is not severe.

The agency recognizes that there are effective governmental control programs in place in the United States to assure generally that unlawful pesticide residues are unlikely to occur. For pesticides, these controls include pesticide registration, applicator licensure, and government sampling and enforcement programs. Likewise, unapproved food and color additives are generally unlikely to occur in juice products because prudent processors would not intentionally add them to their products. Thus, for crops grown in the United States, a processor may ordinarily conclude that the controls for pesticide use are such that it is not reasonably likely that unlawful pesticide residues will be present in crops (including residues at levels above tolerance). A processor is responsible for assessing the adequacy of control for pesticide use for crops grown outside the United States and determining whether such controls are sufficient to make it unlikely that unlawful pesticide residues will be present. If foreign governmental controls are sufficient, HACCP controls would not likely be necessary in the processor's HACCP plan. If foreign governmental controls are not sufficient, the processor may need to include appropriate controls in its HACCP plan.

Similarly, unapproved food and color additives would be reasonably likely to occur only if, because of their presence in the production plant and the potential for formulation errors, there was a real likelihood that they may be inadvertently added to the product or added at higher than the allowable rate. A food or color additive may also be used on the product by a processor's supplier. This may pose a hazard where the food or color additive is a potential allergen or causes sensitivity reactions in susceptible individuals. For example, a processor may make several types of juice drinks, some containing FD&C Yellow No. 5. The likelihood and severity of a reaction to Yellow No. 5 is a factor that must be considered in determining whether the unintended presence, whether by misformulation or cross contamination, of the ingredient or additive in a food is reasonably likely to occur and, therefore, constitutes a potential hazard.

Therefore, the agency concludes that if unlawful pesticide residues and unapproved food and color additives are hazards that are reasonably likely to occur, it is appropriate that a processor identify them in its hazard analysis and include them in its HACCP plan.

(Comment 68) Several comments suggested that pesticide control should be handled as an agreement between processor and grower, not as a CCP.

The agency advises that if an agreement between a processor and a grower adequately assures that unlawful pesticide residues will not be a hazard that is reasonably likely to occur, then controls for that particular hazard need not be included in the HACCP plan. Agreements between processors and growers on pesticide issues may be particularly useful for produce grown in areas where government controls may not be sufficient to ensure that unlawful pesticide residues are not a hazard that is reasonably likely to occur.

(Comment 69) One comment noted that unapproved food and color additives are not an issue for orange juice because it has a standard of identity.

The existence of a standard of identity, such as for orange juice or tomato juice, is no guarantee that an unapproved food or color additive has not been intentionally or inadvertently added to the juice product. However, as noted previously, if a processor's hazard analysis establishes that unapproved food and color additives are not a hazard that is reasonably likely to occur, such additives do not need to be controlled as part of a HACCP plan.

(Comment 70) One comment requested that proposed § 120.7(b) be withdrawn as the list of what a processor should evaluate because it is already covered under part 110 and can be addressed by prerequisite programs.

The agency stated in the proposal that it was including in proposed § 120.7(b) (now codified as § 120.7(d)) some elements that would be useful for juice processors to consider in a hazard analysis (63 FR 20450 at 20468) (Ref. 2). Although CGMP's and SSOP's address a wide variety of situations and hazards, a particular food hazard may be reasonably likely to occur in the absence of its control and, therefore, necessitate HACCP controls. To assist processors in identifying all hazards that are reasonably likely to occur in their products, and their public health impact, FDA is, therefore, retaining the list in § 120.7(d) to guide processors in their hazard analyses.

(Comment 71) One comment requested that FDA revise the list of what processors should consider in evaluating the safety of their products to include cooling, ice, and water quality specifically.

The list in § 120.7(c) simply provides examples to guide processors and is not intended to be all inclusive. Ice and water quality are issues that generally will be addressed in the SSOP requirement in § 120.6(a)(1). Therefore, the agency is not modifying § 120.7(c) as requested. However, because the list in § 120.7(c) is guidance for processors, it does not preclude a processor from considering ice and water quality in its hazard analysis. If ice or water quality poses a hazard that is reasonably likely to occur, then the hazard must be addressed in the HACCP plan.

E. HACCP Plan

The agency proposed that processors have and implement a written HACCP plan for a given process whenever a hazard analysis of that process establishes that there are one or more food hazards that are reasonably likely to occur during such processing. The written HACCP plan is to include the following seven principles: (1) Conduct a hazard analysis, (2) determine the critical control points, (3) establish critical limits, (4) establish monitoring procedures, (5) establish corrective actions, (6) establish verification procedures, and (7) establish recordkeeping and documentation procedures. These seven elements are derived from the NACMCF principles of HACCP.

(Comment 72) One comment requested that FDA delete the term ''during processing'' in § 120.8(a) because some of the problems in the past have come from fruit contaminated on receipt and the term could be read to mean that only hazards that could occur during processing should be considered in the hazard analysis.

The agency does not agree with the comment. Section 120.7 requires that processors conduct a hazard analysis to determine the hazards that are reasonably likely to occur in their juice. If a hazard is reasonably likely to occur in the juice, the source of the hazard is immaterial. Therefore, FDA is not revising § 120.8(a) to delete the term ''during processing.''

(Comment 73) One comment requested that FDA delete proposed § 120.8(b)(2)(ii) because it appears to contradict the definition for processing in proposed § 120.3(h)(1) (finalized as § 120.3(j)(1)). The comment asserted that § 120.8(b)(2)(ii) states that CCP's should include food hazards that occur before, during, and after harvesting, yet processing is defined as excluding harvesting, picking, or transporting raw materials, which places it beyond the control of a processor.

The agency is not making the requested change because the language in question, along with the definition of

processor in § 120.3(k), serves to identify those who are required to comply with part 120 and is not a basis for excluding potential food hazards from consideration. Specifically, the definition of processing in § 120.3(j)(1) excludes the activities of harvesting, picking, or transporting raw materials even if these materials may be intended for use in juice processing under § 120.3(k). Only those engaged in ''processing'' juice are ''processors'' and are subject to the requirements in part 120. However, juice processors are responsible for addressing the hazards that may be present in/on the foods produced during their process, including hazards that result from characteristics of the incoming produce. One way to address potential hazards presented by incoming materials is by examining those materials when received and rejecting those that may contain hazards. Another way is to process juice in a manner to control pathogens or other hazards that may have been present on incoming materials. Therefore, FDA believes that the definition of ''processing'' does not conflict with § 120.8(b)(2)(ii) and is not making the requested change.

F. Legal Basis

The agency proposed in § 120.9 that failure of a processor to have and to implement a HACCP system that complies with §§ 120.6, 120.7, and 120.8, or otherwise to operate in accordance with the requirements of this part, renders the juice products of that processor adulterated under section 402(a)(4) of the act (21 U.S.C. 342(a)(4)).

(Comment 74) A number of comments asserted that FDA lacks the statutory authority to require juice processors to establish HACCP programs. Several comments claimed that section 402(a)(4) of the act cannot be read to authorize a broad range of HACCP controls and to provide that the failure to observe any of those controls would render food prepared under such conditions adulterated within the meaning of section 402(a)(4) of the act.

FDA disagrees with these comments. As shown below, the agency has ample authority to require juice processors to establish HACCP systems.[4]

FDA is issuing these regulations under the authority of the act and the Public Health Service Act (PHS Act). Specifically, FDA is relying on sections 402(a)(4) of the act and 701(a) of the act (21 U.S.C. 371(a)) and section 361 of the PHS Act (42 U.S.C. 264).

Under section 402(a)(4) of the act, a food is adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health. It is important to recognize that section 402(a)(4) of the act addresses conditions that may render a food injurious to health, rather than conditions that have actually caused the food to be injurious. See *United States* v. *1,200 Cans, Pasteurized Whole Eggs, Etc.*, 339 F. Supp. 131, 141 (N.D. Ga. 1972). *See also United States* v. *H.B. Gregory, Co.*, 502 F.2d 700, 705 (7th Cir. 1974), *cert. den.* 422 U.S. 1007 (1975). As noted in the notice of proposed rulemaking, 63 FR 20450 and 20457 (Ref. 2), the question is whether the conditions of a juice processing operation are such that it is reasonably possible that the juice produced by that operation may be rendered injurious to health. Based upon the information available to the agency and filed in the record of this proceeding, FDA has concluded that, if a juice processor does not incorporate certain basic controls into its procedures for preparing, packing, and holding juice, it is reasonably possible that the juice may be rendered injurious to health and, therefore, adulterated under the act. FDA is authorized by 21 U.S.C. 371 to adopt regulations for the efficient enforcement of the act.

FDA believes that the comments disputing the agency's authority to issue these regulations advocate an unduly narrow interpretation of the act generally and of section 342(a)(4) specifically. It is well-settled that the act is to be interpreted broadly so as to achieve its goal of public health protection. *United States* v. *Bacto-Unidisk*, 393 U.S. 784, 798 (1969). Section 402(a)(4) of the act deems adulterated food that is prepared, packed, or held under ''insanitary'' *conditions.* The term ''insanitary'' is not defined in the act. ''Sanitary'' describes that which ''pertains to health, with especial [sic] reference to cleanliness and freedom from infective and deleterious influences,'' Black's Law Dictionary, 6th Ed.(1990); use of the prefix ''in'' denotes the absence or opposite of sanitary. Thus, ''unsanitary conditions'' are those that contribute to unhealthiness generally, including unclean conditions or those that promote infection or disease.

The case law interpreting section 402(a)(4) of the act is consistent with this broad reading of ''insanitary conditions.'' In particular, in *United States* v. *Nova Scotia Food Products Corp.*, 568 F.2d 240 (2d Cir. 1977), the Second Circuit rejected a restrictive reading of 402(a)(4) of the act, concluding that this section provided the FDA with authority to establish by regulation processing parameters to control or eliminate harmful substances present in food intended for further processing. *See United States* v. *Nova Scotia Foods*, 417 F.S. 1364, 1368–1369 (E.D.N.Y. 1976), *aff'd supra*, 568 F.2d 240. At issue in *Nova Scotia* were FDA's regulations governing the time, temperature, and salinity for processing smoked fish, 568 F.2d at 243, 247 to 248, and provisions designed to minimize the outgrowth and toxin formation of *Clostridium botulinum Type E*, 568 F.2d at 243. The regulations in question defined sanitary conditions for processing such fish; fish processed under conditions not complying with the regulation were deemed adulterated within the meaning of section 402(a)(4) of the act, 21 CFR 128a.2 (1971); 35 FR 17401 (November 13, 1970) (Ref. 60). Although the Court posited that ''insanitary conditions'' could be narrowly interpreted to refer to insanitary conditions in the plant, such as the presence of insects and rodents, the Court rejected this narrow interpretation, 568 F.2d at 245 to 246, and held that under section 402(a)(4) of the act, ''insanitary conditions'' may include ''inadequate sanitary conditions of prevention'' (568 F.2d at 247). In rejecting the narrower reading of 402(a)(4) of the act, the Court recognized a ''larger general purpose on the part of Congress in protecting the public health'' (568 F.2d at 248).

This final rule requires that juice processors implement and maintain HACCP systems. As discussed in detail above, HACCP systems are designed to prevent, control, or eliminate hazards that are reasonably likely to occur during food production, including hazards that are present in in-coming materials, such as pathogens and other contaminants. Under the final rule, § 120.9, the failure of a juice processor to establish and maintain an adequate HACCP system renders juice produced under that system adulterated within the meaning of section 402(a)(4) of the act. Thus, the provisions of this final rule are essentially comparable to those addressed in *Nova Scotia.*

In addition, FDA relies on its authority under the Public Health

[4] Comments on the seafood HACCP final rule raised similar questions as to FDA's authority to require seafood processors to establish HACCP systems and to require recordkeeping and record access. In response to the proposed juice HACCP rule, one trade associations filed a copy of its comments on the seafood HACCP proposal. The agency's detailed response to the comments on the seafood proposal, set out at 60 FR 65098–65012, is incorporated by reference into the preamble of this final rule.

Service Act in issuing this regulation to the extent that the regulation seeks to control illnesses caused by pathogenic microorganisms. Under section 361 of the PHS Act (42 U.S.C. 264), the Surgeon General is authorized to issue and enforce regulations to prevent the introduction, transmission, or spread of communicable diseases from one State to another State; this authority has been delegated to the Commissioner of Food and Drugs, 5 CFR 5.10(a)(4). See *State of Louisiana* v. *Mathews*, 427 *F. Supp. 174, 176 (E.D. La. 1977).* The record in this rulemaking amply demonstrates that juice can function as a vehicle for transmitting food-borne illness caused by pathogens such as *Salmonella* and *E. coli* O157:H7. Juice produced in one State and shipped and sold in another State may be contaminated with pathogens and thus may result in the transmission of food-borne illness from State to State. The record similarly establishes that juice may be produced and sold to a visiting consumer in one State, with the consumer subsequently taking the juice to a second State. Given that juice can function as a vehicle for transmitting human pathogens, this situation creates the possibility that food-borne illness will be transmitted from one State to another. In light of the record of this proceeding, FDA has concluded that a system of HACCP controls is necessary to prevent the spread of communicable disease via consumption of contaminated juice, and that the PHS Act provides the agency with the authority to establish such HACCP requirements for juice.

(Comment 75) Several comments challenged the agency's authority to require that certain records be maintained and that FDA be granted access to those records. The thrust of these comments is that the act does not explicitly authorize the agency to require food processors to maintain records or to require access to records maintained by food processors. The comments observed that section 704 of the act (21 U.S.C. 374), the act's general records access provision, contains specific authorization for agency access to records relating to drugs and restricted medical devices but that, by its terms, the authority of section 704 does not extend to records relating to foods. Thus, the comments conclude that the records access provisions of the juice HACCP proposal are unlawful.

FDA disagrees with this comment because the agency has adequate authority under the act and the PHS Act both to require the maintenance of records and to compel official access to such records for the efficient enforcement of the act. Importantly, FDA is not relying on its authority in section 704 of the act to require the keeping of HACCP records and to require official access to such records. As discussed in the response to the previous comment, in terms of the act, this final rule implements section 402(a)(4) and utilizes FDA's authority in section 701(a) of the act to issue regulations for the efficient enforcement of the act. FDA is similarly relying on sections 402(a)(4) and 701 to establish the recordkeeping and access to records requirements of this rule. That this is sufficient authority is established in the caselaw.

In particular, in *National Confectioners Assoc.* v. *Califano*, 569 F.2d 690 (D.C. Cir. 1978), the D.C. Circuit held that FDA had authority to establish recordkeeping requirements for food processors. In *Confectioners*, the recordkeeping provisions of the regulations were challenged on the grounds that they would permit prosecution where processing conditions were completely sanitary, but required records were deficient. Such an outcome, it was argued, would be beyond the scope of section 402(a)(4) of the act, one of the particular sections relied upon as authority for the regulation as a whole. The court rejected this argument, holding that the principal consideration was whether the statutory scheme as a whole justified the regulations. Although the records in question in Confectioners were coding and distribution records that FDA desired in order to facilitate recalls, the court's ruling as to the validity of the regulations was not limited to recalls or shipping records. Indeed, *Confectioners* is appropriately read to authorize FDA to establish regulations that have a limited scope, are not unreasonably onerous, and clearly assist in the efficient enforcement of the act (569 F.2d 693 n. 9). In addition, the *Confectioners* court recognized that FDA has a role both in preventing and in remedying commerce in adulterated foods, and that the act imposes on the FDA an equal duty to perform each role (569 F.2d at 694).

It is widely accepted that recordkeeping and inspectional access to records are essential components of a HACCP-type system. Through records maintenance and review, a processor can, over time, develop a comprehensive picture of its process and identify shortcomings or potential shortcomings. Similarly, records maintenance and access provide the appropriate regulatory authorities with the opportunity to oversee, in a comprehensive way, the operation of the processor's HACCP plan, thereby ensuring that contaminated juice products will not enter the marketplace.

Like the records at issue in *Confectioners*, the records at issue with respect to this final rule are designed to prevent the introduction into commerce of adulterated foods (569 F.2d at 694). In this case, the recordkeeping and access required under this final rule meet the *Confectioners* test. First, the requirements are limited. The HACCP recordkeeping and record access requirements in the final rule are tied specifically to the CCP's, i.e., those points in the process at which control is essential if there is to be assurance that the resultant product will not be injurious to health is to be achieved. Second, this limited amount of recordkeeping assists FDA in the efficient enforcement of the act. By focusing on the CCP's, the requirements ensure that the processor and the agency focus on those aspects of processing that present the greatest threat to food safety; by documenting whether the HACCP plan and its preventive controls are being followed, these records enable regulators to verify proper operation of the HACCP system or identify malfunctioning of the system, again ensuring that adulterated foods are not produced and distributed to consumers. As such, the record-keeping requirements assist in the effective and efficient enforcement of the act. Finally, the HACCP recordkeeping burden is not unduly onerous because the required records are limited to the development of appropriate controls and documenting those aspects of processing that are critical to food safety. The documentation required in the final rule is narrowly tailored to ensure that only essential information needs to be recorded and maintained. Because the preventive controls required by HACCP are essential to the production of safe food as a matter of design, the statutory scheme is benefited by agency access to records that demonstrate that these controls are being systematically applied.

Similarly, FDA's authority under the PHS Act (42 U.S.C. 264), provides a separate and sufficient basis for the recordkeeping and records access provisions of this rule, at least to the extent that these requirements relate to the transmission of communicable disease. The record of this proceeding clearly shows that juice can function as a transmitter of human disease caused by foodborne pathogens, such as *Salmonella* and *E. coli* O157:H7. Likewise, the record demonstrates that a system of preventative controls, such as those based upon HACCP, will control or eliminate this risk from juice

consumption. As discussed in more detail below, records for the HACCP operation, and official access to these records, are central to the effectiveness of HACCP. Thus, the PHS Act clearly authorizes the records maintenance and access requirements of this final rule.

(Comment 76) A few comments stated that the factual and legal justifications for mandatory HACCP relate to the presence of pathogens in the final product, which is not true of the pasteurized juice industry. Comments maintained that section 402(a)(4) of the act does not authorize a broad range of controls and that seafood HACCP was predicated on the conclusion that there were sufficient hazards in all fishery products. One comment stated that the factual predicate relied upon in the seafood rule does not exist for juice. The comment maintained that a review of the data in the proposed rule indicates that microbiological hazards gave rise to the entire HACCP proceeding and these hazards do not exist in pasteurized and shelf stable juices.

The agency addressed the legal authority for this rule in the response to comment 74. FDA disagrees that the factual predicate for juice HACCP is not adequate. The record demonstrates that there are significant potential hazards in the production of juice, including pasteurized and shelf stable juices. These potential hazards in juice can be divided along the lines of the NACMCF food hazard definition: Microbiological, chemical, and physical. Microbiological hazards can be controlled with some type of heat treatment or other process that prevents, reduces, or eliminates the pathogens. Chemical hazards are not normally affected by heat and other treatments that are used to reduce the microbial contamination of foods and thus, must be controlled by other means (*e.g.*, rejection of incoming materials with high lead levels). Likewise, physical hazards must be controlled in some manner other than by thermal or equivalent treatments. All three types of hazards require that the specific hazard be identified (*e.g.*, bacterial species; mycotoxin identity; foreign matter present, such as glass), a means for preventing or controlling the hazard identified, and the means of control consistently and effectively used. The public health effects of microbial hazards are most often acute, although long-term, chronic effects have been identified (*e.g.*, arthritis). Chemical hazards are most often associated with chronic adverse health affects, although they may also have immediate, acute affects (*e.g.*, excess tin leaching from container lining can cause vomiting). Physical hazards cause acute health affects, such as cuts in the mouth from glass or metal fragments in the food. These hazards are discussed in more detail below.

Microbial hazards—There is a long history of foodborne illness outbreaks associated with microbial contamination of a variety of juices. The public health consequences may be minimal (some gastrointestinal distress), severe (hospitalization, HUS), or fatal. Among the pathogens that have been associated with juices are *E. coli* O157:H7, *Salmonella, Cryptosporidium*, and certain viruses. Identified sources of pathogens include water, fruit, processing under insanitary conditions, and infected workers and food handlers.

Juices, particularly fruit juices, have traditionally not been considered vehicles for human pathogens. Fruit juices, in particular, are acidic, and such acidity generally would inhibit the growth of most pathogens. Over the past few decades, however, it has become well documented that some pathogens have adapted to this acidic environment, making juices susceptible to microbial contamination and subsequent survival of the pathogens in the juice products.

Regarding the comment that pasteurized juices should not be subject to HACCP, is without foundation because ''pasteurized'' products may potentially contain chemical or physical hazards. HACCP systems control all types of food hazards, not just the microbial hazards that adequate heat treatments will control. In recognition of the lethality of the heat treatment that shelf stable and concentrated juice products receive, FDA has modified the pathogen control requirements in § 120.24 for these product groups. This modification to the proposed rule is discussed in detail in the response to comment 140.

Chemical hazards—There is also a history of foodborne illness outbreaks caused by a variety of chemical hazards in foods. These hazards include the presence of tin, lead, and poisonous plant materials. FDA recall data show that additional types of chemical substances with the potential to cause illness or injury have triggered recalls of products from the market (*e.g.*, food ingredients that cause allergic-type reactions such as FD&C Yellow No. 5), cleaning solutions, copper from copper pipe fittings on processing equipment. Symptoms of reported juice outbreaks usually are limited to acute gastrointestinal effects. Chronic effects of chemical contaminants are difficult to assess because long-term monitoring of the health of individuals that experience illness or injury caused by chemical hazards is required and there are no data indicating that this type of monitoring occurs. Some chemical hazards, such as patulin, have known chronic effects of sufficient public health concern that FDA is in the process of issuing guidance documents concerning maximum levels that should be present in foods (Refs. 19 and 24).

Sources of chemical contaminants in juices include packaging materials, plant (botanical) material, processing and cleaning equipment, formulation errors, contaminated ingredients, and contaminated fruit (*e.g.*, patulin in apples). Unlike microbial contaminants, chemical contaminants cannot be destroyed or easily removed from contaminated foods, and thus, appropriate controls must be established to prevent the contamination in the first instance.

Physical hazards—FDA recall data indicate that glass and fragments of other packaging materials frequently cause companies to recall juice products. However, the agency has no data on illnesses or injuries caused by those packaging materials.

(Comment 77) One comment stated that *United States* vs. *Nova Scotia Foods Products Corporation* cannot be read to authorize HACCP controls. The comment maintained that this case cannot be said to support FDA's proposal to impose a complex and detailed regulatory scheme on pasteurized products. Additionally, the comment stated that since FDA cannot demonstrate a need or legal justification for HACCP for pasteurized products, its authority to require recordkeeping and record inspection under such a HACCP program has no statutory basis.

In the response to comment 74, the agency has explained at some length the basis for its reliance on *United States* v. *Nova Scotia Foods*, 417 F.S. 1364, 1368–69 (E.D.N.Y. 1976), *aff'd supra, 568 F.2d 240.* Similarly, in the response to comment 75, FDA has explained at length the legal basis for the recordkeeping and records access provisions of this final rule. In sum, both the rule itself and the recordkeeping provisions are clearly authorized by the act and the PHS Act.

G. Corrective Actions

FDA proposed to require in § 120.10 that processors take appropriate corrective actions whenever a deviation from a critical limit occurs. All corrective actions must be fully documented in records and are subject to verification under § 120.11(a)(iv)(B).

(Comment 78) One comment requested that FDA revise § 120.10(a)(1)

and (b)(3) to remove the wording ''otherwise adulterated'' because it broadens the scope of the rule beyond food safety and the focus of HACCP should be on food safety. The comment further stated that adulteration is covered in part 110 and should not also be covered in part 120.

The agency disagrees that the requested revisions are necessary. HACCP plans only address food hazards that are reasonably likely to occur. Under § 120.3(g) a ''food hazard'' is defined as ''any biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control.'' Thus, a HACCP plan is already focused on food safety. FDA also disagrees that adulteration is addressed exclusively by part 110. In fact, the legal basis for this final rule is, in part an adulteration provision, 402(a)(4) of the act and juice not processed under conditions not complying with this final rule is adulterated (see § 120.9).

(Comment 79) A few comments suggested that in § 120.10(b)(5) the words ''timely validation'' probably should be ''timely verification'' or ''timely review'' and that in § 120.13(a)(3) the term ''verifying'' should be used in place of ''validating'' to be consistent with NACMCF's HACCP guidelines.

The agency agrees with the comments. When there is a process deviation, processors must undertake a review to see if there have been sufficient changes such that a revalidation of the HACCP plan is warranted. The fact that processors have discovered a deviation indicates that the HACCP plan is working. Therefore, FDA is modifying § 120.10(b)(5) to use the term ''timely verification'' and § 120.13(a)(3) to use the term ''verifying.'' As noted previously, the agency is defining the terms ''validation'' and ''verification,'' in § 120.3(p) and (q), respectively.

H. Verification and Validation

(Comment 80) One comment requested that FDA not require a review of consumer complaints in the HACCP program. The comment maintained that review of consumer complaints is untimely because the product has already been processed and reached the consumer. Additionally, the comment stated that consumer complaints, or lack thereof, cannot attest to the effectiveness of a process. Another comment suggested that it should be up to the management to determine which consumer complaints need followup in relation to HACCP compliance. One comment stated that only consumer complaints that indicate a deviation should be held for HACCP review.

The agency disagrees that processors should not review consumer complaints as part of their HACCP programs. The agency recognizes that review of consumer complaints is of limited use as a preventive tool because the consumer making the complaint already has the product. However, such review may alert the processor to a problem that, if resolved, would prevent recurrence of the problem with other consumers. The agency also recognizes that the receipt or absence of complaints does not alone attest to the adequacy of a HACCP system. However, it is FDA's experience that consumer injury or illness complaints can identify problems traceable to inadequate controls at the food processing facility (Ref. 61). Where information that has potential relevance to food safety is available to a processor as a result of its own consumer complaint system, it is entirely appropriate for the processor to consider that information in assessing the adequacy of its HACCP program. FDA concludes, therefore, that processors should evaluate, as part of their HACCP verification procedures, the consumer complaints that they receive to determine whether the complaints relate to the adequate performance of control measures or reveal unidentified hazards.

FDA agrees that it is up to management to determine which consumer complaints need followup in relation to HACCP compliance as part of its verification procedures. This final rule does not require that processors hold consumer complaints for HACCP record review, except as the processor deems necessary as documentation of verification procedures.

(Comment 81) One comment requested that FDA revise § 120.11(a)(1)(iii) by adding at the end of the sentence ''where these are other than standard operating procedures or CCP's'' to clarify that testing required under standard operating procedures or CCP's is not optional.

The agency disagrees that the requested revision of § 120.11(a)(1)(iii) is appropriate. The requested revision would make the testing mandatory as part of verification activities for SOP's and CCP's. This was not the intent of the provision. In the preamble to the proposal, the agency acknowledged the shortcomings of end-product testing as a process control, especially microbiological testing, but encouraged inclusion of testing in HACCP systems where it is appropriate. SOP's and CCP monitoring requirements do not necessarily need to be end-product or in-process tested, except where FDA is requiring end-product testing. Monitoring could consist of ensuring that the product was processed within time/temperature parameters or time/sanitizer concentration parameters. Therefore, FDA is not making the requested modification.

(Comment 82) One comment suggested that verification should include actual times and temperatures taken and recorded and that there should be penalties for noncompliance.

The agency agrees with the comment. Verification activities include timely review of monitoring records in accordance with § 120.11(a)(1)(iv). Monitoring records must include actual measurements (*e.g.,* times and temperatures) in accordance with § 120.8(b)(7), except as exempted by § 120.24. Consequently, verification must include checking the actual measurements that are recorded in the monitoring records. As proposed, the rule has an enforcement mechanism. Specifically, under § 120.9, failure of a juice processor to have and to implement a HACCP system in accordance with part 120 will render the juice products of that processor adulterated under section 402(a)(4) of the act. Penalties for noncompliance are FDA refusing entry to imported products and instituting legal actions such as seizure, multiple seizures, or injunction, against unlawful products or their producers.

(Comment 83) One comment maintained that weekly review of production records is inadequate and suggested that records be reviewed before each batch of product leaves the plant.

FDA disagrees with the comment. The agency stated in the proposed rule that weekly review of HACCP monitoring and corrective action records would provide the industry with the necessary flexibility to move a highly perishable commodity like fresh juice through processing and distribution without interruption, while still facilitating timely feedback of information. FDA notes that the comment provided no information to demonstrate that weekly review of records is inadequate. In fact, weekly record review will quickly indicate whether the HACCP system is out of control on a regular basis, which is a sign that the system is not adequate to assure safety and that revalidation of the system is required. Thus, the agency concludes that weekly review of monitoring and corrective action records is adequate for verification purposes. FDA notes that the requirement for weekly review does not preclude a processor from reviewing

production records on a more frequent basis if the processor wishes to do so.

(Comment 84) One comment suggested that FDA revise § 120.11(a)(1)(iv)(A) to provide for values that are outside critical limits and for which corrective actions are taken (covered in § 120.11(a)(1)(iv)(B)).

The agency disagrees that the requested revision of § 120.11(a)(1)(iv)(A) is necessary because under § 120.11(a)(1)(iv)(B) processors must review records to ensure that the records are complete and to verify that appropriate corrective actions were taken. Therefore, FDA is not making the requested modification.

(Comment 85) Several comments pointed out that the proposed annual validation requirement in § 120.11(b) is not consistent with NACMCF HACCP guidelines. The comments requested that, instead, FDA require validation whenever there are significant process changes or equipment/system failures.

The agency is not persuaded that it should modify the requirement for annual validation. Section 120.11(b) is consistent with the NACMCF HACCP guidelines in that processors must validate their process as needed (Ref. 17). The NACMCF provided as examples whenever there is an unexplained system failure; a significant product, process or packaging change occurs; or new hazards are recognized. FDA has simply defined ''as needed'' as at least annually or whenever any changes in the process occur that could affect the hazard analysis or alter the HACCP plan in any way. Therefore, FDA is not modifying § 120.11(b) as the comments requested.

(Comment 86) One comment requested that FDA not require a processor to validate the HACCP plan any time changes occur in the prerequisite programs. The comment requested that FDA revise § 120.11(b) to delete this requirement.

The agency agrees with the comment. It is rare that a change in SSOP's will make the HACCP plan ineffective. Validation is not a paper exercise and may be time consuming and expensive. Therefore, FDA is modifying § 120.11(b) to delete the proposed requirement. FDA notes that the final rule requires revalidation when there is any change in the process, including a change in the SSOP's, that decreases the effectiveness of the HACCP plan.

(Comment 87) One comment expressed concern that the proposed validation requirements would have the effect of locking producers into one supplier and that this would stop product development and innovation.

The agency does not agree with the comment. All food processors must take safety considerations into account when contemplating changes in their processes, regardless of whether they are operating under a HACCP system. The agency recognizes that validation could be costly if frequent changes are made in the process that could affect the hazard analysis or alter the HACCP plan and, thus, processors may be reluctant to make changes, even if the changes have the potential to improve the process or the safety of the final product. A change in the supplier of raw ingredients may be a change requiring revalidation. However, a prudent processor will check new suppliers before making any changes to determine that the supplier will not be a source of any safety concerns. Because HACCP systems need to be revalidated only when changes in the process occur that could affect the hazard analysis or alter the HACCP plan in any way, not every change will require revalidation. Similarly, because a hazard analysis needs to be revalidated only when there are process changes that could reasonably be expected to affect whether a food hazard exists, not every process change will require revalidation of the hazard analysis. Therefore, FDA concludes that the requirements of § 120.11(b) and (c) are important for the public safety and will have minimum impact on conscientious processors.

I. Records

The agency proposed that processors maintain records documenting their HACCP system. FDA also proposed general record requirements, and other provisions or requirements dealing with documentation, record retention, official review, public disclosure, and records maintained on computers.

(Comment 88) One comment was concerned that the agency was trying to get access to processors' CGMP records under § 120.12(a)(1) and that this could be a disincentive for companies to keep thorough records.

The agency disagrees with the comment. Section 120.12(a)(1) requires that processors maintain records documenting the implementation of the SSOP's in § 120.6. SSOP'S are select CGMP sanitation requirements that the agency believes are so important to the effective implementation of HACCP that they require separate, specific provisions. The agency believes that the sanitation controls in § 120.6 are of significant importance to the proper implementation of HACCP because sanitation controls, such as controls preventing contamination from pests, have a direct impact on the presence or absence of pathogens during processing, which in turn, directly affects the effectiveness of the HACCP plan. Access to specific SSOP records is important to investigators making reasonable judgements about whether the HACCP plan is working properly. Accordingly, the final rule requires that SSOP records must be maintained and made available during inspections. However, the agency has no intention of requiring, and processors need not make available to FDA, any other CGMP-related records.

(Comment 89) One comment recommended that the agency delete from the regulation any reference to records for end-product or in-process testing. The comment stated that individual processors would keep testing records for FDA review only if it is part of the verification of their HACCP plan.

The agency disagrees that any modification of the regulation is necessary and is not making the requested change. The regulation only requires that end-product or in-process testing records associated with verification of the HACCP plan be available for FDA review and thus, is consistent with the comment. As discussed in section III.L.6, the agency is establishing periodic end-product testing requirements for purposes of process verification of citrus juices that use fruit surface treatment to achieve the 5-log reduction in the pertinent pathogen; processors are required to provide FDA with access to these records.

(Comment 90) One comment stated that a processor with only one location should not have to provide its location on all records, as required in § 120.12(b)(1).

The agency agrees with the comment and is modifying § 120.12(b)(1) to read as follows: ''The name of the processor or importer and the location of the processor or importer, if the processor or importer has more than one location.''

(Comment 91) Two comments stated that date and time may not be necessary on all records. One comment contended that the date and time are only important on monitoring and corrective action records and, therefore, should only be required on these records.

The agency believes that the date of the activity is important on all HACCP records. The date allows the processor and the FDA investigator to assess whether the record is current, to identify when any deviation occurred, and to track corrective actions. However, the time of an activity is not necessary on records other than

monitoring and corrective action records (*i.e.*, it is not necessary on the hazard analysis or HACCP plan). Therefore, the agency is modifying § 120.12(b)(2) to state that the time of the activity need not be included on records required under § 120.12(a)(2), (a)(3), and (a)(5).

(Comment 92) One comment suggested that there is no need for the hazard analysis to be signed unless there is no HACCP plan because the hazard analysis did not indicate the need for a HACCP plan.

FDA disagrees with the comment. The signature of the most responsible individual onsite at the processing facility or by a higher level official of the company is important for both the hazard analysis and the HACCP plan. The signature reflects the fact that management has reviewed, accepted, and is responsible for the content of the hazard analysis and any resulting plan. Therefore, the agency concludes that both the hazard analysis and any resulting HACCP plan must be signed.

(Comment 93) One comment suggested that the final rule should allow initialing of records instead of a signature, as is done with low acid canned foods.

The agency disagrees with the comment. The food canning establishment registration and the food process filing form for low acid canned foods both require the signature of an authorized individual. Other low acid canned food records must be signed or initialed (§ 113.100). Part 120 has similar requirements for juice product records. Section 120.12(b)(3) states that all records shall include the signature or initials of the person performing the operation or creating the record. However, given their centrality in a HACCP program, it is important that the hazard analysis and the HACCP plan be reviewed and authorized by the most responsible individual onsite at the processing facility or by a higher level official of the processor so as to signify that management of the firm is aware of and has accepted these records (§ 120.12(c)). Therefore, the agency is not modifying part 120 to permit the initialing of the hazard analysis and the HACCP plan.

(Comment 94) One comment argued that consumer complaints often involve quality issues and are primarily handled at headquarters facilities, not processing plants. Therefore, the comment stated that consumer complaint records should not be part of HACCP recordkeeping requirements.

The agency points out that consumer complaint records are not required to be maintained or access given to them under part 120. Processors are required to review consumer complaints as a part of their verification procedures (§ 120.11(a)(1)(i)) to determine whether complaints relate to the performance of the HACCP plan or to reveal previously unidentified hazards. Processors may choose to include consumer complaints in their HACCP records to document verification of the HACCP system, but it is not required.

(Comment 95) One comment stated that the period that records must be held is out of line with product shelf life because fresh juice only lasts 14 days. The comment suggested that records could be kept for 3 months rather than 1 to 2 years.

FDA disagrees with the comment. Some problems, such as trends in the frequency of process deviations, may not be easily recognized in a ''snapshot'' record review. By reviewing records covering a longer period of time, a processor may be able to identify certain process deviations. Moreover, while it may be true that most fresh products will be unusable within 3 months, some products are processed for longer shelf-life (such as flash pasteurized, refrigerated juices), and retention times of less than 1 year do not provide for sufficient information for the processor's or FDA's verification activities. (See § 120.11(b).) Therefore, FDA has made no changes to § 120.12(d)(1).

(Comment 96) One comment requested that FDA revise § 120.12(d)(1) to read ''Subject to part § 120.14, all records required by this part * * *,'' because there are other importer requirements for recordkeeping outlined in § 120.14.

The agency disagrees with the comment. Section 120.12(d)(1) requires both processors and importers to retain all records required by part 120. Under § 120.12(d)(1), importers must retain the records required under § 120.14 at the importer's place of business in the United States. Therefore, the agency concludes that the modification is not necessary.

(Comment 97) One comment noted that proposed § 120.12(d)(2) requires processors to maintain records related to the adequacy of equipment or processes. The comment stated that if equipment is old or modifications have been made to it, firms may have trouble getting a letter to that effect from the manufacturer. Therefore, the comment stated, scientific studies will have to be performed to determine adequacy, which will be costly, especially for small processors. The comment stated that the requirement is not consistent with parts 113 and 114. It stated that a written communication summarizing requirements to achieve an adequate process would be adequate.

FDA has reevaluated the provision in § 120.12(d)(2) and concludes that it does not afford any additional significant protection to consumers and may add unnecessary burdens for processors. Therefore, the agency is deleting § 120.12(d)(2) and recodifying paragraphs § 120.12(d)(3) and (d)(4) as § 120.12(d)(2) and (d)(3), respectively.

(Comment 98) One comment suggested that FDA restrict recordkeeping requirements to records produced at the manufacturing facility. The comment stated that data used to establish processes should be maintained by the individual or organization that developed the record, not by the processing plant.

FDA disagrees with the comment. It is vital that each processing plant maintain or have access to all records required under part 120, that pertain to products produced by that plant for purposes of both processor review and FDA inspections. The agency has made provision for offsite storage of records, to the extent feasible, to reduce plant storage burden. Specifically, under § 120.12(d)(2), electronic records are considered to be onsite if they are accessible from an onsite location and comply with § 120.12(g). In addition, under § 120.12(d)(2), offsite storage is allowed for certain monitoring records after 6 months following the date that the monitoring occurred as long as the records can be retrieved and provided onsite within 24 hours. Finally, under § 120.12(d)(3), seasonal processors may store records at a reasonably accessible location at the end of the seasonal pack.

Records (such as the hazard analysis, HACCP plans, and verification, including validation, records for products processed in the plant) are needed by both the processor and FDA to determine whether the HACCP system or systems are properly implemented and effective. HACCP systems and associated records may be tailored to each specific processing facility and for different products processed in the facility. Therefore, the agency concludes that all records required by part 120 must be retained at the processing facility to which they relate (or reasonably accessible when offsite storage is permitted) or at the importer's place of business in the United States. As discussed in previous comments, FDA recognizes that processors may review information (*e.g.*, consumer complaints) to develop/evaluate their systems that is not required to be maintained and to which processors are not required to grant FDA

access. Processors may maintain this information at any location that is convenient for the processor.

(Comment 99) One comment pointed out an inconsistency between the preamble to the proposed rule that stated that after 6 months the SSOP and HACCP monitoring and corrective action records could be stored offsite, and the codified language in proposed § 120.12(d)(3) that refers to the storage of SSOP records and the HACCP plan offsite.

FDA agrees that the proposal's preamble and codified were inconsistent. The agency realizes that some juice processors may be required to store records that could require a great deal of space (*e.g.*, the SSOP and HACCP monitoring and corrective action records) and that there may not be adequate storage space in the processing facility for all of these records. However, because of their direct relevance to ensuring safe processing operations at a facility, FDA has concluded that records dealing with the HACCP plan must remain on site for at least 6 months. After that period, such records may be stored off-site if they can be retrieved and returned on-site to the plant within 24 hours so that plant managers and FDA investigators have ready access to the records for use in evaluating the effectiveness of the HACCP plan. Therefore, FDA is modifying § 120.12(d)(2) to refer to paragraphs (a)(1) and (a)(4) instead of (a)(1) and (a)(3).

(Comment 100) One comment requested that FDA delete § 120.12(e) because the agency does not have the statutory authority to see consumer complaints.

The agency advises that consumer complaints are not required records under § 120.12(a) and the rule does not seek to require that FDA be given access to such records. Thus, the agency concludes that no action is necessary in response to this comment.

(Comment 101) Several comments expressed concern about the confidentiality of records associated with an abandoned process. They stated that a manufacturer's processing methods are often considered trade secret even for products that have been abandoned. The comments suggested that the agency make provisions for this in the final rule and handle abandoned product records in the same manner as existing product information. One comment added that current process lines may use technology similar to that used for an abandoned product and that abandoned products may be brought back into production.

The agency advises that the agency intended that proposed § 120.12(f) not permit public disclosure of processing records except where they have been previously disclosed to the public or where they relate to an abandoned product or ingredient and are no longer trade secret or confidential commercial or financial information. FDA acknowledges that the proposal was less than clear as to the status of an abandoned product process. To clarify the final rule, FDA is striking the work ''thus'' from § 120.12(f) so that the trade secret status of a product process may be maintained by the processor and the information not necessarily subject to public disclosure even though the particular product has been abandoned. The public availability of such information will be evaluated by FDA on a case-by-case basis.

(Comment 102) Several comments requested that HACCP documents in FDA's possession not be made available under the Freedom of Information Act (FOIA).

FOIA provides consumers and others with the opportunity to obtain records in the possession of Federal agencies, including FDA, upon request. There are, however, some restrictions on the types of records available under FOIA. For example, confidential commercial information and trade secrets are exempt from disclosure 5 U.S.C. 552(b)(4). The agency concluded in the seafood HACCP final rule (60 FR 65096 at 65138) (Ref. 62), that HACCP plans, as a general rule, meet the definition of trade secret information, and thus, even if these plans are in agency files, they likely would not be available under FOIA. However, because FDA is bound by FOIA and the agency's implementing regulation in 21 CFR part 20, the agency is unable to exclude categorically all HACCP records in agency files from public disclosure.

J. Training

The agency proposed that only individuals trained in HACCP be responsible for certain key functions in a HACCP system. The agency is correcting an error in § 120.13(a)(3), as proposed, so that the section references § 120.10(b)(5) instead of § 120.10(c)(5) because there is no paragraph (c)(5).

(Comment 103) Several comments requested that FDA provide training for the juice industry.

FDA has limited resources to use for training. Therefore, the agency has no plans at present to provide specific HACCP training for the juice industry. However, the agency is interested in cooperating with States and the industry in the development of training programs. FDA worked with the Seafood Alliance to develop a seafood HACCP curriculum and training courses. A similar cooperative effort would be very beneficial in juice processing. Also, the agency is in the process of developing a juice HACCP hazards and controls guide, which will assist juice processors in the development of their HACCP systems.

(Comment 104) One comment questioned whether the agency will acknowledge the equivalency of juice HACCP training, as mentioned in § 120.13(b), offered by other parties (such as a trade association or academic institution) as it did for seafood HACCP. The comment asked how and who would determine training adequacy. Another comment suggested that equivalency of training programs would be better dealt with by establishing training objectives, such as the system used in meat and poultry HACCP, rather than specific materials and curricula.

FDA believes that the development of seafood HACCP training, through the Seafood Alliance, was beneficial for all parties. A basic curriculum was developed, which the agency reviewed, that was available for the industry's use. The agency has encouraged trainers to evaluate their courses against the materials developed by the Alliance and to make modifications necessary to ensure that programs were consistent with and provided at least an equivalent level of instruction to the Alliance course. FDA is very interested in cooperating with all interested parties, including academia, consumer groups, and the juice industry, to develop training programs that incorporate the most appropriate objectives and materials. FDA will acknowledge the equivalency of training in the same manner as is done for seafood HACCP.

(Comment 105) One comment argued that criteria for adequate HACCP training should be left up to the States to determine, but did not provide any support for this opinion. The comment also asked that FDA provide States with guidance and funding to carry out HACCP training for existing State personnel and to certify HACCP specialists.

The agency currently intends to provide training to States, through contracts and State partnerships. The agency recognizes that the effectiveness of juice HACCP hinges on consistent implementation and regulation throughout the United States and training, particularly for investigators, plays an important role in such consistency. As noted above, FDA is interested in cooperative work with

States, academia, and industry to develop training programs.

(Comment 106) One comment stated that individual companies should be permitted to determine when experience can substitute for HACCP training. Another comment argued that experience can never substitute for training, although the comment contained no data or other information to support the claim.

FDA believes that in certain circumstances, appropriate job experience can be an adequate substitute for formal HACCP training. FDA is aware that some juice processors have had successful HACCP programs in place for a long period of time and, as a result, employees working with those systems have gained a working knowledge about HACCP that is more than adequate to meet the training requirement. Moreover, FDA's experience is that other segments of the food industry have HACCP programs in place and employee experience gained working with those systems may be transferred successfully to juice processing. It is the responsibility of processors to determine that their HACCP system is functioning appropriately and is in compliance with part 120, a responsibility that includes ensuring that those individuals involved in designing and implementing the HACCP system are qualified.

(Comment 107) One comment suggested that FDA develop a test to determine whether particular job experience can substitute for HACCP training. The comment asked if FDA is developing such a test.

FDA has no plans to develop a test to determine whether job experience can substitute for HACCP training. Job experience that is equivalent to training gained under an adequate standardized HACCP curriculum is certainly one way that individuals may gain the training required in § 120.13(a). However, as noted, it is the responsibility of individual companies to ensure that qualified individuals conduct the hazard analysis and develop the HACCP plan, whether such individual is qualified through training or job experience.

K. Application of Requirements to Imported Products

The agency proposed in § 120.14 specific requirements for importers of juice products because FDA typically does not inspect foreign food establishments. Under § 120.14 of the proposed rule, importers of juice either must ensure that all juice offered for entry into the United States has been processed in compliance with part 120 or import such juice from a country that has an appropriate memorandum of understanding (MOU) with the United States. In addition, importers must maintain records that document the performance and results of the affirmative steps taken to demonstrate compliance with § 120.14.

(Comment 108) Several comments contended that the juice HACCP regulation should not apply to imports. However, other comments disagreed. A few comments suggested that only imported fresh juice be covered, not juices that have been documented to have been thermally processed to meet the 5-log performance standard.

The agency advises that this final rule will cover all imported and domestic fresh or processed juices. First, under the act, all products in interstate commerce, whether imported or domestic, must adhere to the same standards. Moreover, imported juices may have many of the same potential food hazards as domestic products. FDA discussed outbreaks associated with imported juices in the proposed rule (63 FR 20450 at 20450) (Ref. 2), and some of the recent outbreaks discussed in response to comment 26 were associated with imported juice (Refs. 46 and 47). In addition, imported juices may contain food hazards not normally associated with domestic products. The differences in the types of food hazards may be the function of a number of factors, including differences in processing systems and sources of raw ingredients. The fact that HACCP is based on prevention of specific hazards makes it applicable, in general, to food processing wherever the processing occurs. Therefore, the agency agrees with those comments that stated that the rule must apply equally to imported and domestic juice products, because the potential risks are the comparable. The safety of juice must be ensured regardless of where it is produced.

(Comment 109) One comment suggested that FDA clarify the reference to ''imported food'' in the introductory sentence of § 120.14 to identify that juice is the specifically covered product.

The agency agrees with this suggestion and has revised the introductory sentence of § 120.14 by replacing the word ''food'' with the word ''juice.''

L. Process Controls

1. Performance Standard

The agency proposed to require that juice processors, except those that are subject to part 113 or part 114, include in their HACCP plans control measures that will produce at least a 5-log (10^5) reduction in the pertinent microorganism. As proposed, the pertinent microorganism means the pathogen that is likely to occur in juice and that is most resistant to the pathogen reduction technology used and, if it occurs, is likely to be of public health significance. The proposed reduction must be for a period at least as long as the shelf life of the product when stored under normal and moderate abuse conditions.

(Comment 110) Several comments advocated a regulatory scheme of HACCP without the performance standard proposed by FDA. The comments argued that a performance standard is not necessary to ensure the safety of all products (*e.g.*, citrus). Comments stated that requiring a performance standard negates the strength and function of HACCP and indicates that FDA does not trust HACCP alone. The comments asserted that FDA should require either the performance standard or HACCP, but not both.

The agency disagrees that having the performance standard as an integral part of HACCP weakens the HACCP system. As NACMCF has pointed out, the performance standard enhances HACCP by establishing the appropriate level of health protection that must be achieved (Ref. 25). The 5-log reduction performance standard assures public health protection for consumers and assists processors by establishing a minimum microbial standard for safe juice. Particularly for non-heat treated juice, the 5-log reduction requirement provides a standard against which processors can measure the effectiveness of combinations of HACCP controls. Including a performance standard as part of HACCP sets a goal for processors without mandating the means by which they must achieve that goal and also provides a means of determining the equivalence of alternative strategies for controlling pathogens. Finally, FDA disagrees with the suggestion that a performance standard alone will ensure safe juice. As noted previously, there are hazards in addition to microbial contamination, and a performance standard alone does not address the chemical and physical hazards that may be present in juice.

(Comment 111) Many comments stated that the final rule should identify a safety goal instead of a performance standard and let industry decide how to meet it.

FDA points out that the performance standard in § 120.24 is a microbial safety goal and that the final rule allows the industry to decide how to achieve the safety goal. Elsewhere in this

preamble, FDA has included guidance on the application of the 5-log standard, and FDA also intends to issue a juice HACCP hazards and controls guidance. Both of these forms of guidance are available to the juice industry to help in deciding how to achieve the safety goal. Therefore, the agency concludes that no modification is necessary in response to this comment.

(Comment 112) A few comments suggested that producers who do not use dropped fruit should be able to use HACCP without a performance standard. One comment contended that a 5-log reduction is not necessary when the source of the fruit is known and processors follow CGMP's.

This comment did not provide evidence to persuade FDA that using tree-picked fruit, along with HACCP, would make the 5-log performance standard unnecessary. In fact, produce, in general, including tree picked fruit, may not be pathogen free. Agricultural water, birds, insects, and harvesters are vectors that can potentially contaminate produce even though the produce has not come into contact with the ground. Even if pathogens are present on or in the produce used to make juice, processors can make safe juice by attaining the 5-log reduction performance standard.

(Comment 113) Many comments stated that the 5-log performance standard was not appropriate because processors would have to pasteurize their juice to meet the standard. A few comments stated that the 5-log performance standard is unreasonable, counterproductive, and precludes consideration of harvesting and farming practices that help ensure safety.

The agency disagrees with the comments. The performance standard in § 120.24 allows for the use of alternative technologies. The basis for 5-log is discussed in response to comment 124. As noted in section III.L.4, application of 5-log must occur where the treatment has direct contact with any and all pathogens that may be present. For most juices, this will entail direct treatment of the juice after extraction. For citrus juice only, the available data and information show that surface treatments can be used to meet all or part of the performance standard. In either case, treatments should be applied at a single location under the processor's control and immediately before packaging, in order to prevent post-process contamination of the juice. Although fruit producers and juice manufacturers are encouraged to follow GAP's, GAP's such as water and manure management are generally aimed at minimizing the potential for contamination rather than eliminating pathogens that may be present. Thus, use of GAP's would not be a substitute for the 5-log reduction treatment.

(Comment 114) A few comments suggested that, in addition to the 5-log reduction performance standard, producers should be given the option that Food Safety and Inspection Service (FSIS) gives for fermented sausage, which is batch testing to determine that the product contains less than a certain level of pertinent pathogens and then use a 2-log reduction on the batch tested.

FDA disagrees with the comments' suggestion. Juice is significantly different from a fermented meat product in that a fermented meat product is typically inoculated with bacterial cultures as part of the production process. The growth of the added microorganisms modifies the food environment so that pathogenic bacteria are inhibited or inactivated; there is no comparable inoculation and inhibition activity with juice. Moreover, this process occurs over an extended period of time (3 to 6 weeks is common), which allows time for test results to be completed. Juice, especially juice that is minimally processed, must be processed and consumed within a significantly shorter period than fermented products and, thus, extensive microbial testing of finished, processed products is not practical. Therefore, because there is no counterpart in juice processing to the inhibition or inactivation of pathogens by an added bacterial culture, the agency concludes that batch testing to establish that juice contains a minimum level of pertinent pathogens followed by a 2-log reduction in the pertinent pathogen is not an appropriate substitute for the 5-log reduction performance standard.

(Comment 115) Several comments maintained that there are no data to show that certain combinations of preventive steps are not adequate to ensure juice safety. One comment argued that a combination of grading, washing, sanitation, and current extraction techniques are sufficient to meet the 5-log reduction.

FDA is not prohibiting the use of appropriate cumulative controls to attain the 5-log reduction for citrus products. However, as discussed in section III.L.4, FDA has determined that the 5-log reduction must occur where the treatment has direct contact with all pathogens, if they are present. Further, cumulative controls must be completed in a single production facility under the control of the processor, be effective against the pertinent pathogen, be validated, and be vigorously implemented to ensure that the full 5-log reduction is consistently achieved under commercial processing conditions. GAP's and CGMP's that do not meet these criteria would be in addition to, but not count as part of, the 5-log reduction. The agency notes that it is the responsibility of the processor to demonstrate that combinations of preventive steps are adequate to achieve the 5-log pathogen reduction standard.

(Comment 116) A few comments expressed concern that no attention was being given to preventing the presence of pathogens in juice.

Prevention of pathogens in juice is the reason HACCP was proposed and is being finalized. The agency has always taken the position that food safety is enhanced by the use of the highest quality incoming materials. The agency strongly encourages growers to implement preventive controls and has issued GAP guidance to assist growers in the production of safe produce that is not contaminated. FDA is issuing part 120 to assist processors in establishing preventive controls. Specifically, § 120.7(b) provides that the hazard analysis shall include hazards that can be introduced both within and outside the processing plant environment, including hazards that can occur before, during, and after harvest. In addition, § 120.7(d) requires that processors evaluate product ingredients to determine their potential effect on the safety of the finished food.

(Comment 117) One comment requested that FDA explain how the performance standard applies to each different juice (apple, citrus, vegetable, and blends).

FDA advises that the performance standard in § 120.24 applies to all juice, including blends of more than one type of juice. Processes for attaining a 5-log reduction will vary significantly depending on the target pathogen and the type of juice produced. Therefore, it is up to each processor to determine how best to apply the performance standard to its process. FDA intends to develop a juice HACCP hazards and controls guidance for juice that will provide processors information on the application of the performance standard in addition to that provided in this final rule. The scientific literature is another source of information for processors on recent developments to attain the 5-log reduction for various types of fruits and vegetable juices. Guidance documents from State agencies may also provide information.

(Comment 118) One comment suggested that all processors should be required to meet the chosen performance standard the same way.

The agency disagrees with the comment. FDA specifically chose not to mandate that processors use a particular method to meet the performance standard in order to provide flexibility and to encourage innovation. Different methods that have been validated to meet the 5-log reduction standard can be effective in controlling pathogens to the appropriate level, which is the goal of the performance standard. Mandating a specific technology for processors to use would eliminate the incentive for processors to develop new and possibly improved alternative methods. FDA does not want to limit innovative approaches to achieving food safety or the flexibility for processors to choose the most appropriate method for a particular operation.

(Comment 119) Some comments requested a zero tolerance for *E. coli* O157:H7 in juice. One comment was concerned that the NACMCF may have recommended a higher threshold of risk than consumers would consider acceptable. It stated that there is no acceptable level of risk with regards to *E. coli* O157:H7 because it is so virulent that a single organism could be deadly. The comment sought scientific evidence that the 5-log performance standard will truly kill these organisms, as opposed to represent a reasonable number of organisms killed.

The agency disagrees with the comments. FDA notes that no food processing method can be shown scientifically to achieve a ''zero'' level for a pathogen or any other contaminant potentially present in the processed food due to the detection limits of the relevant analytical methods. For example, the methods used to detect *E. coli* in juice in several State surveys had a detection limit of < 1 cell per 3.33 milliliter (mL) juice. Thus, a negative result does not necessarily mean that the microorganism is not present, just that it is not present at detectable levels. Furthermore, if pathogens are not distributed homogeneously throughout a product, they may be present in the product but not in the sample tested. Conversely, food processing methods can be shown scientifically to reduce, by mathematical increments (*i.e.*, by ''logs''), the level of pathogens that may be present in juice and, as a result, to reduce the risk of illness from juice. FDA has received no comments to undermine the assumption based on the NACMCF recommendation that the 5-log performance standard will adequately protect consumers from *E. coli* O157:H7 and other pathogens.

(Comment 120) One comment contended that a 5-log performance standard is unenforceable and that FDA should set pathogen reduction goals similar to those established for meat and poultry.

FDA disagrees that the 5-log performance standard is unenforceable. The reasons FDA did not set a zero tolerance for pathogens, as was done for certain pathogens in meat and poultry, already have been discussed in the response to comment 114. By virtue of the requirements of part 120, FDA believes that the performance standard is enforceable. That is, as part of their HACCP plan, processors must have a validated procedure for achieving a 5-log reduction in the pertinent pathogen for their process and also must have documentation to demonstrate to FDA that the standard is being achieved. Processors who cannot meet these requirements will not be in compliance with part 120 and thus, will be subject to regulatory action.

(Comment 121) A few comments suggested that FDA use ''safe harbor'' guidelines rather than require the 5-log reduction to ensure juice safety.

The comment did not define the term ''safe harbor.'' FDA assumes, however, that by ''safe harbor'', the comment means that FDA would provide guidance, such as times and temperatures for thermal treatments, that, if complied with, would be deemed to achieve the 5-log reduction, thus providing a basis to conclude that the processor is in compliance with § 120.24. FDA is currently working with industry to develop guidance on how to achieve the 5-log reduction, and has already met with the apple industry and citrus juice industry to discuss technological options for achieving the performance standard. Although the agency is developing guidance to assist processors in achieving the 5-log reduction, FDA does not intend such guidance to provide a ''safe harbor''. Thus, juice processors will not be absolved from adopting HACCP and demonstrating through validation and verification that they have met the performance standard.

(Comment 122) One comment noted the statement in the agency's PRIA statement (63 FR 24254 at 24264) (Ref. 6) that other methods of meeting the performance standard may not be as effective as pasteurization or prevent as much illness seems to indicate an agency lack of confidence in methods other than pasteurization.

FDA disagrees with the interpretation of the PRIA statement. The statement referenced from the PRIA reads ''To the extent that processors adopt controls for these hazards other than flash pasteurization which are less effective, the percentage of cases prevented may be smaller than those estimated here.'' The benefits of the rule with regard to illness prevention were developed based on the amount of illness that would be prevented if all juices were pasteurized because, at the time the proposal was published, pasteurization was the primary effective, commercially implemented method for controlling pathogens in juice that had been validated to meet the performance standard. Since the publication of the proposal, it has become evident that there may be methods other than pasteurization, some of which may require FDA approval for their use, that could be used to treat juice (*e.g.*, use of UV irradiation, high pressure). While it is true that pasteurization treatments significantly exceed the 5-log pathogen reduction performance standard, the statement in the PRIA was not intended to imply that methods other than pasteurization are not effective at preventing illness or that these other methods cannot meet the 5-log reduction performance standard.

(Comment 123) One comment noted that pasteurization would add a complicated and unnecessary step to cider production that will take time and require documentation.

FDA is not requiring in this rulemaking that juice be pasteurized. This rulemaking requires that juice be processed under a HACCP system that contains a control or controls that have been validated to achieve a 5-log reduction in the target pathogen. A juice processor may choose to meet the 5-log reduction requirement by pasteurizing product or by any other validated means. Although pasteurization is the primary option available for cider at this time, this final rule does not preclude the development or use of alternative technologies to achieve a 5-log reduction. For example, FDA recently amended the food additive regulations to provide for the safe use of ultraviolet (UV) irradiation to reduce human pathogens and other microorganisms in juice products (65 FR 71056, November 29, 2000) (Ref. 75). Importantly, however, the processor chooses to meet the 5-log reduction requirement, the process utilized by the processor must be validated and verified as achieving a 5-log reduction in the pertinent microorganism. The risks associated with consumption of cider and other juices are well established (see 63 FR 20450 (Ref. 2) and section II.C of this final rule) and justify regulatory requirements that processors establish controls for pathogens and the other hazards associated with juice.

2. Magnitude of Reduction

(Comment 124) Many comments questioned the scientific basis for the 5-log reduction performance standard. A few comments contended that it was too stringent based on actual numbers of ubiquitous coliform bacteria found in cider in State surveys. In support, a survey submitted as part of a comment questioning the basis of a 5-log reduction standard showed that samples of apples in cider mills in Maryland contained an average of only 3-logs of ubiquitous coliform bacteria and no generic *E. coli* or *E. coli* O157:H7. Some comments asserted that a 5-log performance standard is premature considering that the source of *E. coli* O157:H7 contamination in apple juice is not known and suggested that FDA adopt a 3-log performance standard until scientific data are developed to support the need for a 5-log standard. The comments stated that without data to provide baseline numbers for contamination of juice, any performance standard selected might be inappropriately stringent or lax. The comments maintained that the 5-log standard is particularly excessive if a processor is using CGMP's and only uses prime fruit.

Conversely, one comment suggested that the 7-log performance standard used by other high risk food processors would afford more consumer protection. It suggested that the agency compare the protection offered by 5, 6, and 7 log performance standards because *E. coli* keeps proving to be more resistant to controls than previously thought and because a 5-log reduction may not be adequate for all strains of *E. coli.*

FDA discussed the cider survey results in the response to comment 36. In that discussion, the agency noted the limitations of the analytical methods and advised that the survey results did in fact affirm that risk factors such as fecal coliforms, an indicator of the possible presence of pathogens, are present in cider operations and could give rise to microbial food safety hazards in the finished juice.

In establishing the 5-log standard, FDA is relying on the advice of a panel of recognized food safety experts, the NACMCF. In making this recommendation, the Fresh Produce Working Group of the NACMCF considered various situations that could occur with juice (Ref. 63). First, they considered what levels of *E. coli* might typically occur in juice and added a standard 100-fold safety margin. The Working Group then considered a worst case scenario where produce could be contaminated with bovine feces, a source of *E. coli* O157:H7. They determined that a 5-log reduction would both eliminate the *E. coli* O157:H7 contamination and provide a safety margin. In addition to the information factored into determination of the 5-log reduction performance standard, regulatory precedents were considered. The 5-log pathogen reduction performance standard is used by FDA for *Salmonella* inactivation for in-shell egg pasteurization and by FSIS for inactivation of *E. coli* O157:H7 in fermented sausage. The agency has evaluated the NACMCF advice and concluded that the 5-log performance standard recommended by the NACMCF is the most appropriate standard to ensure that juice is safe.

This pathogen reduction performance standard, in combination with the requirement that measurement of the 5-log reduction begins after cleaning and culling of citrus fruits and, for all other juices, when the treatment has direct contact with any pathogens in the juice (discussed in the response to comment 131), provides adequate public health assurance while minimizing the impact of treatments on the sensory attributes of the juices (Ref. 64). While a 3-log reduction could be adequate under certain circumstances, it does not ensure that juice is safe under all circumstances that may occur. In contrast, the 5-log reduction performance standard has a built-in safety factor that provides additional consumer protection.

In light of the comments, FDA has considered a 6- or 7-log reduction standard and concluded this additional level of reduction is not necessary to compensate for possible future microbial resistance. The 5-log reduction refers to numbers of microorganisms, not resistance of microorganisms. Strains of microorganisms may become more resistant to heat, acid, sanitizers or other controls over time. Because microorganisms are capable of developing resistance, it is critical that juice processors periodically verify and validate their process to determine the continued effectiveness of the process. If resistance occurs, processors may need to make appropriate changes in their process so that their process continues to attain a 5-log reduction in pathogens. Therefore, the agency concludes that increasing the performance standard to attain a greater log reduction is not necessary to compensate for possible future increased resistance of pathogens.

(Comment 125) One comment asserted that a 1000-fold safety factor is not consistent with other performance standards set by FDA, although the comment did not reference any specific performance standards. The comment maintained that a performance standard should be based on actual levels of pathogens found in or on fruit plus a 1- or 2-log safety factor.

FDA has concluded that the 5-log performance standard recommended by the NACMCF is the most appropriate standard to assure that juice is safe. In the response to comment 124, FDA discussed how the Fresh Produce Working Group of the NACMCF arrived at the 5-log pathogen reduction performance standard. This performance standard includes the customary 100-fold safety factor, not a 1,000-fold safety factor as asserted by the comment. Therefore, the agency concludes that the 5-log value is consistent with other performance standards set by FDA and, in fact, was arrived at using the 100-fold (2 log) safety factor the comment suggested.

(Comment 126) Several comments stated that 5-log is not an appropriate performance standard for citrus juice because, in trial studies, researchers have not been able to inoculate fruit with sufficient numbers of microorganisms to measure a 5-log reduction. One comment stated that minimum safety performance criteria should be established for citrus because the likelihood of contamination in citrus juices is not high. However, another comment suggested that a 5-log performance standard would be appropriate for orange juice because it can be attained without heat and a 3-log performance standard would be appropriate for apple juice because this may be the maximum attainable without heat treatment.

FDA proposed the 5-log performance standard based on safety considerations and on the recommendation of the NACMCF (Ref. 63). As mentioned in the response to comment 124, while a 3-log reduction could be adequate under certain circumstances to ensure that juice is safe, the 5-log performance standard has a 2-log safety factor that offers additional consumer protection. In addition, the agency found in its review of performance criteria for other foods, that a 5-log reduction in pathogens is the standard for product safety in several cases (Ref. 63). Although the target pathogen may differ among juice types and, thus, change the specific processing parameters (*e.g.,* temperature, processing time) for attaining a 5-log reduction, FDA maintains that the 5-log performance standard is appropriate for all juices. The one area where FDA has data to suggest differences between citrus juice and other juices is with respect to the

potential for pathogen infiltration. Specifically, the available data show that the potential internalization of pathogens in sound, intact citrus fruit is not likely to present a significant public health risk (see the response to 132). Thus, for citrus juice only, the agency has determined that surface treatments may be used to achieve the 5-log reduction standard. Accordingly, citrus juice processors have an additional option in how to achieve the performance standard (*i.e.,* 5-log reduction), but the standard is the same.

FDA also rejects the comment's implicit suggestion that the performance standard should be based on what is technically feasible. In order to assure safe food, a performance standard must be based on safety, not on whether it is attainable using only certain technologies, such as heat treatment. Presenters at the Florida and California FDA workshops on the 5-log pathogen reduction (November 12, 1998 and November 19, 1998) and FDA research presented at the December 8 to 10, 1999, NACMCF meeting demonstrated that researchers could and had inoculated fruit with pathogens to a level that permits measurement of a 5-log reduction. Therefore, FDA is not persuaded that the performance standard should be different for different produce used to make juice.

(Comment 127) Several comments noted that the 5-log performance standard was chosen by NACMCF and that there was no representative of the fresh juice industry on the Committee. The comments maintained that NACMCF may not have considered written comments that were submitted after the public meeting when making its recommendation.

The NACMCF based its recommendation for a 5-log performance standard for juice on safety considerations, which included a scientific evaluation and rationale for a 5-log reduction standard. FDA reviewed the advice from NACMCF and chose to propose the same standard for HACCP systems for juice because the agency determined that the 5-log standard is supported scientifically. The structure of the NACMCF and the way it functions allow for public comment during the meeting, which comments the Committee considers in developing its recommendations. The fresh juice industry presented their views to the NACMCF during the meeting in question. FDA, on the other hand, typically announces a period of time during which comments related to the public NACMCF meeting may be submitted. In reaching its conclusion to propose a 5-log reduction standard, the agency considered written comments, including comments submitted after the meeting, on the appropriateness of the 5-log reduction standard, along with comments presented at the NACMCF meetings and the NACMCF recommendations.

(Comment 128) A few comments requested that FDA not require small producers to meet the 5-log performance standard until alternatives to pasteurization are validated. The comments argued that pasteurization is too costly for small producers.

The agency understands the small processors' concerns. However, the 5-log reduction is based on safety, and therefore, processors must meet the standard in § 120.24, in their HACCP systems in order for public health to be protected. FDA has documented outbreaks that have been attributed to small processors (Ref. 65). In recognition of the circumstances of small processors, however, the agency is establishing staggered compliance dates such that there is an additional 1 year for small processors and an additional 2 years for very small processors to comply with the HACCP final rule. Importantly, such processors must use the label warning statement if they are not processing their product to achieve the 5-log reduction. FDA believes that this approach does not substantially compromise safety and at the same time provides accommodation to small and very small processors. Therefore, the agency declines to modify the regulation to exempt small producers from the 5-log performance standard.

3. Pertinent Pathogens

(Comment 129) Some comments provided views on the types of microorganisms that should be considered the pertinent microorganism for measuring the 5-log reduction. One comment contended that the chosen target organism must make scientific sense based on their extremes of pathogenic viability across multiple reduction steps. A few comments stated that *Listeria monocytogenes* should not be a target pathogen for the performance standard because there is no history of problems with *Listeria* in juice. However, other comments stated that *E. coli* O157:H7 and *L. monocytogenes* are both appropriate target pathogens, especially because *Listeria* contamination is a risk to pregnant women. One comment also stated that *Salmonella* is not an appropriate target microorganism because it is not as acid-resistant as *E. coli* O157:H7.

FDA has concluded that target pathogens must be chosen on the basis of historical association with a product and the way in which the product is processed. For example, there have been apple juice outbreaks associated with *E. coli* O157:H7, *Salmonella* spp., and *Cryptosporidium parvum. Salmonella species* have been associated with outbreaks from orange juice. The NACMCF recommended the use of *E. coli* O157:H7 or *Listeria monocytogenes* as the target organism, as appropriate. This recommendation is based on the number of known outbreaks of *E. coli* O157:H7 in juice and the ubiquitous nature of *L. monocytogenes.* FDA advises that if *L. monocytogenes* becomes a source of outbreaks in the future, especially affecting pregnant women, then processors must consider whether *L. monocytogenes* should serve as the pertinent microorganism for their product.

Processors must also consider the manner in which they are achieving the 5-log reduction and the microbial resistance to the process. For example, a new technology may be effective in attaining a 5-log reduction of *E. coli* O157:H7 in apple juice, but may allow the survival of *Cryptosporidium. E. coli* O157:H7 is known to be unusually acid-resistant and *L. monocytogenes* is relatively heat-resistant. The 5-log pathogen reduction standard applies to the most resistant microorganism of concern under the processing conditions used. If the microorganism is resistant to a particular treatment and the treatment does not therefore deliver a 5-log reduction in the microorganism, then, obviously, the 5-log reduction standard has not been met. FDA plans to provide additional information in its Juice HACCP hazards and controls guidance to assist producers in identifying the pertinent microorganism for measuring the 5-log standard.

(Comment 130) Several comments requested that FDA clarify how surrogate microorganisms should be chosen to validate cumulative steps used to achieve a 5-log reduction (*e.g.,* use of sanitizers). One comment requested that FDA require industry to use an agreed upon ''cocktail'' of surrogates to validate processes.

FDA advises that surrogates should be equally or more resistant to the processing conditions than is the target pathogen to assure that the process also destroys the pathogen. As noted in the response to comment 129, one treatment may be effective in reducing one type of pathogen but have less or no effect on another. FDA will be providing additional guidance on the selection and effective use of surrogate microorganisms for process validation in its juice HACCP hazards and controls guidance. FDA believes that it is the

responsibility of the producer to validate the processes it chooses to use in manufacturing juice products, including determining appropriate surrogate microorganisms. Therefore, FDA is not requiring use of a ''cocktail'' of surrogates to validate processes.

In choosing and using surrogates, it is important to remember that a cumulative 5-log reduction must be achieved. Therefore, a processor must have evidence that there is a total reduction of 5 logs in the surrogate population and that the same 1- or 2-log reduction is not being counted repeatedly. In other words, if one step reduces the surrogate by 2 logs, the next step must reduce the surrogate by an additional number of microorganisms. In addition, care must be taken that there is no growth of microorganisms between steps.

4. Application of the Performance Standard

(Comment 131) Several comments maintained that, because of the possibility that pathogens may become internalized into fruit (or vegetables), the treatment(s) will need to be applied after the juice has been extracted so that the treatment has intimate (*i.e.,* direct) contact with pathogens. One comment suggested that FDA require at least part of the treatment be applied directly to the juice. Conversely, another comment maintained that, except for warm apples in cold water, the potential for pathogen infiltration is hypothetical. Even then, according to the comment, use of potable water and hygienically maintained tanks could control pathogen internalization despite a temperature differential that could cause water to be pulled into the fruit.

As stated previously, FDA believes that, for all fruits and vegetables, the pathogen reduction control process must begin at the point where the pathogen reduction treatment directly contacts the pathogens. Inherent in the NACMCF recommendation of the 5-log pathogen reduction standard was the assumption that the treatment(s) would be applied in a way that would effectively reduce the entire population of the microorganism of concern by 5-log. In making this recommendation, NACMCF did not contemplate treatments that may eliminate some pathogens while not reaching others, as would be the case for surface treatment of produce susceptible to pathogen internalization. In fact, the NACMCF specifically advised that surface treatments would have little effect on pathogens if they are internalized.

Contrary to the comment, the potential for infiltration is not hypothetical because information and data from the scientific literature demonstrate that, under certain conditions, microorganisms can become internalized. (Refs. 13 and 14) Such internalization may occur through natural plant structures or through decayed or damaged sites on the fruit or vegetable. Water, insects, and birds, all of which may carry human pathogens, can serve as pathogen vectors, resulting in contamination of fruits and vegetables. Internalization may occur before or after harvest although submerging warm harvested fruit in cold water (such as dump tanks and flumes) increases the potential for infiltration into susceptible produce. Similarly, exposing vulnerable external points of fruit or vegetables may also cause water to be taken-up along with pathogens if they are present. Accordingly, for most fruits and vegetables, this means that the pathogen reduction treatment must be applied to the juice after extraction. Moreover, processors should include in their HACCP plans, where appropriate, precautions to avoid or minimize the potential for infiltration (such as by avoiding submerging warm fruit in colder water). In addition, while CGMP's and SSOP's, such as using potable water and sanitary operating conditions during washing, are a base for HACCP, they will not necessarily prevent or correct pathogen infiltration into fruits and vegetables. If pathogens have become internalized in fruit or vegetables, wash treatments, even if conducted consistent with CGMP's, will not eliminate them.

In the case of citrus fruits, FDA considered in the preamble to the proposed rule that the structure of citrus fruits prevented internalization of microorganisms, and thus, for citrus fruits, pathogenic microorganisms are likely to be restricted to the surface of the fruit. As such, FDA tentatively concluded that surface treatments of citrus fruit would satisfy the criterion for direct contact with all pathogens and could, therefore, be counted towards the 5-log reduction standard (see also the response to comment 132).

In response to comments challenging this agency conclusion and in the absence of scientific studies directly on this topic, FDA conducted two studies to determine the validity of its assumption, and made the results available for public comment. The results of one study provided evidence that internalization, survival, and growth of human bacterial pathogens may occur inside oranges. The results of the second study demonstrated that there is uptake of water by oranges and grapefruit when there is a transitory pressure differential between the interior and exterior of the fruit. At the December 1999 NACMCF meeting, FDA asked the NACMCF to consider the potential for internalization of microorganisms by citrus fruits. The NACMCF concluded that it is theoretically possible for microorganisms to internalize in sound, intact citrus fruit under conditions where a temperature differential between fruit and wash water may cause water to be drawn into the fruit. The Committee stated that while this was demonstrated in laboratory conditions, the probability of its actual occurrence under current industry practices was not demonstrated. Accordingly, the NACMCF concluded, based on the available evidence, that the potential internalization and survival of pathogens in sound, intact citrus fruit is not likely to present a significant public health risk.

FDA agrees with the NACMCF conclusion. Importantly, the comments did not provide any data for FDA to conclude otherwise. Thus, the agency is requiring in § 120.24 that the 5-log standard be met by treatments applied directly to the juice, except that citrus juice processors may use treatments to fruit surfaces, provided the 5-log reduction process for citrus begins after cleaning and culling and is accomplished in a single production facility under the control of the processor. (The terms ''cleaning'' and ''culling'' are discussed below in the response to comment 132.)

At the present time, FDA believes that only citrus fruits have been demonstrated to be adequately impervious to internal contamination such that it is reasonable to rely on surface treatments of these fruits, and therefore, use of surface treatments to achieve all or part of the required 5-log pathogen reduction is restricted to citrus fruit. Whenever sufficient scientific data are provided to the agency to establish that, for other fruits and vegetables, it is appropriate to begin the 5-log reduction process at other points than the extracted juice or that establish that surface treatment is no longer an acceptable method to contribute to the 5-log reduction for citrus fruit, FDA will review this conclusion.

(*Comment 132*) A number of comments contained suggestions or asked for clarification about where to start treatment for purposes of calculating the 5-log pathogen reduction. A few comments maintained that processors grading fruit to reduce potential contamination, and processors using other best management practices,

should be able to count these practices towards the 5-log reduction standard. One comment claimed that FDA should allow the measuring of pathogen reduction to begin prior to processing to achieve and count reductions in pathogens from proven sources, such as by cleaning and culling dirty or damaged fruit. Another comment maintained that a 2-log reduction is possible from using tree picked apples instead of drops and that this practice (i.e., excluding drops) should be counted towards achieving the 5-log reduction.

In contrast, several comments stated that the earliest possible point to start counting the 5-log reduction is with clean, sound fruit. One comment maintained that, while overtly damaged fruit carry a greater risk of contamination, apparently sound fruit may also be contaminated and that, therefore, culling is not a screen for microbial contamination.

FDA agrees that food safety is enhanced by the highest quality incoming materials. However, as noted in response to comment 112, FDA does not believe that GAP's (such as using tree picked fruit) or CGMP's (such as washing and culling fruit) are a replacement for the 5-log reduction. Nor can these practices substitute for a portion of the 5-log treatment. Establishment of the 5-log pathogen reduction standard as adequate public health protection was based upon certain starting conditions, including cleaning and culling the produce, and the principal that the pathogen reduction treatment must directly contact the microbiological hazard. As noted, for juice made from fruits and vegetables in which there is a potential for pathogen infiltration, such contact is likely to occur only after the juice has been extracted; for citrus, where pathogen internalization is unlikely under current industry conditions, the 5-log reduction process does not need to start with the extracted juice but may begin with exterior decontamination of fruit after cleaning and culling.

FDA is defining in § 123.3(a) and (f) the terms ''cleaned'' and ''culled'' as described by NACMCF to establish the starting point for surface treatments for citrus. *Cleaned* means washed with water of adequate sanitary quality. *Culled* means separation of damaged fruit from undamaged. For processors of citrus juices using treatments to fruit surfaces to comply with § 120.24, *culled* means undamaged, tree-picked fruit (*i.e.,* USDA choice or higher quality). For all juices, cleaning and culling operations would be part of CGMP's, and fruit being tree-picked is not applicable to the 5-log reduction. This is consistent with the NACMCF recommendation that cleaning and culling of citrus fruits not be considered part of the 5-log reduction of pathogens. The agency notes that all produce used for making juice must be cleaned and culled prior to the start of the 5-log reduction according to CGMP's. However, FDA is defining these terms to clearly set forth the basic starting conditions for the 5-log reduction, especially in regard to surface treated citrus.

(*Comment 133*) One comment suggested developing a standard for fruit for juicing that includes no dropped fruit, no blemishes or dimples, and rinsing with pathogen-free water. The comment suggested that beginning with fruit of a standardized quality would not count toward the 5-log reduction, but would ensure that all processors start with fruit of the same high quality. One comment argued that treatments that can achieve a 5-log reduction in pathogens when applied to sound, clean fruit may be adequate for producing safe product but questioned whether a greater reduction might be necessary if starting with fruit that was dirty or damaged.

FDA is not setting a standard for fruit quality or expressly prohibiting the use of drops in most juices. As with any food, FDA encourages the highest possible quality incoming materials in the production of juice. The Produce Working Group of the NACMCF arrived at the 5-log reduction recommendation by considering a ''worse case'' scenario where fruit was heavily contaminated with feces, as might occur with the use of drops. The Committee concluded that a 5-log reduction treatment would eliminate pathogens and provide a 100-fold safety margin. Thus, FDA concludes that the 5-log reduction applied directly to the juice will eliminate pathogens that may otherwise be introduced by the use of drops. FDA cautions, however, that juice producers that are exempt from or that have not yet adopted HACCP, including the 5-log reduction standard, can reduce their risk of producing contaminated product by avoiding drops and by culling tree picked fruit before extraction.

The agency is establishing a standard for citrus fruit that is treated only with surface treatment. For these juices, drops may not be used. The NACMCF suggested, and FDA agrees, that for citrus juices, only tree-picked fruit should be used, and fruit should be cleaned and culled to be USDA choice or higher quality. Although pathogen infiltration is unlikely in sound, intact citrus fruit, drops and damaged fruit are likely to be more susceptible to pathogen infiltration and, therefore, should not be used for juice that relies on surface treatment.

Furthermore, in some cases, damage incurred when fruit drops to the ground may foster nonmicrobial contamination such as the mycotoxin patulin, which may occur in damaged apples. Patulin, if present in the apples, will not be decreased by the 5-log performance standard. In these cases, the processor must have controls in place to ensure that the final juice does not contain unsafe levels of the mycotoxin.

(*Comment 134*) Several comments urged FDA to define sound fruit. A few comments noted that culling is a subjective process and therefore may not be consistently applied. One comment suggested that the agency establish mandatory common minimum standards and technologies (*e.g.,* black lighting) to ensure consistency in culling operations. Another comment suggested that FDA specify that fruit be culled of unsound fruit before dirty fruit is placed into a flume where it might contaminate sound fruit.

In the case of citrus juice where a surface treatment is used to achieve, at least in part, the 5-log reduction, the agency has specified that the fruit shall be ''culled'' and ''cleaned.'' As noted, these terms are defined in § 120.3. Fruit and vegetable grading criteria (*e.g.,* for USDA choice level or higher, as will be required for surface treated citrus fruit) have been established by USDA. Although there may be some degree of subjectivity in culling citrus fruit, visibly damaged fruit is apparent and is unlikely to meet the requirements for USDA choice level or higher. Application of CGMP's, along with the 5-log performance standard beginning at a point after cleaning and culling of citrus fruit, should overcome any potential risks that may result from subjective processes such as culling.

As stated in response to comment 132, FDA is not setting a standard for fruit where the juice is treated after extraction to achieve a 5-log reduction, although processors may consider including standards for incoming fruit as appropriate to their operations in establishing a HACCP plan. Additional guidance will be provided in the agency's juice HACCP hazards and controls guidance.

(*Comment 135*) Several comments requested that FDA develop a guide for industry that states the log reduction achieved for each potential processing step. A few comments requested that pasteurization guidelines for juice be published in a guide, and one comment asked whether or not heat treatment at

161 °F for 15 seconds results in the appropriate 5-log reduction in juice. Another comment questioned how to calculate a 5-log reduction for banana juice.

FDA plans to publish a juice HACCP hazards and controls guidance to assist the juice industry in implementing these regulations. FDA intends that the guidance will contain pasteurization guidelines and information about achieving the performance standard in other ways. The agency is unable to comment on whether a heat treatment of 161 °F for 15 seconds results in a 5-log pathogen reduction without information about the characteristics of the juice as well as the thermal resistance characteristics of the pathogen of concern. Appropriate 5-log pathogen reduction treatments for specific juices (such as banana juice) will vary, depending on the characteristics of the juice (*e.g.,* acidity, viscosity, percentage of pulp) and processing conditions. Processors may find it necessary to consult additional resources to determine and implement the most appropriate process to achieve the 5-log pathogen reduction, such as information from State public health or agriculture agencies, universities, extension services, and private consultants. The agency emphasizes that it is the processor's responsibility to validate the chosen pathogen reduction process to assure its effectiveness in consistently achieving a 5-log or greater reduction.

(Comment 136) Many comments expressed confusion about the use of cumulative steps to reach the 5-log pathogen reduction requirement. A few comments also requested that FDA clarify exactly what would be required if two different processors perform steps that in the final product add up to a 5-log reduction. A number of comments stated that separating cumulative pathogen reduction steps by time and or by location is not acceptable. These comments argued that such separation provided opportunities for recontamination of product and regrowth of any existing pathogens that had not yet been eliminated in the product, that any multiple step intervention should take place in a single location, and urged FDA to ensure time between treatments is kept to a minimum once an intervention sequence is begun. Several comments on transporting juice between facilities suggested that FDA require that bulk transport juice (*e.g.,* juice shipped in tanker trucks) be pasteurized upon arrival at the final facility because of the potential for contamination during transport.

FDA agrees with the comments expressing concern about the potential for recontamination or regrowth of surviving pathogens if individual treatments designed to achieve a 5-log reduction are separated by time or space. At the December 8 to 9, 1999, meeting of the NACMCF, FDA asked the Committee to consider certain questions about the application of the 5-log reduction standard, focusing on citrus juices. Questions included the impact of separation in time and space between cumulative steps in the 5-log reduction process. The Committee members agreed that separating steps in the 5-log reduction by time, and especially by location, is likely to increase the risk of failure of the pathogen reduction process (Ref. 12). Thus, the NACMCF recommended that all the steps needed to achieve the required 5-log reduction should occur under one firm's control and within a single production facility. These restrictions are designed to reduce the risk of recontamination of juice already processed to achieve all or part of the 5-log reduction. Both time and the act of transportation, between processors, present an opportunity for recontamination. Even if a processor moves product from one building to another within the same facility, this movement must be accomplished under CGMP's and the processor must insure that recontamination does not occur. As noted, there have been several recent outbreaks of microbially contaminated fresh juice; investigation of these outbreaks establish that the concern about recontamination is not just theoretical because the evidence suggests that transportation may have played a role in these outbreaks. In April 2000, FDA was notified by CDC of a foodborne disease outbreak involving over 140 reported cases from 10 States. CDC determined that the illness was caused by *Salmonella* Enteritidis in unpasteruized orange juice, a component of which had been imported in bulk. Previously, in July 1999, an outbreak of *Salmonella* Serotype Muenchen occurred in 15 States and 2 Canadian provinces with over 300 cases reported. Again, the product was fresh orange juice, a portion of which was imported. In this second outbreak, several serotypes of *Salmonella* were isolated from tanker truckloads of juice tested at the United States/Mexican border (Ref. 67).

FDA agrees with the NACMCF recommendations that all the steps needed to achieve the required 5-log reduction should occur under one firm's control and within a single production facility. Although the NACMCF recommendation focused on citrus juice, based on the comments, FDA believes that this recommendation should be extended to all juices. Because of the potential for contamination at a facility over which the final processor/packager has little or no control and because of the potential for contamination during bulk transport, FDA has concluded that there should not be any carryover from one facility to another of any portion of pathogen reduction that contributes to a total 5-log pathogen reduction. If a treated juice is transported to another facility for final packaging or blending and packaging operations, the entire 5-log reduction must be repeated. To clarify this point, the agency is adding paragraph (c) to § 120.24 to state that processors must complete the 5-log performance standard and final product packaging within a single processing facility under CGMP's.

FDA also notes that, for citrus juice producers relying on surface treatments for the 5-log reduction, the single facility criterion also applies to the requirement that processors start with clean, choice or higher grade fruit. Although some juice processors may receive fruit that has been cleaned and graded at another facility, fruit may require additional cleaning and culling to remove any fruit damaged in storage or transit. It is the responsibility of the final juice processor (*i.e.*, the processor at the location where the 5-log treatment will be applied) to ensure that fruit is clean and of appropriate grade before beginning the 5-log reduction.

Even within a single production facility, time between cumulative steps may provide an opportunity for growth or recontamination. Therefore, processors should include in their HACCP plans controls to protect against regrowth of pathogens between steps (*e.g.*, limiting hold time and/or temperature) and to prevent recontamination of the juice during or after processing (*e.g.*, aseptic handling between steps or between treatment and packaging).

FDA also agrees with the concern expressed by comments on the potential for juice to be contaminated during bulk transport. This is an area of particular concern to the agency because, as mentioned above, bulk transport appears to be a common factor in several recent outbreaks. However, the agency has no information nor was any information submitted by comments that the 5-log reduction standard applied to juice in general would not be sufficient to ensure the safety of juice that is shipped in bulk, provided that the transported juice receive the entire

5-log reduction at the facility where it will be packaged. Therefore, FDA is not requiring at this time that juice shipped in bulk between facilities be subject to additional treatment.

(Comment 137) One comment expressed concern that a cumulative process will be more easily overwhelmed by especially dirty fruit than would a single kill-step process. The comment contended that the risk of contamination in a multi-step process is increased over the risk in a single kill-step process because of the potential that contamination can be introduced between steps. One comment expressed concern that validation studies on a cumulative 5-log reduction cannot account for all variables and, thus, meeting the performance standard cannot be guaranteed.

HACCP principles and this final rule require that a processor validate the HACCP plan for its particular process under commercial operating conditions. This validation requirement exists for plans utilizing both single-step and cumulative pathogen reduction controls. FDA recognizes that within a processing system time delays may occur between stages of the treatment; the processor must take any delays into consideration, establish appropriate controls, and validate the HACCP plan for that system. The 5-log reduction performance standard was established to ensure the safety of juice regardless of the pathogen reduction system chosen or the microbial load of the incoming fruit. Furthermore, as discussed in response to comment 132, citrus juice processors using surface disinfection to achieve all or part of the 5-log reduction must start with cleaned and culled fruit as defined in § 120.3 (a) and (f).

(Comment 138) Several comments maintained that juice should be packaged immediately before or after the intervention treatment. One comment stated that a processor could hold and cool a heat treated product before packaging if sufficient controls were in place to preclude recontamination of the product.

As noted earlier, time between cumulative steps and between application of the 5-log reduction and packaging increases the risk of failure (see response to comment 136). Therefore, to reduce the risk of recontamination, juice should be packaged immediately before or after application of the 5-log pathogen reduction treatment. The potential for recontamination between application of the 5-log reduction treatment and packaging (such as might occur when product is held and cooled) should be considered in the development of the HACCP plan and appropriate controls established that are designed to prevent recontamination. Processors not packaging juice immediately after treatment should have sufficient controls in place (*e.g.,* aseptic equipment) to ensure the safety achieved by the 5-log reduction can be consistently maintained.

(Comment 139) One comment asked if the regulation allowed for the application of 5-log reduction to a juice ingredient at any time (*e.g.*, before or after blending). The comment argued that the juice ingredient used to manufacture dairy beverages usually receives a 5-log treatment by the supplier and that the finished beverage is often pasteurized at the dairy.

Juice that is intended for use in further manufacturing is generally shipped in bulk. As discussed in the response to comment 136, the NACMCF recommended and FDA agrees that if bulk transport juice will be repackaged at another facility, the 5-log reduction process must be performed on the juice at the facility where it is packed into final packages. If treated juice is packaged into a bulk-type sterile package, such as a single use sanitary tote, then reprocessing is not necessary unless it is repackaged. If juice shipped in sterile totes is to be repackaged at a different facility, the juice product sold to consumers must be retreated to attain the 5-log reduction at the facility where final packaging is performed. As discussed earlier, separation in time and location increases the risk of failure of the HACCP system, including the 5-log reduction. Therefore, FDA is not providing for carryover of any part of the 5-log reduction when juice, not in its final packaged form, is transported between two facilities.

Juice destined for use as an ingredient in another juice beverage must also undergo a 5-log reduction process. The processor may choose either to treat the juice ingredients before blending or to treat the final product, so long as the entire 5-log reduction is completed in a single production facility under the control of the processor and the processor minimizes time between treatment and packaging.

(Comment 140) Several comments noted that shelf-stable juices are processed well in excess of the 5-log reduction necessary for pathogen control. The comments requested that FDA exempt shelf-stable juice producers from a CCP for pathogen reduction because the shelf-stability of the product is proof that their process greatly exceeds safety performance criteria. Comments also requested that the same consideration be given to concentrated juices.

The agency agrees with the comments and is providing an exemption from the requirements of § 120.24 for shelf-stable and concentrated juices, under specific conditions. Shelf-stable juice products are generally processed at high temperatures in a single step to destroy spoilage microorganisms and enzymes (Ref. 68). These temperatures far exceed what is needed to attain the 5-log reduction in the pertinent pathogen. Therefore, FDA concludes that it is reasonable to exempt a processor of shelf-stable juices from the requirements of § 120.24, if the firm uses a single thermal processing step to attain shelf-stability.

FDA also recognizes that the production of thermally concentrated juice utilizes thermal treatments similar to those used for the production of shelf-stable juices (Ref. 68). A thermal concentration process generally consists of an initial thermal treatment, similar to that used for shelf-stable juices, followed by several thermal evaporation steps. For this reason, the agency has concluded that when a thermal processing step is used before a thermal evaporation process, the processor should be exempt from the 5-log reduction requirement.

Accordingly, FDA is adding § 120.24(a)(2) exempting juice processors using a single thermal processing step sufficient to achieve shelf-stability of the juice or a thermal concentration process that includes thermal treatment of all ingredients from the requirements of § 120.24 (the 5-log reduction requirement). When completing the written hazard analysis as required by § 120.7, processors of shelf-stable and concentrated products using a thermal treatment need not identify pathogens as a hazard that is reasonably likely to occur. To demonstrate that its process is sufficient for the exemption, a processor must include a copy of the thermal process used to achieve shelf-stability or concentration in its written hazard analysis as required by § 120.7.

Shelf-stable or concentrated juice processors are not exempt from the requirement to conduct a written hazard analysis because of the possibility that chemical or physical hazards may be reasonably likely to occur. However, if, based on its hazard analysis a processor exempt from § 120.24 determines that there are no chemical or physical hazards that are reasonably likely to occur in its juice product, then that processor is not required to have a HACCP plan. Juice processors that do not have a HACCP plan need not

comply with the following provisions of part 120:

- § 120.8, HACCP plan
- § 120.10, Corrective actions
- § 120.11(a) (except paragraph (a)(1)(i)), Verification
- § 120.11(b), Validation of the HACCP plan
- § 120.12(a)(3) and (a)(4), Required records
- § 120.24(a) (except paragraph (a)(2)), Process controls
- § 120.25, Process verification for certain processors

FDA anticipates that, in the future, processors making shelf-stable or concentrated juice may use alternative nonthermal processing technologies. While the control mechanism of these nonthermal technologies may eliminate spoilage microorganisms, the effect on pathogens is uncertain. Therefore, the exemption under § 120.24(a)(2) does not extend to nonthermal processes.

5. Validation of the Performance Standard

(Comment 141) One comment stated that the cost of validating a 5-log reduction procedure would be prohibitive to small producers because the validation studies would have to take place in a pilot plant. Another comment stated that processors should be able to validate procedures and critical control limits based on literature reviews, in-plant experience, recommendations from consultants, and routine testing.

The agency disagrees with the comment that argued that validation would be too expensive for small processors because it would have to take place in a pilot plant. FDA notes that validation studies need not occur in a pilot plant. There are several options available to a processor in validating its 5-log reduction procedure and in establishing critical limits. Although it is preferable to establish limits for CCP's and validate individual processes in a pilot plant or in the processing facility where they will be carried out, FDA recognizes that this may not be feasible for small processors. As suggested by the second comment, many alternatives are available. For example, small processors that use identical procedures for producing juice could validate these processes cooperatively. It is also acceptable to use referenced procedures for achieving a particular log reduction provided a processor can demonstrate that the referenced procedure is being followed exactly (or more stringently), as outlined in the literature, and is effective in the processor's operation. Small producers may also elect to use proven technologies (*e.g.,* thermal treatments) that have been extensively validated, and as such can be readily adopted with minimal need to conduct in depth microbiological validation testing.

FDA was unsure what the second comment meant when referring to ''routine testing'' as a way to validate HACCP. It may be that the comment was referring to ''verification'' (*e.g.,* routine testing and monitoring) to ensure that the HACCP plan is functioning correctly, rather than ''validation''. Verification and validation are further discussed in the following section.

6. Process Verification

(Comment 142) Several comments expressed concern about the effectiveness of cumulative steps in meeting the 5-log reduction. One comment pointed out that the efficacy of a cumulative step process for citrus assumes perfect grading and that the interior of citrus is sterile. The comment stated that perfect grading is not possible because pathogens that may have entered the fruit through a microperforation may not be detected and the fruit could have a contaminated interior. The comment also maintained that no steps in the cumulative process described in the proposed rule were designed to prevent reproduction of pathogens in the juice during storage. A few comments concerned about the effectiveness of cumulative treatments argued that FDA should require end-product testing to verify HACCP for all non-pasteurized juice. One comment advocated continuous testing for unpasteurized juice and periodic testing for pasteurized juice. Conversely, one comment maintained that, in most cases, microbial testing is not necessary nor is it the best method for verifying HACCP. However, this comment suggested that microbial testing be required for citrus juice using surface treatments to achieve 5-log since, according to the comment, there are few other steps that can be used to verify cumulative processes that include surface treatment.

FDA's response to these comments requires an understanding of the differences between two HACCP concepts: validation and verification. Verification includes all activities, except monitoring, that establish the soundness of the HACCP plan and that the system is operating according to the plan. Many verification activities, such as process verification, are an on-going (*e.g.,* daily or weekly) part of operating under a HACCP plan. Validation is a subset of verification activities that occurs when a HACCP plan is first set up and whenever significant changes are made that may have an impact on the effectiveness of the system. Validation focuses on collecting and evaluating scientific and technical information to determine whether the HACCP plan, when properly implemented, will effectively control all hazards that are reasonably likely to occur. In contrast, verification assesses whether the HACCP plan, once established, is working properly.

FDA disagrees that microbiological testing of the final juice should be required of all juice manufacturers. If juice is treated to achieve a 5-log reduction in a target pathogen after the juice is expressed, the extent of the reduction (>100,000-fold) in combination with the low levels of pathogens that have been detected in untreated juice would likely result in a post-treatment level of microorganisms that is too low to be detected using reasonable sampling and analytical methods. Moreover, microorganisms are not likely to be uniformly distributed throughout the juice and, accordingly, may not be present in the sample tested even though they are in the juice. This can result in false negative test results. Determination that the product has been adequately treated is more effectively verified by review of the monitoring records for the appropriate CCP. Thus, as a general rule, FDA is not requiring end product testing as part of verification for processes where the juice itself has been directly treated. The exception to this general rule is that processors of citrus juice that use surface treatments to achieve the 5-log reduction performance standard will be required to conduct end product testing to verify that their HACCP system, including the cumulative step 5-log reduction, is operating as it is designed to operate. This verification testing is discussed in more detail below. Of course, even where not required, processors may elect to use end product testing as part of the verification of the HACCP plan.

Conversely, except for techniques like pasteurization, where industry has a long history and experience of using time-temperature parameters as an indicator of microbial destruction, a processor will likely need to conduct studies using samples inoculated with pathogens (or surrogates) to confirm that their HACCP process does result in a 5-log reduction in the pertinent pathogen.

In light of comments expressing concern about the efficacy of cumulative steps, including surface treatment of cleaned and culled citrus fruit, FDA has evaluated the need for additional forms of process verification for some

products. As noted, verification is designed to demonstrate that the HACCP plan is achieving the level of process control intended and thus producing safe food on a continuing basis. Verification is broader than ongoing process monitoring alone. The purpose of monitoring is to measure and document that those identified steps that must operate within specified limits on a continuing basis in order to control a foodborne hazard (*i.e.,* CCP's) are in fact operating within specifications. Ideally, monitoring involves continuous, ''real-time'' measurements so that process deviations can be detected and corrected immediately.

Conversely, verification entails both the periodic review of monitoring data and the acquisition of additional data to assess whether the HACCP plan is functioning as intended. The additional data are not necessarily data relating to a CCP, but could be data relating to another step in a process that reflects the effectiveness of a prior CCP(s) (*e.g.,* sampling of citrus fruit surfaces for levels of acid resistant mesophilic aerobic microorganisms after treatment of the fruit with an acidic antimicrobial wash). Furthermore, since verification data are only acquired on a periodic basis, types of analyses that require too much time to be effective means for monitoring CCP's can nevertheless be highly effective tools for verifying a HACCP plan. Verification activities may include review of CCP-monitoring records; collection of either in-line or finished product samples for microbiological, chemical, or physical analysis; and direct observations of monitoring activities and corrective actions. The frequency of verification activities will vary depending on factors such as the type of process, volume of product, the results of prior monitoring and verification activities, and past frequency of process deviations.

As discussed in detail previously, at its December 1999 meeting, the NACMCF considered at length the effectiveness of surface treatment to eliminate microbiological concerns related to citrus fruits. There has been a continuing question of whether the integrity of the outer surface of citrus fruit is sufficiently impervious such that pathogenic microorganisms cannot enter the fruit. If the surface were sufficiently impervious, surface treatments might effectively reduce the risk from microbiological hazards. The NACMCF (1999) concluded that the potential for the uptake and growth of bacterial pathogens such as *Salmonella* Hartford and *E. coli* O157:H7 by intact citrus fruit is unlikely, given current industry practices, and that surface treatment of intact, healthy citrus fruit should adequately reduce microbiological risks. However, the NACMCF also concluded that under certain limited conditions, internalization of pathogenic bacteria is possible. Further, the NACMCF noted that surface treatments of fruits would have little effect on internalized pathogenic microorganisms (Ref. 12). In addition, although the NACMCF concluded internalization of pathogens in sound citrus is unlikely under current industry practices, FDA research confirmed that if a temperature differential exists between the fruit and wash water, washing may cause internalization of pathogens in citrus and other produce through indiscernible punctures of the skin.

The NACMCF observed that while microbiological testing is seldom effective as a means of monitoring a CCP, such testing can play a role in verifying HACCP programs (Ref. 17). Similarly, the International Commission on Microbiological Specifications for Foods (Ref. 69) has recognized microbiological testing of product as one type of HACCP verification.

In relation to HACCP and citrus juice manufacture, the NACMCF (Ref. 12) recommended that periodic microbiological testing of juice be a component of the HACCP verification activities undertaken by those citrus juice manufacturers who rely on surface treatment of fruit to achieve all or part of the microbiological performance standard (5-log reduction).

Because of continuing questions about the possibility of pathogen internalization and because of the lack of alternative verification steps available for processors using cumulative steps, including surface treatments, to achieve the 5-log reduction, FDA concludes that, for citrus juices that rely solely or in part on surface treatments, periodic microbial testing to verify the effectiveness of cumulative processes is integral to the process control verification. Therefore, in § 120.25, FDA is requiring microbial testing for such juice products. This testing is in addition to verification and validation requirements set forth in § 120.11.

(Comment 143) As noted above, several comments argued that FDA should require microbial testing for some or all juices. Some comments favored microbial testing of finished product but did not specify sampling plans or methods. A few comments suggested that FDA could permit companies to test for indicator organisms because *E. coli* O157:H7 is hard to detect. One comment argued that such a requirement would eliminate the need for a HACCP system.

FDA disagrees with the comment that maintained that end product testing would eliminate the need for HACCP for juice. As discussed in response to comment 142, microbial testing is limited in its ability to detect process deviations in a timely manner, especially for products with a short shelf-life, such as fresh juice.

FDA agrees with the comment that suggested that indicator organisms could be used for process verification. While microbiological testing for specific pathogens might be a direct means of verifying that a surface treatment is effective and that pathogens have not been internalized in the fruit, analyses for individual pathogens can be highly complex. Testing for pathogens also has limitations, including the potential for pathogens to be present at low levels compared to other microorganisms and the detection limit of the test. There is also the question of which pathogens that may be present on the surface of the fruit should be the focus of any testing. For example, testing for *Salmonella, E. coli* O157:H7, and *Cryptosporidium parvum* might be appropriate since all three have been implicated in disease outbreaks related to juices. Another limitation of testing for pathogens is that testing for one pathogen (*e.g. Salmonella*) will not detect another (*e.g., E. coli* O157:H7), even if the second pathogen is present. An alternative would be to select a microorganism whose presence is indicative of a loss of process control. Since all three of the pathogens above are fecal in origin, the ideal indicator microorganism would be one that is indicative of fecal contamination.

FDA has considered several different possible indicator microorganisms and has concluded that biotype I *Escherichia coli* (*i.e.,* generic *E. coli*) is the most suitable indicator microorganism for verifying the effectiveness of surface treatments in attaining the 5-log reduction standard. This microorganism is generally regarded by the scientific community as the best indicator microorganism for processes intended to control fecal contamination (Refs. 15 and 70). When present, generic *E. coli* generally occurs at levels several magnitudes greater than the levels of enteric pathogens that are associated with fecal contamination. Consequently, testing for generic *E. coli* is more likely to detect product where the 5-log reduction standard has not been achieved. Thus, FDA concludes that any citrus juice manufacturer that relies solely or in part on surface treatment of

the fruit to achieve the 5-log reduction performance standard shall, for each different type of juice product produced, conduct analyses of the final product for biotype I *Escherichia coli.*

The next issue is how the analysis should be performed. Historically, the juice industry has used the standard 3-tube MPN (most probable number) method in FDA's Bacteriological Analytical Manual (BAM) for analysis of coliform and *E. coli* in juices. However, this method has several limitations. First, as noted in a paper entitled ''Derivation of Sampling Plan to Meet the Testing Requirement in the Juice HACCP Final Rule for Citrus Juices That Rely Solely Or in Part on Surface Treatments to Achieve the 5-Log Reduction Standard'' (''Surface Treatment Sampling Plan'') (Ref. 71), the BAM method can only analyze a small sample size of 3.33 mL with a detection limit of 0.3 *E. coli*/mL. In addition, the high acidity of some juices, including most citrus juices, can interfere with the detection efficiency of the test. Using an analytical method that can test a larger sample size (*i.e.,* 20 mL) and by including an enrichment step to reduce interference by acidity should improve an analysis for generic *E. coli* and thus assist a citrus juice processor using surface treatments to verify whether the process is achieving the 5-log reduction. Consequently, FDA has developed the method, ''Analysis for *Escherichia coli* in Juices—Modification of AOAC Official Method 992.30,'' to detect the presence or absence of *E. coli* in a 20 mL sample of juice (consisting of two 10 mL subsamples) (Ref. 72). In the future, FDA intends to place this method in the BAM. After publication of this final rule, the method will be available on FDA's Internet site at www.cfsan.fda.gov.

In order to facilitate uniform and effective application of this requirement, FDA has added to § 120.25, specific requirements for sample collection and testing. Under this provision, one 20 mL sample, consisting of two 10 mL subsamples, of finished juice shall be analyzed for the presence of generic *E. coli* from each 1,000 gallons of juice produced per day. If less than 1,000 gallons of juice are produced per day, samples must be taken for each 1,000 gallons produced, or once every 5 working days that the facility is producing that juice, whichever comes first. If either 10 mL subsample is positive for *E. coli*, then the 20 mL sample is recorded as being positive for generic *E. coli*.

In addition to the general corrective action requirements in § 120.10, FDA is also adding requirements in § 120.25 to spell out the specific steps that should be taken if a processor subject to the requirements of § 120.25 finds one or more juice samples positive for *E. coli*. Generic *E. coli* is relatively ubiquitous. Thus, the occasional sample that is positive for *E. coli* does not necessarily indicate that microorganisms of fecal origin are not restricted to the surface of the fruit or that surface treatments are insufficient to assure product safety. Nevertheless, an occasional positive sample should prompt a review of the monitoring records relating to the 5-log reduction standard to determine whether pathogen reduction treatments and post process controls designed to prevent re-contamination are being properly delivered. Because generic *E. coli* is an indicator of fecal contamination, processors finding generic *E. coli* in a single sample may consider testing another sample of the same juice for specific pathogens of concern, such as *Salmonella* and *E. coli* O157:H7, to determine whether, in fact, pathogens are present in the juice. FDA is not requiring pathogen testing for the occasional, single positive for *E. coli*. However, if the review of monitoring records or the additional testing shows that the 5-log reduction has not been achieved, such as a sample is found to be positive for the presence of a pathogen or a deviation in the process or its delivery is found, the processor shall take corrective action as set forth in § 120.10 of this final rule. Corrective action requirements for a single positive generic *E. coli* are set forth in 120.25(d).

More than an occasional 20 mL sample positive for generic *E. coli* is an indication that the HACCP process is not sufficient to assure product safety. Under § 120.25, processors relying in whole or in part on surface treatments of the fruit shall have in place a sampling and testing plan sufficient to distinguish between the occasional positive sample and more frequent positives that are indicative of a failure to deliver the 5-log reduction. One way to distinguish between a chance event and an event that results from other factors (such as a failure to deliver the 5-log reduction) is to examine a defined series of tests and assess whether the unusual happens too frequently to be due to chance alone. FDA has evaluated the available data and information, and based on that analysis, has determined that two positives in any series of seven contiguous tests is an appropriate criterion in a sampling plan designed to signal a citrus juice processor relying on surface treatments that its 5-log reduction standard has not been achieved. This standard would alert processors relatively quickly that their system is not delivering the 5-log reduction and, at the same time, would have a relatively small incidence of ''false alarms'' for processors who are achieving a 5-log reduction. The statistical basis for this criterion is described in the paper entitled ''Derivation of Sampling Plan to Meet the Testing Requirement in the Juice HACCP Final Rule for Citrus Juices That Rely Solely Or in Part on Surface Treatments to Achieve the 5-Log Reduction Standard'' (Surface Treatment Sampling Plan) (Ref. 71).

FDA acknowledges that there were certain limitations in the data it had available to estimate *E. coli* levels that would be expected in juice not treated to reduce pathogenic microorganisms. For example, available data on *E. coli* levels in citrus juice were limited to orange juice. However, FDA believes that the sampling plan set out in the Surface Treatment Sampling Plan (Ref. 71) can appropriately be applied to all types of citrus juice. Orange juice represents a significant portion of the citrus juice market. For those citrus juices that have a lower occurrence of *E. coli* compared to orange juice, using the same sampling plan will provide an equivalent or greater level of food safety assurance for consumers without increasing any burden, such as the risk of false alarms, for processors. Moreover, a single standard sampling plan will simplify implementation and evaluation of HACCP for citrus juice processors using surface treatments. Other aspects of the data, including its limitations, are discussed in the Surface Treatment Sampling Plan (Ref. 71). FDA believes that the assumptions made, based on its review of available data, were sufficiently sound and reasonable to support this sampling plan. Therefore, FDA is specifying in § 120.25(e) that finding two samples positive for *E. coli* out of a series of seven sequential tests indicates that the 5-log reduction was not achieved. As additional data become available, the agency will consider those data and make adjustments in the HACCP regulation or in the Juice HACCP hazards and controls guide as appropriate.

Under § 120.25(e), if a processor finds two positives out of seven tests, the control measures to achieve the 5-log reduction would no longer be considered adequate. This would require immediate action to ensure that no product enters commerce that was produced where the 5-log reduction was not achieved, because inadequately processed juice creates the potential for the transmission of foodbourne

illnesses. In addition, the processors would need to determine the source of the failure and to take steps to correct the failure. Corrective actions must include a review of the monitoring records for control measures to attain the 5-log reduction standard, and the processor must correct those conditions and practices that are not met. If the review of monitoring records or the additional testing shows that the 5-log reduction has not been achieved, such as a deviation in the process or its delivery, the processor shall take corrective action as set forth in § 120.10 of this final rule. The processor should also review the aspects of the HACCP plan relating to the 5-log reduction standard to determine whether the conditions and practices specified in the plan relating to the 5-log reduction standard are being met. If those conditions and practices are being met, and no other source of the problem can be found (*e.g.,* post process contamination), the processor should conclude that the treatment, although delivered as intended, was not able to achieve the intended 5-log pathogen reduction. In such case, the processor shall revalidate its HACCP plan in relation to the 5-log reduction standard.

While the control measures relating to the 5-log reduction standard are being evaluated, and until all corrective actions have been completed, including, if necessary, revalidation of those aspects of the HACCP plan relating to the 5-log reduction standard, the processor must use an alternative process or processes to achieve the 5-log reduction after the juice has been expressed. Processors should consider why the monitoring and verification results are not in accord, such as through an inadequate process or a failure in process delivery, and whether an alternate approach to achieving the 5-log reduction is needed. Once these steps have been taken, processors may again use the validated approach that relies solely or in part on surface treatments rather than the alternative process.

FDA has concluded that two positive *E. coli* samples in a series of seven tests indicate that the control measures to attain the 5-log reduction standard are inadequate and immediate corrective actions are necessary. Two positives in a window larger than seven tests may be due to chance rather than a failure to deliver the 5-log reduction. However, processors may wish to review test results over a larger window as a possible early warning that the process may be approaching failure. FDA intends to provide additional information in its Juice HACCP hazards and controls guide to assist processors in ensuring their review is sufficiently extensive to determine that no trends towards loss of control are occurring.

The agency concludes that new § 120.25 is a highly effective tool for verifying the 5-log reduction standard for processors using surface treatments. In addition, FDA is modifying § 120.11(a)(1) to include new paragraph (vi) to clarify that the activities in § 120.25 are part of the processor's verification activities.

7. Other Issues

(Comment 144) One comment requested that FDA clarify what is meant by moderate abuse conditions. The comment stated that *E. coli* may be less tolerant under these conditions, so moderate abuse could be a kill step for *E. coli*.

FDA discussed what it considered to be moderate abuse in the proposal (63 FR 20450 at 20478) (Ref. 2). FDA acknowledges that in some circumstances moderate abuse such as slightly elevated temperature in an acidic juice may actually decrease the numbers of certain microorganisms. If a processor intends to use a specific period of elevated holding temperature as a treatment, then the processor must validate the treatment as required for any CCP.

(Comment 145) A few comments asked that FDA eliminate the requirement that the 5-log reduction be maintained throughout shelf-life of the product. The comments maintained that there is no risk of recontamination once the juice is bottled.

FDA agrees that there is little risk of recontamination after a juice is bottled if the container is not damaged and the juice is handled under CGMP's. However, because of the importance of attaining the 5-log reduction for juice to be safe, it is reasonable that juice retain this characteristic throughout the period that it is available for consumption by consumers. Therefore, FDA is not amending § 120.24.

(Comment 146) One comment suggested that the performance standard should be phased in as data on meeting the performance standard becomes available. Another comment suggested that initially, a 3-log reduction could be required, then the following year a 4-log reduction would be required and finally a 5-log reduction.

The agency does not agree. FDA is providing ample opportunity to accommodate processors that may have difficulty implementing the 5-log reduction performance standard. First, the agency has required, since the effective date of the juice labeling final rule, that juice be treated to control pathogens (*i.e.*, meet a 5-log reduction performance standard) or bear a warning label statement. Since that same time, FDA also has been working with the juice industry, through workshops and programs, on the development of techniques that meet the performance standard. Finally, depending on their size, processors will have 1 to 3 years to implement this rule because the agency is providing additional time for small and very small businesses to implement their HACCP systems. Therefore, FDA concludes that it has already provided the means and reasonable time for processors to identify and implement available means to meet the 5-log reduction performance standard.

M. HACCP Enforcement Issues

(Comment 147) One comment requested that FDA establish a preapproval system for HACCP including plant registration, filing of HACCP plans, regular inspections, validation and verification of HACCP plans with microbial testing and tracebacks.

FDA believes that a preapproval system for HACCP plans would unduly burden the agency's resources without substantially increasing public health benefits. The effectiveness of a HACCP plan, including monitoring, recordkeeping, and verification, can best be evaluated under actual operating conditions. Therefore, as part of its enforcement plan for juice HACCP, FDA plans to do inspections of juice processing facilities to ensure compliance with the HACCP regulations after they become effective. These inspections will include collection and analysis of product samples for pathogens and other contaminants.

The agency is putting juice processors on notice that FDA is committed to inspecting all high risk firms annually, even before the effective date of this final rule, and intends to include sample collection and analysis as an integral part of that process. In the agency's view, processors of untreated juices, including firms producing citrus juices using surface treatments, fall into the category of high risk firms.

(Comment 148) One comment stated that tracebacks are very important and the need for information relating to origin of the product was not covered in the proposed rule.

FDA agrees that tracebacks are important and believes that the ability to traceback from a foodborne illness outbreak to the source is critical to controlling the size and duration of the outbreak. The source of an outbreak may

be contaminated raw produce or contamination of product during production and distribution. Processors must implement CGMP's to address raw produce suitability for processing and, if there are hazards that are reasonably likely to occur in raw produce, implement HACCP controls for such hazards. The recordkeeping requirements of this rule mandate that all records include the identity of the product and the production code where appropriate. The purpose of these requirements is to ensure that records maintained under part 120 can be readily linked to a product and to the timeframe in which the product was manufactured. Linking a record to a specific product will be especially important when a product must be isolated or recalled. The information required in § 120.12 will help ensure that, when tracebacks are necessary, they can be carried out efficiently.

(Comment 149) One comment suggested that third party inspections should be done to validate HACCP and the results should be publicized.

FDA encourages such self-regulated programs within industry as third party inspections. Validation of the HACCP plan may be done by any individual, including a third party, that has been trained in accordance with § 120.13. The validity of the HACCP plan will ultimately affect the overall compliance status of firms, as determined through the inspection process. This status is public information.

(Comment 150) One comment suggested that FDA should model its HACCP regulation after that of FSIS with more frequent and less lenient inspections and validation testing.

Differences in the way FDA and FSIS implement their HACCP programs are due to differences in the products being regulated. Also, FSIS's authority and funding provides for the presence of inspectors in meat and poultry plants on a daily basis, whereas FDA's authority and resources do not require or allow for such frequent inspections. FDA, to the extent it is able, will work with juice processors during inspections to properly implement part 120.

(Comment 151) A few comments questioned whether FDA was planning to ask states to enforce the HACCP regulations in light of the agency's limited resources. Another comment stated that the States should verify compliance with any applicable safety regulations.

FDA cannot mandate that a State ensure that a firm is complying with FDA regulations. However, FDA has a long history of working cooperatively with the States to enforce food safety regulations, and the agency hopes to continue these cooperative relationships with States in the context of juice HACCP. FDA notes that some States adopt FDA requirements as their own laws and regulations; with those States, the final rule will effectively be enforced by the States.

(Comment 152) One comment requested that first inspections of HACCP systems be nonregulatory.

The agency recognizes the benefits of a nonregulatory (*i.e.*, educational) first inspection of implementation of a new HACCP system. For the seafood HACCP program, FDA elected to make the first inspection educational, rather than regulatory, as long as there were no urgent public health problems. FDA chose that approach because, for most processors, the first inspection provided the first direct feedback from the agency on the status of the firm's HACCP system. FDA will consider whether the same approach is warranted for some or all juice processors.

(Comment 153) One comment questioned the type of training that FDA would be providing its investigators to ensure that they understand the relevance of microbial data and that they will not go on ''witch hunts'' to find something wrong with the facility.

FDA's food processor investigators have considerable experience with HACCP in that most are currently conducting seafood HACCP inspections. Investigators are trained to look for violations of FDA regulations and to employ discretion and good judgment (*e.g.*, consider the significance of the violation) in determining how inspectional findings are handled. Further, an investigator's significant inspectional findings are reviewed by multiple higher level FDA employees to confirm the violation prior to the initiation of any regulatory action by the agency.

N. Miscellaneous Issues

(Comment 154) One comment suggested that FDA develop a juice HACCP pilot program.

FDA currently has a HACCP pilot program that includes juice processors. To date, two pasteurized juice processors and one fresh juice processor have completed the HACCP pilot program. FDA has used experience gained from the participation of these juice processors in the HACCP pilot program in proposing and finalizing this rule (Ref. 73).

(Comment 155) Several comments stated that FDA should not impose regulations on industry that will scare consumers into buying only certain foods (i.e., pasteurized juices).

It is not the aim of this rulemaking to scare consumers into buying only certain foods, such as pasteurized juices. However, juices have been the source of a number of outbreaks of illness and the death of one child, as well as have contributed to the death of an elderly man. Juices have also been the source of chemical and physical contaminants that have adverse public health effects, such as high lead levels, the presence of patulin, and the presence of glass pieces. For these reasons, the agency has determined that measures are necessary to ensure that juice is safe and to prevent additional illnesses and deaths, particularly among at risk groups. The primary purpose of this rulemaking is to protect the public, not scare them. FDA believes that these measures will promote public confidence in the safety of juice products.

IV. Effective Date

FDA proposed that any final rule based on the proposal become effective 1 year after its date of publication in the **Federal Register**. Further, FDA proposed that any final rule based on the proposal would not be binding on small businesses as defined in § 120.1(b)(1) until 2 years after publication in the **Federal Register**; and for very small businesses as defined in § 120.1(b)(2), the final rule would not be binding until 3 years after publication in the **Federal Register**.

(Comment 156) Many comments expressed concern that small businesses have the longest time to comply with the rules, even though outbreak data indicate that these producers are most likely responsible for producing contaminated juice.

The agency considered, in the HACCP proposal, the various issues surrounding the need for processors to immediately implement HACCP programs and the need to consider options to minimize the burden of the cost of implementation to small businesses (63 FR 20450 at 20463) (Ref. 2). To address the most immediate concerns (*i.e.*, pathogens) with juice, FDA has since finalized the warning label statement regulation in § 101.17(g) and has engaged in extensive education to alert consumers to the problems of consuming untreated juice. All juice shipped in interstate commerce or made from ingredients shipped in interstate commerce, including that produced by small businesses, that has not been processed to achieve a 5-log reduction in pathogens must be labeled with a warning for consumers (§ 101.17(g)). Thus, even if not produced under a HACCP system, the products of these

small businesses will have some safeguards to protect public health. In addition to the label warning requirement, FDA encourages processors to implement a HACCP system as soon as possible to reduce hazards in juice rather than use the warning label statement. Consequently, the agency has decided to focus initial implementation of HACCP on processors that produce the largest quantity of juice and thus have the potential of affecting the largest number of consumers should contaminated product reach the marketplace.

(Comment 157) Several comments requested that the regulations become effective for all processors 1 year after the rule is finalized and several comments requested that the regulations become effective for all processors 2 years after the rule is finalized.

The agency disagrees with the comments. As noted, FDA considered various options for the implementation of the effective date in the proposed rule. The final rule requires that the bulk of juice produced in the United States will be processed under a HACCP system within 1 year. The agency realizes that it may take longer for small and very small businesses to fully implement HACCP systems and has extended the effective date for one or 2 years, respectively, to give them adequate time to comply.

V. Final Regulatory Impact Analysis

A. Introduction

FDA has examined the impact of this final rule under Executive Order 12866. Executive Order 12866 directs Federal agencies to assess the benefits and costs of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). Under the Executive Order, a regulatory action is ''significant'' if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million; adversely affecting some sector of the economy in a material way; or adversely affecting competition or jobs. A regulation is also considered a significant regulatory action if it raises novel legal or policy issues. FDA finds that this final rule is a significant regulatory action as defined by Executive Order 12866.

The Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121) defines a major rule for the purpose of congressional review as having caused or being likely to cause one or more of the following: an annual effect on the economy of $100 million; a major increase in costs or prices; significant effects on competition, employment, productivity, or innovation; or significant effects on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. In accordance with the Small Business Regulatory Enforcement Fairness Act, OMB has determined that this final rule is a major rule for the purpose of congressional review.

In addition, FDA has determined that this rule is not a significant rule under the Unfunded Mandates Reform Act of 1995 (UMRA) requiring benefit-cost and other analyses. Under UMRA a significant rule is defined as ''a Federal mandate that may result in the expenditure by State, local and tribal governments in the aggregate, or by the private sector, of $100,000,000 (adjusted annually for inflation) in any 1 year''.

This Final Regulatory Impact Analysis reflects changes made in the regulation from the proposed rule to the final rule and changes in estimates as a response to comments. It also includes responses to comments on the PRIA. Where there were no changes in the estimates provided in the PRIA, the estimates are summarized here. Interested persons are directed to the text of the PRIA (Ref. 6) for a fuller explanation of the estimates over which there was no controversy or changes. The PRIA discussed a number of regulatory alternatives. FDA received some comments on these alternatives, however, none were specifically economic in nature. Thus, FDA's responses to comments on these alternatives are given in section III.1. There were no specific economic comments on the regulatory alternatives outlined in the PRIA.

B. Factors Considered in Developing This Analysis

This final rule requires all juice processors (as defined in the rule), regardless of size, to implement a HACCP program with a 5-log reduction (that is, a 100,000-fold reduction in pathogens) performance criterion. In the proposed rule, FDA tentatively exempted retailers. In addition, FDA tentatively decided to exempt as retailers very small businesses that make juice on their premises and whose total sales of juice and juice products do not exceed 40,000 gallons per year and who sell directly to consumers and other retailers. Based on the comments and other information, FDA has determined that it is necessary to cover such very small businesses. The estimated benefits and costs for this final rule reflect this change in the coverage of the rule.

Table 1 gives the time to the effective dates by size of firm in terms of time from the date of publication of this final rule.

TABLE 1.—TIME TO EFFECTIVE DATE BY SIZE OF FIRM

Firm size	Time to effective date
Large firms	12 months.
Small firms	24 months.
Very small firms	36 months.

For purposes of this rule, the agency is defining large processors as those who have more than 500 employees, small processors as those who have less than 500 employees and very small processors as those who have: (1) Total annual sales of less than $500,000, or (2) that have total annual sales of greater than $500,000 but total annual food sales of less than $50,000, or (3) that employ fewer than 100 full-time equivalent employees and annually sell less than 100,000 units of the juice in the United States.

This rule follows the implementation of the juice labeling rule, which covers juice that is packaged and has not been subjected to a 5-log reduction treatment. Because the coverage of the juice labeling rule and this juice HACCP rule overlap, and because to some extent both rules address microbial hazards associated with juice, it is necessary to take into account the benefits and costs estimated for juice labeling to avoid double-counting benefits and costs for juice HACCP.

C. Benefits

This analysis provides estimated benefits due to reduced adverse health effects. Presented here is a summary of the analysis provided for the proposed rule. Comments are addressed, and any changes from the analysis for the proposed rule are detailed in each section as appropriate.

FDA uses the following steps to estimate health benefits:

1. The most significant hazards in juice are described in terms of severity and duration;

2. The hazards are described in terms of resulting health effects and symptoms when they cause illness;

3. The health effects and symptoms are translated into consumer utility losses;

4. The utility losses are translated into values in terms of lost dollars (this gives the cost per case for every combination

of level of severity and for the specified duration for each hazard);

5. The average annual number of reported cases associated with juice covered by this final rule are listed;

6. The factors used to account for under reporting of foodborne illness are explained;

7. The estimates of the average annual number of cases are given;

8. The estimated number of cases is divided according to level of severity;

9. The percentages of each type of hazard expected to be prevented by the proposal are listed; and

10. The total health benefits of the proposal are derived by multiplying steps 4, 7, and 8.

That is, TB = RC x CF x CR x V, where

TB = total health benefits in dollars,

RC = number of reported cases,

CF = under reporting correction factor,

CR = percent of cases reduced,

V = dollar value per case averted (medical costs + value of pain and lost function).

One comment stated that FDA had underestimated the amount of untreated juice consumed and, therefore, had underestimated the number of cases of illness associated with juice. FDA disagrees that the cases of illness addressed by the rule have been underestimated due to incorrect consumption estimates. FDA did not estimate the number of illnesses based on consumption. Instead, the agency estimated the number of illnesses by multiplying confirmed illnesses associated with juice by factors accounting for under-reporting of foodborne illness. Thus, FDA does not agree with this comment.

One comment questioned the model used to calculate benefits and asked if it has been ''calibrated.'' The comment did not explain how the word calibrated is used in this case. FDA assumed that it meant to compare the estimates obtained using this model with the actual number of illnesses related to juice. FDA has used this model to calculate benefits for rules involving microbial hazards since 1994. The model is an adaptation of peer-reviewed research on estimating the costs of illness and injury (Ref. 74). The model is the best method known to FDA for estimating the benefits of rules involving microbial hazards, and is similar to that used by FSIS for similar rules. Because the actual number of cases of illness is not observable, it is not possible to compare the model's estimates to the actual number of illnesses.

1. Description of Microbial Hazards in Juice

The most significant health risks associated with juice products are those that result from microbial contamination. There are other non-microbial potential hazards related to juice that this rule is designed to control. FDA does not have enough data to quantify benefits for these non-microbial hazards. From 1992 to 1998 the hazards associated with commercially processed, packaged juice produced by nonretail establishments included *Bacillus cereus, Cryptosporidium parvum, E. coli* O157:H7, and *Salmonella* non *typhi*. Most of the information in section C of this document (Benefits) is taken from ''Appendix: Preliminary Investigation into the Morbidity and Mortality Associated with the Consumption of Fruit and Vegetable Juices'' (Ref. 6, the Appendix). The Appendix includes hazards other than those for which benefits have been estimated in this analysis. The hazards considered in section C of this document are those for which the risk is highest, meaning that they are the most significant in terms of probability of occurrence and/or severity of outcome.

Some comments stated that *C. parvum* should have been included in the estimate of benefits for the HACCP proposal. The comments cite FDA's inclusion of *C. parvum* in the list of hazards in the Appendix. FDA included *C. parvum* as a hazard addressed by the labeling rule but not as a hazard addressed by the proposed HACCP rule. The only documented cases of juice-related *C. parvum* illnesses from commercially produced products from 1992 to 1996 were from juice produced by processors making less than 40,000 gallons per year. Because these processors were included under the retail exemption from the proposed HACCP rule, the proposed HACCP rule would not have addressed the *C. parvum* hazard. Because this final HACCP rule covers all processors regardless of the volume of juice they produce, *C. parvum* is a hazard addressed by this final rule.

2. Description of Health Effects and Symptoms of Microbial Hazards in Juice

In order to quantify the loss (disutility) that individuals experience from becoming ill, the pain, suffering, and mobility loss must be scaled. Individuals who become ill suffer losses of functional status in terms of mobility, ability to do other physical activity, and ability to engage in social activities. Individuals who become ill also experience additional losses from the symptoms of the illness.

One comment stated that symptoms and functional effects associated with some cases are more severe than those described by FDA. FDA agrees with this comment. However, it is equally true that symptoms and functional effects associated with some cases are less severe than those described by FDA. The symptoms and functional effects described by FDA were developed with the assistance of medical doctors at FDA and are those of a typical case for each level of severity for each hazard. Effects vary to a considerable degree across cases of any illness or disease. Such variance is not captured by this analysis. However, FDA believes that the use of typical cases is appropriate for this analysis.

3. Utility Losses From Microbial Hazards in Juice

Decreases in functional status and symptoms and problems associated with illness translate into values of disutility. Utility losses for survivors are derived by multiplying the total disutility per day by the number of days that symptoms of the illness persists. This gives the utility loss for survivors in terms of the number of quality adjusted life days (QALD's) for each case of the categories of severity for each hazard. A QALD is a day of perfect health.

4. Value of Losses From Microbial Hazards in Juice

FDA values a QALD at $630. The value of utility losses for survivors comes from multiplying the number of QALD's lost due to the illness by the value of a QALD. This represents the value of pain and function losses that individuals experience. Additionally, there are the societal costs of medical treatment. These costs are shared generally between insurance companies and individuals. They include all aspects of medical expenses (*e.g.*, physician visits, laboratory tests, prescriptions and therapies, hospital stays). The value of losses per case is the sum of the value of utility losses for survivors and the medical costs for the categories of severity for each hazard.

5. Distribution of the Reported Cases per Year for Microbial Hazards in Juice

The analysis for the proposed rule used the average number of reported cases from 1992 through 1996 for each hazard for the types of products covered by the rule.

Some comments claimed that FDA had miscalculated the benefits of the HACCP proposal by including outbreaks associated with non-commercially

produced juice. Although other parts of the proposed rule and the Appendix refer to outbreaks associated with non-commercially produced juice, the estimate of the benefits of the HACCP rule was based only on outbreaks associated with commercially produced juice.

Some comments stated that FDA had miscalculated the average number of cases per year. These comments used data presented in the Appendix to recalculate the average number of cases per year. The comments were confused because the Appendix lists several outbreaks that were associated with non-commercially produced juice. Because this regulation covers only commercially produced juice, outbreaks associated with non-commercially produced juice were not included in the calculation of the average annual number of cases. Thus, the average annual number of cases was properly calculated.

Tables 2 and 3 should clarify which outbreaks FDA has used in this analysis, and why some outbreaks were not used.

TABLE 2.—JUICE OUTBREAKS (1992 TO 2000) USED TO CALCULATE BENEFITS

Product and year of event	Hazard	Number of cases	Source of data on event
Orange juice, 1994	*B. cereus*	85	FDA recall data.
Orange juice, 1995	*Salmonella spp.*	62	Outbreak data.
Apple juice, 1996	*E. coli* O157:H7	70	Outbreak data.
Apple juice, 1996	*E. coli* O157:H7	14	Outbreak data.
Apple juice, 1996	*C. parvum*	31	Outbreak data.
Apple juice, 1996	*E. coli* O157:H7	1	Pennsylvania State Health Dept.
Orange juice, 1999	*Salmonella muenchen*	423	Outbreak data.
Apple juice, 1999	*E. coli* O157:H7	9	Oklahoma State Health Dept.
Orange juice, 2000	*Salmonella enteritidis*	88	Outbreak data.

TABLE 3.—JUICE OUTBREAKS (1992 TO 2000) NOT USED TO CALCULATE BENEFITS

Product and year of event	Hazard	Number of cases	Source of data on event	Reason not included
Orange juice Mixing Compound, 1992.	*Salmonella agona*	25	FDA recall Data	Orange Julius compound is mixed with juice at the retail location but does not contain juice.
Apple juice, 1993	*C. parvum*	160	Outbreak Data	Juice not made by commercial establishment.
Juice flavored Drinks, 1993.	*C. parvum*	Unknown	FDA recall Data	Approved municipal water supply was contaminated, rule not expected to prevent such occurrences.
Carrot juice, 1993	*Clostridium botulinum*	1	Washington State Health Dept.	Home-made product.
Orange juice, 1993	Unknown	23	Ohio State Health Dept.	Contamination likely caused by consumer.
Watermelon Juice, 1993.	*S. spp.*	18	Florida State Health Dept.	Home-made product.
Apple juice, 1996	*E. coli* 157:H7	6	Outbreak data	Juice not made by Commercial establishment.

Some comments claimed that FDA's analysis had not taken into account the efforts to control hazards made by the industry after the October 1996 outbreak. To estimate the number of illnesses that the proposed rule would prevent, FDA used the most recent 5-year period for which final CDC numbers were available. In the analysis of the proposed rule, FDA did not include 1997 in the estimate of illnesses that the rule would prevent because there was too great of a possibility that illnesses that had actually occurred had not yet been reported. FDA can now add the 1997 to 2000 experience to the 1992 to 1996 experience. By doing so FDA addresses this comments concern. The average number of cases reported per year for each hazard is described in table 4.

TABLE 4.—AVERAGE REPORTED CASES PER YEAR FOR MICROBIAL HAZARDS IN JUICE (1992 TO 2000)

Hazard	Average No. of cases reported per year
B. cereus	2
C. parvum	3
E. coli O157:H7	10
Salmonella (non-typhi)	64

6. Estimates of Factors Needed To Offset Underreporting of Foodborne Illness

It is widely recognized that the total number of foodborne illnesses is much greater than those numbers reported to the CDC. In order to compensate for the rate of underreporting, the number of known cases associated with a hazard (*i.e.*, reported to CDC) is multiplied by factors that are estimated to account for underreporting.

One comment took issue with the underreporting correction factors used by FDA. The comment stated that no underreporting correction factor should ever exceed 100. In the analysis accompanying the proposed rule, FDA used two estimates of underreporting correction factors that have been widely cited on this issue. FDA does not agree that underreporting correction factors should never exceed 100. The appropriate correction factors are those based on the best information available, without any limit created by a predetermined number.

Since the PRIA, CDC has published estimates of foodborne illness; in this final estimate of costs and benefits, FDA

is relying on these recent CDC estimates. The estimates of underreporting correction factors used in the PRIA relied heavily on research that was over 20 years old. In some cases, the research preceded the recognition that *E. coli* O157:H7 was a pathogen. The correction factors based on this research required a significant amount of adaptation, extrapolation and interpolation by FDA. By relying on the recent CDC estimates of foodborne illness to determine correction factors, FDA is reducing its reliance on dated research and its own extrapolations. FDA believes that the estimates of benefits based on CDC estimates of foodborne illness should be more objective.

The underreporting correctiion factors calculated from the CDC reported by Mead et al, show the relationship between estimated total cases and culture-confirmed total cases. The factors are based on surveys estimating the probability that: (1) A person who becomes ill seeks medical care, and (2) the probability that the physician will obtain a stool culture from the person, and (3) the probability that the laboratory will test for the pathogen. The factor for a particular pathogen is the inverse of the multiplicative product of those three probabilities. FDA is relying on the CDC point estimates of the average number of cases per year and the CDC underreporting factor. Because CDC did not provide ranges for these estimates, FDA has insufficient information to probide a range of estimates for the benefits of this rule. FDA's use of a point estimate for the number of illnesses should not, however, be interpreted as implying the absence of uncertainty about these estimates.

For two of the hazards in this analysis, *E. coli* O157:H7 and *Salmonella*, FDA has used correction factors based on the ratio of total estimated cases to active surveillance cases estimated. FDA has used these factors for these hazards because the juice outbreaks for these hazards associated with this rule were discovered through the active surveillance of the FoodNet system. The FoodNet system is designed to identify interstate outbreaks and to more thoroughly discover cases associated with an outbreak.

For *B. cereus* FDA has used a correction factor based on the ratio of total estimated cases to reported outbreak cases. FDA has used this factor for this hazard because the juice outbreaks for this hazard associated with this rule were discovered through the standard outbreak reporting process. *B. cereus* is not a hazard tested for in the FoodNet system, and because of its mild symptoms is very likely to be underreported.

For *C. parvum* FDA has used a correction factor based on the ratio of total estimated cases to 10 percent of the estimated passive surveillance cases. According to CDC, reported outbreak cases account for only 10 percent of the cases accounted for through passive surveillance. FDA has used this factor for *C. parvum* because the juice outbreaks for this hazard associated with this rule were discovered through the standard passive surveillance process. *C. parvum* is not a hazard tested for in the FoodNet system, nor is it on the list of hazards reportable to CDC. Because of its mild symptoms it is very likely to be underreported.

The correction factors used in this analysis are given in table 5.

TABLE 5.—ESTIMATES OF FACTORS NEEDED TO OFFSET UNDERREPORTING OF FOODBORNE ILLNESS

Hazard	Correction factor
B. cereus	380
C. parvum	1,071
E. coli O157:H7	20
Salmonella (non-typhi)	38

7. Estimates of Juice-Associated Cases Per Year

In table 6, FDA has estimated ranges of the likely annual number of cases that occur for each of the four pathogens studied.

TABLE 6.—ESTIMATE OF JUICE-ASSOCIATED CASES COVERED PER YEAR

Hazard	Case
B. cereus	3,420
C. parvum	3,210
E. coli O157:H7	200
Salmonella (non-typhi)	2,430

8. Estimate of Juice-Associated Cases per Year Not Prevented by Labeling Rule

FDA estimated that the juice labeling rule would prevent up to 140 juice-associated illnesses (10 *C. parvum*, 40 *E. coli*, 90 *Salmonella*) as consumers avoid consumption of untreated juice. This HACCP rule will effectively supersede the labeling rule for all those processing establishments covered by the labeling rule. Therefore, once it goes into effect, the HACCP rule will be responsible for prevented juice-related illnesses and not the labeling rule. However, this analysis should attribute to the juice HACCP rule prevention of only those illnesses that would not have been prevented by the juice labeling rule had this rule not superseded it. To estimate the potential benefits of this HACCP final rule, FDA subtracted 140 cases that were estimated to be prevented by the labeling rule (assuming that 16 percent of consumers read the label and do not consume untreated juice) from the estimates provided in table 6. The 16 percent consumer response estimates are the largest estimates of consumer response that FDA has made for the juice labeling rule. Therefore, subtracting the 16 percent consumer response estimates from the estimates of the total number of juice-related illnesses yields the lowest number of illnesses that may be prevented by this juice HACCP final rule. Table 7 gives estimates of the number of juice-related illnesses per year not prevented by the juice labeling rule. The estimates in table 7 come from subtracting the estimated 140 cases prevented by the labeling rule from the estimated cases in table 6.

TABLE 7.—THE ESTIMATED NUMBER OF JUICE-ASSOCIATED CASES NOT PREVENTED BY THE LABELING RULE DIVIDED ACCORDING TO LEVEL OF SEVERITY

Hazard	Severity	Percent	Cases
	Mild	99	3,390
	Moderate	1	30
	Severe	.03	1
B. cereus	Total cases	100	3,421
	Mild	90	2,890
	Moderate	9	290
	Severe	.7	20
	Death	.02	1
C. parvum	Total cases	100	3,200

TABLE 7.—THE ESTIMATED NUMBER OF JUICE-ASSOCIATED CASES NOT PREVENTED BY THE LABELING RULE DIVIDED ACCORDING TO LEVEL OF SEVERITY—Continued

Hazard	Severity	Percent	Cases
	Mild	59	95
	Moderate	38	60
	Severe-acute	3	5
	Severe-chronic	4	10
	Death	.0	0
E. coli O157:H7	Total cases	100	160
	Mild	68	1,590
	Moderate	31	730
	Severe	1	20
	ReA-short term	2	50
	ReA-long term	5	120
	Death	5	120
Salmonella (non typhi)	Total cases	100	2,340

9. Percent of Cases Preventable by HACCP Proposal

Table 8 indicates the percent of cases for each hazard expected to be prevented by the rule. In general, most pathogens will be eliminated when a 5-log treatment is applied. For example, *E. coli* O157:H7, *C. parvum* and *Salmonella* should all be completely eliminated from juice by standard methods of flash pasteurization (in the absence of extraordinarily high counts, detrimental human intervention, or equipment failure). However, hazards associated with *B. cereus* will not necessarily be eliminated by heat treatment. This bacterium forms spores that are more difficult to kill by the usual heat process applied to juice.

In the proposed rule, FDA tentatively exempted certain small retail processors. FDA estimated that the exemption for small retail processors would affect 14 percent of the volume of unpasteurized juice. Therefore, the agency estimated that though pathogen controls may be 100 percent effective in controlling some hazards, such controls would only prevent 86 percent of the cases of illness from these hazards, because of the 14 percent of juice not covered. The final rule covers all processors of juice as defined in the final rule; therefore, controls will affect the full volume of juice made by processors. (Retailers are not covered by this rule. Retailers are those businesses that sell only direct to consumers and include grocery stores, supermarkets, farms, roadside stands, restaurants, and eating places.)

TABLE 8.—PERCENT OF CASES PREVENTABLE BY HACCP PROPOSAL

Hazard	Percent of cases preventable by HAACP proposal
B. cereus	10
C. parvum	100
E. coli O157:H7	100
Salmonella (non typhi)	100

Table 9 indicates the number of cases for each hazard expected to be prevented by the rule.

TABLE 9.—ESTIMATES OF JUICE-ASSOCIATED CASES PER YEAR PREVENTED BY HACCP RULE

Hazard	Severity	Percent of cases	Cases
	Mild	99	340
	Moderate	1	0
	Severe	.3	0
B. cereus	Total case	100	340
	Mild	90	2,890
	Moderate	9	290
	Severe	7	20
	Death	.02	1
C. parvum	Total cases	100	3,200
	Mild	59	95
	Moderate	38	60
	Severe-acute	3	5
	Severe-chronic	4	10
	Death	.08	0
E. coli O157:H7	Total cases	100	160
	Mild	68	1,590
	Moderate	31	730
	Severe	1	20
	ReA–short term	2	50
	ReA–long term	5	120
	Death	.04	1
Salmonella (non typhi)	Total cases	100	2,340

10. Estimates of Annual Benefits for HACCP Proposal

The total benefits for the categories of severity for each hazard are derived by multiplying the number of cases prevented by this rule by the estimates of the value of utility losses and medical costs per case. The sum of those benefits for each hazard is the total benefits of this rule for pathogen control. Table 10 gives the estimate of benefits for each hazard.

TABLE 10.—ESTIMATES OF JUICE-ASSOCIATED CASES PER YEAR PREVENTABLE BY HACCP RULE

Hazard	Severity	Dollars
	Mild	$102,000
B. cereus	Total	102,000
	Mild	5,780,000
	Moderate	1,450,000
	Severe	360,000
	Death	5,000,000
C. parvum	Total	12,590,000
	Mild	190,000
	Moderate	240,000
	Severe-acute	165,000
	Severe-chronic.	12,210,000
E. coli O157:H7.	Total	12,805,000
	Mild	1,590,000
	Moderate	1,460,000
	Severe	320,000
	ReA-short term.	350,000
	ReA-long term.	117,120,000
	Death	5,000,000
Salmonella (non typhi).	Total	$125,840,000

Table 11 presents the estimate of annual benefits based on table 10.

TABLE 11.—ESTIMATES OF ANNUAL MICROBIALLY RELATED BENEFITS FOR HACCP PROPOSAL

Hazard	Dollars
B. cereus	$102,000
C. parvum	12,590,000
E. coli O157:H7	12,805,000
Salmonella (non typhi)	$125,840,000
Total	151,000,000

11. Pesticide Residues

There are two potential benefits associated with the regulation of pesticides: (1) Decreases in cancer and other illness caused by chronic consumption of pesticide residues and, (2) social benefits associated with reductions in the costs of recapturing firm goodwill. FDA cannot quantify the cost savings that will occur because of more vigilant monitoring of pesticide residues by firms under a HACCP rule.

12. Summary of Benefits

Table 12 summarizes the benefits of this rule.

TABLE 12.—BENEFITS OF JUICE HACCP RULE

Type of benefit	Annual value
Reduced illness and death from Controlling pathogens.	$151 million.
Reduced harm from physical and chemical hazards.	Not quantified, effects often long-term and probably small.
Total Quantified Benefits.	$151 million

D. Costs

The costs of these rules have been estimated by multiplying the costs for each proposed requirement on a per-plant basis by the number of plants affected by each requirement. Cost per plant will vary by current practice, product, and size.

1. Coverage

In the proposal, FDA tentatively decided that retailers would include processors that are very small businesses, that make juice on their premises, and that directly sell juice or juice products to consumers and other retailers—provided that retail sales of juice and juice products do not exceed 40,000 gallons per year. As noted, FDA has decided in the final rule not to exclude such processors from the rule's requirements. The final rule covers all processors of juice except those who are retailers. Retailers are those businesses that sell only direct to consumers and include grocery stores, supermarkets, farms, roadside stands, restaurants, and other eating places.

Since FDA published the proposed rule, it collected data showing that 24 percent of very small apple juice processors only sell juice direct to consumers. FDA assumes that the same percentage of very small orange juice processors only sell juice direct to consumers. Therefore, about 380 very small apple and 70 very small orange juice processors are exempted from the rule as retailers.

FDA estimated that 5 percent (about 50 plants) of the 900 plants in the FDA Official Establishment Inventory (OEI) would have implemented HACCP as required by this rule by the effective date of the rule even if FDA had not done this rulemaking. No HACCP costs are attributable to this rule for these plants.

Table 13 shows the estimated number of establishments affected by the rule. These numbers exclude the retailers and the 5 percent of plants already doing HACCP.

TABLE 13.—NUMBER OF PLANTS AFFECTED BY THE RULE

Plant type	Number of establishments affected
Juice manufacturers in the OEI	850
Very small apple juice makers	1,220
Very small orange juice makers	230
Total	2,300

2. Length of Production Period

The agency has assumed that 50 percent of the 850 plants in the OEI plus all of the 1,450 very small juice makers affected by the HACCP rule produce seasonally. Table 14 shows the length of the production period for plants producing seasonally and year round.

TABLE 14.—PLANTS' PRODUCTION PERIOD

	Weeks of operation per year	Hours of operation per day	Number of plants
Seasonal	16	12	1,875
Year Round	52	24	425
Total			2,300

3. Cost Estimates by Requirement

a. HACCP costs.
i. CGMP's (§ 120.5)
ii. Prerequisite Program SOP's (§ 120.6)
iii. Hazard Analysis (§ 120.7)
iv. HACCP Plan (§ 120.8)
v. Corrective Actions (§ 120.10)
vi. Verification and Validation (§ 120.11)
vii. Process Verification for Certain Citrus Processors(§ 120.25)
viii. HACCP Records (§ 120.12)
ix. Training (§ 120.13)
x. Imports and Foreign Processors (§ 120.14)
b. Summary of Costs.
c. Take First Year and Recurring Cost Per Activity.

a. *HACCP costs.*—i. *CGMP's (§ 120.5).* No costs are attributed to this section for this rulemaking. In 1996, only 6 percent of the plants inspected were cited for official action. Thus, an overwhelming majority of firms are complying with part 110. Therefore, there is no additional cost of complying with this provision because plants are already complying with part 110. Therefore, FDA assumed that this rule will have no effect on the enforcement of the CGMP's for juice products.

ii. *Prerequisite program SOP's (§ 120.6).—Developing SOP's.* The cost per plant of developing SOP's is approximately $260. If one half of the 850 domestic plants in the OEI and all of the 1,450 very small juice processors do not currently have SOP's, then they will have to develop them to comply with this regulation. Under these assumptions, the total cost for the industry to develop SOP's is approximately $488,000 ($260 x 1,875 plants).

Implementing sanitation controls with corrections of deviations from SOP's. Based on information from inspection reports, FDA assumes that about 30 percent of all 2,300 covered juice plants (about 690 plants) are likely to have sanitation controls that are insufficiently implemented, but which do not warrant administrative or regulatory action. If it costs each of these 690 plants $500 to implement sanitation controls and to correct deviations from SOP's earlier than they would do otherwise, then the total cost for this requirement is $345,000. Because this cost is discounted, it is added as a one-time expenditure in the total costs.

Monitoring and documenting of SOP's. Table 15 shows the distribution of per plant and total industry costs based on the estimate in table 25 for SOP monitoring and documenting needed to comply with this rule.

TABLE 15.—TOTAL ANNUAL COST OF SOP MONITORING AND DOCUMENTING

	Annual per plant SOP monitoring and documenting cost	Number of plants	Annual SOP monitoring and documenting cost
Seasonal	$100	1,662	$166,000
Year round	340	213	72,000
Totals		1,875	238,000

iii. *Hazard analysis (§ 120.7).* FDA estimates that performing a hazard analysis takes 20 labor hours. At $13 per labor hour the cost of performing a hazard analysis is about $250 per plant. Approximately 2,300 plants will need to perform a hazard analysis to comply with this rule. Therefore, the total cost to perform a hazard analysis is approximately $575,000.

iv. *HACCP plan (§ 120.8)—HACCP plan development.* FDA estimates that developing a HACCP plan takes 60 labor hours. At $13 per labor hour the cost of developing a HACCP plan is about $750 per plant. Only those plants that determine from their hazard analysis that they have hazards that are reasonably likely to occur will have to develop a HACCP plan.

Processors that produce shelf-stable or juice concentrate may conclude after their hazard analysis that they need not include pathogen control in any HACCP plan as required by § 120.24(a), if they include a copy of the thermal process in their written hazard analysis. These processors only need a HACCP plan if they have other hazards that are reasonably likely to occur.

Table 16 shows those processors expected to develop HACCP plans.

Adding the categories of processors that develop HACCP plans yields a total of about 1,560 out of the original 2,300 processors that perform a hazard analysis. This may be a small overestimate because some of the citrus processors that now do not make self-stable products may begin to do so because of this rule. It also may be a small overestimate because of the small potential for overlap among the categories.

TABLE 16.—NUMBER OF PLANTS WITH HACCP PLANS

Processors with pathogen Hazards	1,460
Processors with natural toxin Hazards	20
Processors with pesticide Hazards	80
Total processors with HACCP Plans	1,560

Approximately 1,560 plants will need to develop a HACCP plan at a cost of $750 each to comply with this rule. Therefore, the total cost to develop HACCP plans is approximately $1,170,000.

Pathogen controls. In response to this rule, many processors that are not now heat-treating their products are likely to begin doing so. Processors may choose any lawful means to achieve the required 5-log reduction. However, costs here are estimated for pasteurization as the lowest-cost technology now available.

In the PRIA FDA estimated that costs for initiating pasteurization range from $18,000 for a very small seasonal operation to $35,000 for a larger year round operation. FDA received many comments claiming that the initial cost for initiating pasteurization was $30,000 even for a small operation. Because of the number of comments claiming that the initiation of pasteurization would cost $30,000 for a small operation, FDA has used a range for its estimate of the cost of initiating pasteurization for very small processors.

Of the 2,300 processors covered by the HACCP rule only a portion of these will need to initiate pasteurization. In this final rule, processors of shelf-stable juice and juice concentrate will not need to incur additional costs for the control of pathogens. FDA estimates that this new provision in the final rule applies to about 600 processors (70 percent of the processors listed in the OEI) affected by this rule.

FDA estimates that all but 20 of the rest of the affected processors listed in the OEI (230 plants) and 30 percent of the 1,220 very small apple juice processors (370 plants) are already operating pasteurization equipment. Therefore, 600 plants do not need to implement additional pathogen controls.

For the purpose of this analysis, FDA has concluded that it is unlikely that fresh orange juice processors will have to pasteurize their products to achieve a 5-log reduction when a HACCP program is adopted because of the nature of the fruits, the availability of effective surface treatments and the methods of juice extraction commonly used by industry. However, given the information gained from the December 1999 NACMCF meeting on citrus juice and the several recent outbreaks associated with fresh citrus juice, it is clear that most fresh orange processors will need to incur additional costs to implement effective 5-log pathogen reduction controls. In the PRIA, FDA estimated that costs for these processors were limited to the costs of creating and operating a HACCP system with appropriate monitoring and recordkeeping of the necessary CCP's, not to purchasing pasteurizing equipment. In this final analysis, FDA is estimating costs for fresh orange juice processors to improve pathogen controls. Although the measures to improve such controls will not necessarily be pasteurization, FDA is estimating these costs to be equivalent to the costs for initiating pasteurization. FDA only has cost data for pasteurization which is also the only widely-adopted commerical technology for controlling pathogens in juice. Citrus processors may choose to adopt a technology more expensive that the $18,000 to $30,000 estimated here for the implementation of pasteurization. However, the more expensive technologies would likely be adopted for reasons other than compliance with this rule.

Therefore, 20 affected processors listed in the OEI, 300 very small citrus processors and 850 very small apple juice processors (a total of 1,170 plants) will incur costs to implement additional pathogen controls. Table 17 shows the first year total cost of pathogen control attributable to the HACCP rule.

TABLE 17.—FIRST YEAR COST OF PATHOGEN CONTROL ATTRIBUTABLE TO HACCP PROPOSAL

Processor type	Cost per plant	Number of plants	Total
Very small apple juice processors	$18,000–$30,000	850	$15,300,000–25,500,000
Very small orange juice processors	18,000–30,000	300	5,400,000–9,000,000
Juice processors in the OEI	35,000–58,000	20	700,000–1,160,000
Total		1,170	21,400,000–35,660,000

Pasteurization will require ongoing costs for operation and maintenance. FDA estimates these annual costs for labor, utilities, and materials subsequent to the first year to be $7,000 per year for very small processors and $8,000 per year for processors in the OEI. The total cost of pathogen control in subsequent years is given in table 18.

TABLE 18.—SUBSEQUENT YEAR COST OF PATHOGEN CONTROL ATTRIBUTABLE TO HACCP RULE

Processor type	Cost per plant	Number of plants	Total
Very small apple juice processors	$7,000	850	$5,950,000
Very small orange juice Processors	7,000	300	2,100,000
Juice processors in the OEI	8,000	20	160,000
Total		1,170	8,210,000

Other costs are related to processing for pathogen control. The pasteurization of juice causes changes in the characteristics of the products, primarily in terms of texture and taste. Some current consumers of nonheat-treated juice will bear the costs of losing a particular product as well as costs of searching for products with the characteristics that they prefer. Thus, one cost of these regulations is the limited loss of ''fresh'' juice: that is, juice that is not heat (or otherwise) processed.

Some consumer comments indicated a strong preference for fresh juice; however, although FDA expressly asked for comments on this issue in its November 1999 notice, no comments suggested any means of estimating this cost. FDA has no information on how readily consumers will accept pasteurized juice in the place of fresh juice nor does FDA have any other information that could be used to estimate that cost.

Glass and direct food additive HACCP controls. FDA has not attributed any costs for control of glass or unapproved direct food additives although these potential hazards are among those that are likely to be relevant for juice. The agency believes that even if broken glass is determined to be a hazard to processors packing juice in glass, these processors are already currently implementing every feasible control for this potential hazard in order to limit their liability and to provide consumer protection. Additionally, although approximately 25 percent of the processing plants pack juice in glass containers, this number is diminishing rapidly for economic and safety reasons.

Regarding food additives, many juice products contain food or color additives for the purpose of coloring or extending product shelf life. However the agency

believes that even if unapproved food additives are determined to be a hazard, these processors using direct food additives in juice are already currently implementing sufficient controls for these potential hazards as FDA strictly regulates them.

Natural toxin controls. FDA believes that in most every case processors of domestic apples should be able to control natural toxin hazards such as patulin, by processing controls such as washing and culling. This can be accomplished at no additional cost.

Processors using imported juice concentrate are likely to need to initiate a sampling regime for natural toxins. FDA assumes that the 23 large plants will randomly sample 30 shipments per year at a cost of $150 per sample. The total marginal cost of patulin testing is approximately $104,000 (30 tests x $150/test x 23 firms). Costs per plant are $4,500. If any lots are found positive, costs will be incurred for taking corrective action.

Pesticide controls. FDA believes that all 175 affected plants operated by large firms are currently doing a sufficient amount of sampling and monitoring (or receiving supplier certificates) for pesticides residues. Therefore, FDA assumed that there are no additional costs for large firms to control this potential hazard. This does not mean that FDA believes that no large firms will identify pesticides as a hazard that needs to be controlled under HACCP. Large and small firms are more likely than very small firms to use imported produce, which may not be subjected to as strict controls as U.S. produce in all cases. FDA believes that 10 percent of all large and small firms (80 plants total) will determine that pesticide hazards are reasonably likely to occur. However, FDA believes that all large firms are already sufficiently addressing this issue with present expenditures. FDA made this estimate based on its knowledge of the magnitude of the pesticide problem in juice.

If processors determine that pesticide residues are hazards for their product, then they must run pesticide residue tests to ensure that there are no pesticides either over tolerance or used on products for which there is no tolerance. FDA believes that 10 percent of the shipments received by small processors must be covered by a sampling plan. Sixty-five small plants are believed to cover their shipments with a pesticide-sampling plan. Average cost per plant is estimated to be $1,500. The total annual marginal cost of pesticide testing is approximately $98,000 (10 tests x $150/test x 65 firms).

v. *Corrective actions (§ 120.10).—Corrective action plan.* The development of a corrective action plan for juice products is less expensive than revalidation after each deviation from a CL. FDA estimates that a corrective action plan for juice products can be developed in 4 hours with a cost per plant of approximately $50 (about 4 hours of management time).

All of the plants that develop HACCP plans as a result of this rule will develop corrective action plans to comply with this rule. The total cost for 1,560 plants at $50 each to develop corrective action plans is approximately $78,000.

Corrective actions. Plants operating under HACCP plans will take corrective actions when CL's are exceeded for hazards such as pesticide residues, unacceptable fruit for pathogen controls, and presence of natural toxins. Costs of corrective actions are expected to decline as processors gain more experience under a HACCP system and as the number of corrective actions decreases. Tables 19 and 20 show the estimated first year and subsequent year costs of corrective actions per plant.

TABLE 19.—COST OF FIRST YEAR CORRECTIVE ACTIONS

Plant type	Cost per plant	Number of plants	Total cost
Seasonal	$450	1,490	$671,000
Year round	1,460	70	102,000
Totals		1,560	773,000

TABLE 20.—COST OF SUBSEQUENT YEAR CORRECTIVE ACTIONS

Plant type	Cost per plant	Number of plants	Total cost
Seasonal	$110	1,490	$164,000
Year round	340	70	24,000
Totals		1,560	188,000

Verification and validation (§ 120.11).—Verification. The record verification cost per plant per production cycle is given in table 21.

TABLE 21.—COST OF RECORD VERIFICATION

Plant type	Cost per plant	Number of plants	Total cost
Seasonal	$420	1,490	$626,000
Year Round	1,350	70	95,000
Totals		1,560	721,000

Validation. Processors with HACCP plans must validate their HACCP plans during the first year after implementation and at least annually, or whenever any changes occur that could affect or alter the hazard analysis, or

HACCP plan. Further, processors who have no HACCP plans because there are no hazards that are reasonably likely to occur in that process (as may be the case with processors of shelf-stable or concentrated juice), the processor must reassess their hazard analysis when any significant change occurs. Examples of things that may change include: (1) Raw material specifications or sources of raw materials, (2) product formulation, (3) processing methods or systems, (4) packaging, (5) finished product distribution systems, or (6) intended consumers or use by consumers.

Tables 22 and 23 give the estimated cost for validation in the first and subsequent years.

TABLE 22.—COST OF FIRST YEAR VALIDATION

Plant type	Number of validations	Cost per validation	Number of plants	Total cost
Seasonal Small Business	1	$1,000	1,640	$1,640,000
Year Round Business	2	1,000	120	240,000
Year Round Small Shelf-Stable or Concentrate Business	1	1,000	130	130,000
Year Round Large Business	2	600	80	96,000
Year Round Large Shelf-Stable or Concentrate Business	1	600	95	57,000
Totals	2,265	.....	2,065	$2,163,000

TABLE 23.—COST OF SUBSEQUENT YEAR VALIDATION

Plant type	Number of validations	Cost per validation	Number of plants	Total cost
Seasonal Small Business	1	$1,000	1,490	$1,490,000
Year Round Small Business	2	1,000	35	70,000
Year Round Large Business	2	600	35	42,000
Totals	1,630	.....	1,560	1,602,000

vii. *Process verification for certain citrus processors (§ 120.25).* Citrus processors that decide to rely on surface treatments of the fruit to achieve the requisite 5-log reduction (rather than treating the juice directly) are required to sample their final product to verify the effectiveness of the HACCP plan. These processors are required to test two 10 mL subsamples for generic *E. coli* every 1,000 gallons or every 5 days whichever is more frequent. FDA assumes that the cost of testing two 10 mL subsamples for generic *E. coli* is $50. FDA estimates that there are 240 citrus processors that will be affected by this section. To estimate the number of samples, FDA began with the estimated annual U.S. untreated orange juice consumption estimate of 11,700,000 gallons. FDA then assumed that 10 million gallons were packaged for resale and therefore covered by this rule. FDA then assumed that the 180 processors that would sample at a frequency of once every 5 days on average process 750 gallons during that time. These processors are assumed to be seasonal processors operating for only 16 weeks a year. FDA made these assumptions based on its knowledge of microbial testing and beliefs about the volume of untreated packaged juice sold by small processors. That set of processors accounts for 2,160,000 gallons annually. The remaining 60 processors share production of the remaining 7,840,000 gallons resulting in about 130 samples per year per processor.

Table 24 shows the estimated cost for process verification sampling for these citrus processors.

TABLE 24.—ESTIMATED COST FOR VERIFICATION SAMPLING

Sample frequency	Number of samples	Number of processors	Cost per sample cost	Total
Every 5 days	16	180	$50	$144,000
Every 1,000 Gallons	130	60	50	390,000
Total	10,720	240	.....	$534,000

Also, any time that 2 process-verification samples test positive for generic *E. coli* in a series of 7 samples there is a process verification failure. The processor must not sell the product without further processing and must review its monitoring records, reevaluate its HACCP plan, and if no obvious deficiencies in the HACCP plan are discovered, must revalidate its HACCP plan. FDA estimates that even if all citrus processors that rely on surface treatments to achieve a 5-log reduction are fully successful in achieving the 5-log reduction, 2 samples in a series of 7 will test positive for generic *E. coli* once in every 1,000 samples. Based on an estimate of 10,720 samples taken per year, this will occur about 11 times per year. FDA assumes that the cost of further processing of the product will be more expensive than withdrawing and destroying the product, which should not exceed 1,000 gallons. FDA assumes that the cost of withdrawing and destroying the product plus the cost of reviewing monitoring records, reevaluating and revalidating HACCP plan is $20,000. FDA made this assumption based on its experience with such small lot market withdrawls. Therefore, the additional cost of a process verification failure is $220,000 per year. The annualized cost of a process verification failure is $320 for a seasonal processor sampling every 5

days ((16/1,000) × $20,000 = $320) and $2,600 for a year round processor sampling every 1,000 gallons ((130/1,000) × $20,000 = $2,600).

The total cost of process verification testing for untreated citrus juice is $764,000 per year ($534,000 + $220,000 = $764,000).

viii. *HACCP records (§ 120.12).—Monitoring and recordkeeping.* The additional monitoring and recordkeeping that needs to be done throughout the entire plant is estimated to be equivalent to 5 percent of one worker's time (3 minutes per hour of operation per plant). Table 25 shows the annual cost of additional monitoring and recordkeeping per plant. It also shows the distribution of per plant costs and total industry costs for the additional monitoring and recordkeeping needed to comply with this final rule.

TABLE 25.—COST OF MONITORING AND RECORDKEEPING

Plant type	Cost per plant	Number of plants	Total cost
Seasonal	$900	1,490	$1,341,000
Year Round	5,600	70	392,000
Totals		1,560	$1,733,000

Record maintenance and storage. The annual cost of record maintenance and storage per plant is described in table 26.

TABLE 26.—COST OF RECORD MAINTENANCE

Plant type	Cost per plant	Number of plants	Total cost
Seasonal	$360	1,490	$536,000
Year Round	830	70	58,000
Totals		1,560	$694,000

ix. *Training (§ 120.13).—HACCP coordinator training.* Processors may need to employ a HACCP coordinator to carry out the duties specified for such a person. FDA estimates that the cost of HACCP coordinator training is $1,300 for each of the 2,300 processing plants, or a total industry cost of $2,990,000.

Employee training in HACCP. Each processor with a HACCP plan will need to train employees in their HACCP-related activities. This analysis assumes that each plant must train 5 employees or 10 percent of their employees in HACCP-related responsibilities, whichever is greater. Table 27 describes the cost of training each employee for 8 hours annually (the equivalent of 40 minutes per month for 10 percent of the employees) and the total cost of this level of training.

TABLE 27.—COST OF EMPLOYEE TRAINING

Average plant employment	Number of employees trained	Cost per employee	Number of plants	Total cost
3	3	$100	1,459	$437,700
7	5	100	10	5,000
15	5	100	19	9,500
35	5	100	28	14,000
75	8	100	29	23,200
175	16	100	15	27,000
Totals	5,160		1,560	$516,000

x. *Imports and foreign processors* (§ 120.14).—*Importers.* The agency estimates that the cost of these activities will be $10,000 for each of the 120 importers in the first year, decreasing to $5,000 in subsequent years. Total costs for importers is $1,200,000 in the first year and $600,000 in subsequent years.

Foreign juice processors. The estimated first year cost per foreign juice exporter is approximately $26,000, and the cost in subsequent years is $22,000. Therefore the total cost in the first year for 300 foreign processors is approximately $8 million and approximately $7 million in subsequent years. Tables 33 and 34 in the Regulatory Flexibility Analysis, which follows, shows typical costs for large plants that have not already implemented HACCP. The agency assumes that these costs are representative of foreign plants exporting to the United States.

b. *Summary of Costs*—The total quantified costs are approximately $44 to $58 million in the first year and $23 million in all subsequent years. Table 28 summarizes costs of the rule by provision.

C. TABLE 28.—TOTAL FIRST YEAR AND RECURRING COST PER ACTIVITY

Activity	First year costs	Recurring costs
Develop SOP's	$488,000	
Prerequisite Program SOP's	345,000	
Monitoring and Documenting for SOP	238,000	238,000
Hazard analysis	575,000	
HACCP plan	1,170,000	
Pathogen controls	21,400,000–35,660,000	8,210,000
Natural toxin controls	104,000	104,000
Pesticide controls	98,000	98,000
Corrective action plan	78,000	
Corrective actions	773,000	188,000
Verification	721,000	721,000
Validation	2,163,000	1,602,000
Process verification	764,000	764,000
HACCP monitoring and recordkeeping	1,733,000	1,733,000
Record maintenance and storage	694,000	694,000
HACCP coordinator training	2,990,000	
Employee training	516,000	516,000
Importers	1,200,000	600,000
Foreign processors	8,000,000	7,000,000
Totals	44,000,000–58,000,000	23,000,000

E. Summary of Benefits and Costs

FDA has examined the benefits and costs of this rule as required under Executive Order 12866. Over time, the relationship between benefits and costs changes, so that, to compare them properly, benefits and costs must be discounted to the present year (the time at which the decisions are being made). The quantified benefits (discounted annually over an infinite time horizon at 7 percent) are expected to be about $2 billion ($151 million/7 percent) and the quantified costs (discounted annually over an infinite time horizon at 7 percent) are expected to be about $400 million.

VI. Regulatory Flexibility Analysis

FDA has examined the impact of this rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant impact on a substantial number of small entities, the RFA requires agencies to analyze options that would minimize the economic impact of that rule on small entities. The agency acknowledges that this rule is likely to have a significant impact on a substantial number of small entities.

A. Objectives

The RFA requires a succinct statement of the purpose and objectives of any rule that will have a significant impact on a substantial number of small entities. The HACCP rule is being issued to ensure that juice processors control all physical, chemical, and microbial hazards in their products.

B. Definition of Small Business and Number of Small Businesses Affected

The RFA requires a statement of the definition of small business used in the analysis and a description of the number of small entities affected.

Table 29 shows the definition of small business for each type of establishment affected and a description of the number of small entities affected by the rule. The agency has accepted the Small Business Administration (SBA) definitions of small business for this analysis.

TABLE 29.—APPROXIMATE NUMBER OF SMALL PLANTS COVERED BY THESE RULES

Type of establishment	North American industry classification system codes	SBA definition of small by category	Category defined as small by SBA	Percent of No. of small businesses covered
Juice manufacturers in the OEI	311421, 311411	Less than 500 employees	75%	675
Roadside-type apple juice Makers	311421, 311411	Less than 500 employees	100%	1,220
Roadside orange juice Makers	311421, 311411	Less than 500 employees	100%	230
Totals				2,125

C. Description of the Impact on Small Entities

1. Costs to Small Entities

Because there is a broad distribution of products covered, firm types, current processing practices and sizes, it would be misleading to report average per firm costs. However, some idea of the costs can be gained from the following examples. The impacts that the costs will have on a firm will vary depending on the total revenue derived from juice by a firm and the profit (return on sales) associated with juice production. Data on food manufacturing firms indicates that 75 percent of firms have return on sales of less than 5 percent.

The first example (table 30) is of a small seasonal apple cider plant that is now producing nonheat-treated juice, with fruit from a known source, and that has not developed or implemented sanitation SOP's. This plant will need to buy a pasteurizer (or find and validate a different process that achieves a 5-log reduction). The next example (table 31)

is a small plant that is producing orange juice concentrate year round with fruit from a known source, and that has already developed and implemented sanitation SOP's (except that records have not been kept on SOP's). The third example (table 32) is a small plant operating year round producing unpasteurized orange juice, using commingled fruit, and that has not developed or implemented sanitation SOP's.

These three illustrative small plants can be compared to two illustrative large plants. The first large plant (table 33) is a large shelf-stable apple juice plant with many employees that operates year round and that imports some apples and therefore must test for patulin, and has not developed or implemented sanitation SOP's. The second large plant (table 34) is a large shelf-stable tomato juice processor using fruit from a known source and with sanitation SOP's fully implemented.

TABLE 30.—COSTS FOR ILLUSTRATIVE SMALL SEASONAL APPLE CIDER PROCESSOR

Type of cost	Cost in first year	Cost in subsequent years
Develop SOP's	$260	
Sanitation SOP's	500	
Monitoring and Documenting of SOP's	100	$100
Hazard analysis	250	
HACCP plan	750	
Pathogen controls	18,000–30,000	7,900
Corrective action plan	50	
Corrective actions	450	110
Verification	420	420
Validation	1,000	500
HACCP monitoring and recordkeeping	900	900
Record maintenance & storage	360	360
Training of coordinator	1,300	
Employee training	300	300
Totals	24,700–36,700	10,600

TABLE 31.—COST FOR ILLUSTRATIVE SMALL YEAR ROUND CONCENTRATED ORANGE JUICE PROCESSOR

Type of cost	Cost in first year	Cost in subsequent years
Monitoring and documenting of SOP's	$340	$340
Hazard analysis	250	
Validation	1,000	
Training of coordinator	1,300	
Totals	2,900	300

TABLE 32.—COST FOR ILLUSTRATIVE SMALL YEAR ROUND UNPASTEURIZED ORANGE JUICE PROCESSOR

Type of cost	Cost in first year	Cost in subsequent years
Develop SOP's	$260	
Monitoring and documenting of SOP's	340	$340
Hazard analysis	250	
HACCP plan	750	
Pathogen controls	18,000–30,000	7,900
Corrective action Plan	50	
Corrective actions	1,460	340
Verification	1,350	1,350
Validation	2,000	1,000
Process verification testing	7,800	7,800
Annualized cost of Process Verification Failure	2,600	2,600
HACCP monitoring and Recordkeeping	5,600	5,600
Record maintenance & storage	830	830
Training of coordinator	1,300	
Employee training	500	500
Totals	43,100–55,100	28,300

TABLE 33.—COSTS FOR ILLUSTRATIVE LARGE YEAR ROUND APPLE JUICE PROCESSOR

Type of cost	Cost in first year	Cost in subsequent years
Develop SOP's	$260	

TABLE 33.—COSTS FOR ILLUSTRATIVE LARGE YEAR ROUND APPLE JUICE PROCESSOR—Continued

Type of cost	Cost in first year	Cost in subsequent years
Sanitation SOP's	500	
Monitoring and documenting of SOP's	340	$340
Hazard analysis	250	
HACCP plan	750	
Natural toxin control	4,500	4,500
Corrective action plan	50	
Corrective actions	1,460	340
Verification	1,350	1,350
Validation	1,200	1,200
HACCP monitoring and recordkeeping	5,600	5,600
Record maintenance	680	680
Record storage	150	
Training of coordinator	1,300	
Employee training	8,300	8,300
Totals	24,000	20,000

TABLE 34.—COSTS FOR ILLUSTRATIVE LARGE YEAR ROUND SHELF-STABLE TOMATO JUICE PROCESSOR

Type of cost	Cost in first year	Cost in subsequent years
Hazard analysis	$250	
Validation	600	
Training of coordinator	1,300	
Totals	2,000	$0

Some comments stated that the rule would be burdensome on small juice processors and that some processors would have to cease producing juice. FDA is issuing a tiered, extended compliance period giving the smallest firms the most time to comply with the rule. Extending the compliance period by 1 year for small firms could save each one $500 to $31,600 (using a 7 percent discount rate). Extending the compliance period by 2 years for very small firms could save each one $900 to $61,000 (using a 7 percent discount rate). These savings accrue just from delaying the time at which the expenditures for compliance must take place. The amount of savings increases as the cost of compliance increases. One effect of the cost savings will be to reduce small firm failure. FDA believes that this extended compliance period will provide small firms with significant relief in the cost of preparing for HACCP and making necessary changes to comply with this rule.

2. Professional Skills Required for Compliance

The RFA requires a description of the professional skills required for compliance with this rule. Table 35 describes the professional skills required for compliance with the various activities required by this rule.

TABLE 35.—PROFESSIONAL SKILLS REQUIRED FOR COMPLIANCE

Required activity	Section of rule	Professional skills required for compliance
Developing prerequisite program SOP's	§ 120.6	Managers familiar with incoming materials and plant sanitation.
Implementing sanitation controls with corrections of deviations from prerequisite program SOP's.	§ 120.6	Production workers who are able to maintain the sanitation controls as described in the sanitation SOP's and supervisors or managers who can determine what corrective actions are necessary for deviations from SOP's.
Monitoring and documenting of prerequisite Program SOP's.	§ 120.6	Production workers who are appropriately trained to monitor and keep records on observations and measurements for prerequisite program SOP's.
Developing hazard analysis and HACCP plan..	§§ 120.7 and 120.8	Supervisors or managers who fulfill the role of HACCP coordinator as well as microbiologists, chemists, and attorneys.
Implementing pathogen controls	§ 120.8	Production workers who are appropriately trained to monitor and keep records on observations and measurements at CCP's.
Implementing pesticide controls	§ 120.8	Production workers who are appropriately trained to carry out tests, to monitor, and to keep records on observations and measurements at CCP's.
Tracking corrective actions	§ 120.10	Production workers who are trained to take corrective action described in corrective action plans and supervisors or managers who can determine what corrective actions are necessary for deviations from CL's.
Verification	§ 120.11	Supervisors or managers who fulfill the role of HACCP coordinator.
Validation	§ 120.11	Food scientists or food technologists who can perform a scientific review of the process.
Process verification	§ 120.25	Microbiologists and production workers who are trained to take process verification samples and food scientists or food technologists who can perform a scientific review of the process in the event of a process verification failure.

TABLE 35.—PROFESSIONAL SKILLS REQUIRED FOR COMPLIANCE—Continued

Required activity	Section of rule	Professional skills required for compliance
Monitoring and recordkeeping	§ 120.12	Production workers who are appropriately trained to monitor and keep records on observations and measurements at CCP's.
Record maintenance	§ 120.12	Clerical or production workers.
HACCP coordinator training coordinator	§ 120.13	Supervisors or managers who fulfill the role of HACCP.
HACCP employee training	§ 120.13	Clerical and production workers.
Imports	§ 120.14	Clerical workers as well as supervisors or managers who fulfill the role of HACCP coordinator.

3. Recordkeeping requirements

The RFA requires a description of the recordkeeping requirements of the proposed rule. Table 36 shows the provisions for which records need to be made and kept by small businesses, the number of small businesses affected, the annual frequency that the records need to be made, the amount of time needed for making each record, and the total number of hours for each provision in the first year and then in subsequent years.

TABLE 36.—SMALL BUSINESS RECORDKEEPING REQUIREMENTS

21 CFR provisions	Number of small entities keeping records	Annual frequency	Hours per record per small entity	Total hours first year	Total subsequent years
120.6 Monitoring and Recordkeeping of SOP's	1,660	16	0.5	13,300	13,300
	210	52	.....	5,500	5,500
120.7 Hazard analysis	2,125	1	20	42,500	0
120.8 HACCP plan	1,930	1	60	115,800	0
120.8 Pesticide Controls by Supplier Certificate	1,700	160	.02	5,400	5,400
120.11 Verification	1,450	16	2	46,400	46,400
	380	52	[1] 8	39,500	39,500
120.11 Validation	1,450	1	[2] 4	11,600	5,800
	380	2	.....	6,100	3,000
120.12 HACCP records	1,450	1,440	.05	104,400	104,400
	380	8,640	.....	164,200	164,200
120.12 Record maintenance	1,450	16	1	23,200	23,200
Totals	.....	.....	.....	598,000	431,000

[1] First year. [2] Subsequent year.

D. Minimizing the Burden on Small Entities

The RFA requires an evaluation of any regulatory overlaps and regulatory alternatives that would minimize the costs to small entities.

There are two alternatives that the agency has considered to provide regulatory relief for small entities. First, FDA considered and is proposing the option of exempting some small entities from the requirements of these rules. Second, FDA considered and is proposing the option of lengthening the compliance period for small entities.

1. Exempt Small Entities

One alternative for alleviating the burden for small entities would be to exempt them from the provisions of this rule. FDA proposed to exempt retailers who, for the purposes of this rule, the agency tentatively decided would include very small businesses that make juice on their premises and whose total sales of juice and juice products do not exceed 40,000 gallons per year and who sell directly to consumers or directly to consumers and other retailers.

Revenue from sales of 40,000 gallons of nonheat treated juice may be approximately $160,000 with annual profits ranging from $1,600 to $16,000 per year (1 percent to 10 percent). This exemption covered most of the very small businesses, although less than 15 percent of the volume of unpasteurized juice. However, packaged products sold by these types of processors are covered under the labeling rule.

As detailed in response to comment 47, the comments that FDA received on this exemption were almost entirely critical of the exemption. Based upon the comments and other information available to the agency, FDA has decided not to finalize this proposed exemption.

2. Extend Compliance Period

FDA is issuing a tiered, extended compliance period giving the smallest firms the most time to comply with the rule. Extending the compliance period by 1 year for small firms could save each one $500 to $31,600 (using a 7 percent discount rate). Extending the compliance period by 2 years for very small firms could save each one $900 to $61,000 (using a 7 percent discount rate). These savings accrue just from delaying the time at which the expenditures for compliance must take place. The amount of savings increases as the cost of compliance increases.

Additional savings may come as smaller firms learn more efficient compliance strategies from larger firms that must comply earlier and as new, less costly technologies that may be employed by small firms are developed during the extended compliance period. FDA is unable to quantify these additional savings of the extended compliance period although one effect of the cost savings will be to reduce small firm failure.

FDA believes that this extended compliance period will provide small firms with significant relief in the cost of preparing for HACCP and making

necessary changes to comply with this rule.

E. Summary

FDA has examined the impact of this rule on small businesses in accordance with the RFA. This analysis, together with the rest of the preamble constitutes the final RFA. FDA has determined that this rule is likely to have a significant impact on a substantial number of small entities.

VII. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). A description of these information provisions is given below with an estimate of the annual recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Hazard Analysis and Critical Control Point (HACCP) Procedures for the Safe and Sanitary Processing of Juice—Recordkeeping requirements for processors of fruit and vegetable juices

Description: This final rule mandates the application of HACCP procedures to fruit and vegetable juice processing. HACCP is a preventative system of hazard control that can be used by all food processors to ensure the safety of their products to consumers. FDA is finalizing these regulations because a system of preventative control is the most effective and efficient way to ensure that these food products are safe. FDA's mandate to ensure the safety of the nation's food supply is derived principally from the act (21 U.S.C. 321 *et seq.*). Under the act, FDA has authority to ensure that all foods in interstate commerce, or that have been shipped in interstate commerce, are not contaminated or otherwise adulterated, are produced and held under sanitary conditions, and are not misbranded or deceptively packaged; under 21 U.S.C. 371, the act authorizes the agency to issue regulations for its efficient enforcement. The agency also has authority under the Public Health Service Act (42 U.S.C. 264) to issue and enforce regulations to prevent the introduction, transmission, or spread of communicable diseases from one State to another other State. Information development and recordkeeping are essential parts of any HACCP system. The information collection requirements of this rule are narrowly tailored to focus on the development of appropriate controls and documenting those aspects of processing that are critical to food safety. Through this final rule, FDA is implementing its authority under section 402(a)(4) of the act. The information development and recordkeeping requirements of this final rule are likewise an implementation of section 402(a)(4) of the act.

Description of Respondents: Businesses and other for-profit institutions.

In the **Federal Register** of April 24, 1998, the agency requested comments on the proposed collection of information provisions contained in the HACCP proposal. One comment was received. This comment asserted that the change in sequence in the proposed rule for the last two steps of the seven principles of HACCP is a change that will result in many paperwork changes. The seven principles of HACCP have been articulated by the NACMCF.

The agency does not agree with this comment. Prior to 1997, the NACMCF listed establishing recordkeeping and documentation procedures and establishing verification procedures as the sixth and seventh principles of HACCP; this is the order in which the principles are reflected in FDA's seafood HACCP regulation, part 123. When the NACMCF revised its HACCP principles and application guidelines in 1997, it reversed the order of the last two steps. Thus, the sequence in part 120 for the seven principles of HACCP is identical to the sequence most recently outlined by NACMCF. The 1997 change does not require a change in the analytical approach or in the information to be assembled by juice processors as they apply the HACCP principles to their process. The agency does not anticipate that there will be a need for processors to complete additional paperwork simply because there has been a change in the order of the seven principles of HACCP or because there will be a slight difference in the juice HACCP regulation and the seafood HACCP regulation. It is FDA's position that as long as all the essential elements are present in the written HACCP plan, the plan will be complete.

FDA estimates the burden of this collection of information as follows:

TABLE 37.—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR sections	Number of recordkeepers	Annual frequency of records	Total annual records	Hours per record	Total hours
120.6(a) & 120.12(a)(1) & (b)	1,875	1	1,875	4	[2] 7,500
120.6(c) & 120.12(a)(1) & (b)	1,875	365	684,375	0.1	68,437.5
120.7; 120.10 (a); & 120.12(a)(2), (b) & (c)	2,300	1.1	2,530	20	50,600
120.8 (except monitoring records required under 120.8(b)(7)); & 120.12(a)(3),(b)& (c)	1,840	1	1,840	60	[2] 110,400
120.8(b)(7) & 120.12(a)(4)(i), & (b)	1,450	14,600	21,170,000	0.01	211,700
120.10(c) & 120.12(a)(4)(ii), & (b)	1,840	12	22,080	0.1	2,208
120.11(a)(1)(iv); 120.11(a)(2); 120.12(a)(5)	1,840	52	95,680	0.1	9,568
120.11(b) & 120.12(a)(5), & (b)	1,840	1	1,840	4	7,360
120.11 (c) & 120.12(a)(5) & (b)	1,840	1	1,840	4	7,360
120.14(a)(2); & 120.14 (c) & (d)	308	1	308	4	1,232
Totals	First year—476,365.5		Subsequent years—358,465.5		

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] First year only.

The burden estimates in table 37 above are based on an estimate of the total number of juice manufacturing plants (*i.e.*, 2,300) affected by this final rule. Included in this total are 850 plants currently identified in FDA's OEI plus 1,220 very small apple juice manufacturers and 230 very small orange juice manufacturers (see table 13

in section V). The figures in table 36 are derived by estimating the number of plants affected by each portion of this final rule and multiplying the corresponding number by the number of records required annually and the hours needed to complete the record. These numbers were obtained from the agency's final RIA prepared for this final rule.

Moreover, these estimates assume that every processor will prepare SSOP's and a HACCP plan and maintain the associated monitoring records and that every importer will require product safety specifications. In fact, there are likely to be some small number of juice processors that, based upon their hazard analysis, determine that they are not required to have a HACCP plan under this final rule.

Table 37 provides a breakdown of the total estimated recordkeeping burden for the first year and subsequent years. The estimates in this table have been reviewed by the agency's HACCP experts, who have practical experience in observing various processing operations and related recordkeeping activities.

The information collection provisions of this final rule have been submitted to OMB for review.

Prior to the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

VIII. Environmental Impact

The agency has previously considered the environmental effects of the action being taken in this final rule. As announced in the proposed rule published in the **Federal Register** of April 24, 1998 (63 FR 20450) (Ref. 2), the agency determined that under 21 CFR 25.30(j) this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement was required.

(Comment 158) Two comments were received in response to the potential environmental impact of this rule. One comment stated that "* * * the extensive recordkeeping requirements under the juice proposal will increase paper consumption significantly, which will not be considered 'environmentally friendly.' " This comment did not provide evidence to support this assertion.

FDA agrees that the recordkeeping requirement in the HACCP final rule may increase paper consumption. However, the agency disagrees that this increase will be significant. The agency believes that the paper used for the required recordkeeping will be a very small fraction of the overall amount of paper used in the United States. Therefore, this use will not significantly increase the production, use and disposal of paper and, thus, will not result in significant adverse impacts on the environment. Additionally, FDA notes that § 120.12(g) of the final rule permits records to be maintained electronically. When the regulated entities maintain records electronically, the need for paper is reduced.

(Comment 159) One comment on the proposed rule stated that efforts to achieve 5-log reduction will lead to possible excessive pollution of the environment from disposal of unessential sanitizers. This comment did not provide evidence to support this assertion.

The agency has concluded that even if some increase in the use of sanitizing products should result, the products used would be either registered with the U.S. EPA or regulated by FDA for use on food contact articles under § 178.1010 (21 CFR 178.1010) or both. Environmental review is part of EPA's pesticide registration process and is part of FDA's process for listing sanitizing solutions under § 178.1010. FDA expects processors to use all sanitizing products according to directions on product labels and under the supervision of experienced persons. Use of the sanitizing products in this manner should ensure that any increased use will not result in adverse effects on the environment.

The agency has concluded that these comments on the potential for adverse environmental effects will not affect its previous determination that this action will not have a significant impact on the human environment and that an environmental impact statement is not required.

IX. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government (Ref. 75). Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

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List of Subjects in 21 CFR Part 120

Foods, Fruit juices, Imports, Reporting and recordkeeping requirements, Vegetable juices.

Therefore, under the Federal Food, Drug, and Cosmetic Act, under the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR chapter I is amended as follows:

1. Part 120 is added to read as follows:

PART 120—HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS

Subpart A—General Provisions

Sec.
120.1 Applicability.
120.3 Definitions.
120.5 Current good manufacturing practice.
120.6 Sanitation standard operating procedures.
120.7 Hazard analysis.
120.8 Hazard Analysis and Critical Control Point (HACCP) plan.
120.9 Legal basis.
120.10 Corrective actions.
120.11 Verification and validation.
120.12 Records.
120.13 Training.
120.14 Application of requirements to imported products.

Subpart B—Pathogen Reduction

120.20 General.
120.24 Process controls.
120.25 Process verification for certain processors.

Authority: 21 U.S.C. 321, 342, 343, 346, 348, 371, 374, 379e, 381, 393; 42 U.S.C. 241, 242l, 264.

Subpart A—General Provisions

§ 120.1 Applicability.

(a) Any juice sold as such or used as an ingredient in beverages shall be processed in accordance with the requirements of this part. Juice means the aqueous liquid expressed or extracted from one or more fruits or vegetables, purees of the edible portions of one or more fruits or vegetables, or any concentrates of such liquid or puree. The requirements of this part shall apply to any juice regardless of whether the juice, or any of its ingredients, is or has been shipped in interstate commerce (as defined in section 201(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321(b)). Raw agricultural ingredients of juice are not subject to the requirements of this part. Processors should apply existing agency guidance to minimize microbial food safety hazards for fresh fruits and vegetables in handling raw agricultural products.

(b) The regulations in this part shall be effective January 22, 2002. However, by its terms, this part is not binding on small and very small businesses until the dates listed in paragraphs (b)(1) and (b)(2) of this section.

(1) For small businesses employing fewer than 500 persons the regulations in this part are binding on January 21, 2003.

(2) For very small businesses that have either total annual sales of less than $500,000, or if their total annual sales are greater than $500,000 but their total food sales are less than $50,000; or the person claiming this exemption employed fewer than an average of 100 full-time equivalent employees and fewer than 100,000 units of juice were sold in the United States, the regulations are binding on January 20, 2004.

§ 120.3 Definitions.

The definitions of terms in section 201 of the Federal Food, Drug, and Cosmetic Act, § 101.9(j)(18)(vi), and part 110 of this chapter are applicable to

such terms when used in this part, except where redefined in this part. The following definitions shall also apply:

(a) *Cleaned* means washed with water of adequate sanitary quality.

(b) *Control* means to prevent, eliminate, or reduce.

(c) *Control measure* means any action or activity to prevent, reduce to acceptable levels, or eliminate a hazard.

(d) *Critical control point* means a point, step, or procedure in a food process at which a control measure can be applied and at which control is essential to reduce an identified food hazard to an acceptable level.

(e) *Critical limit* means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food hazard.

(f) *Culled* means separation of damaged fruit from undamaged fruit. For processors of citrus juices using treatments to fruit surfaces to comply with § 120.24, *culled* means undamaged, tree-picked fruit that is U.S. Department of Agriculture choice or higher quality.

(g) *Food hazard* means any biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control.

(h) *Importer* means either the U.S. owner or consignee at the time of entry of a food product into the United States, or the U.S. agent or representative of the foreign owner or consignee at the time of entry into the United States. The importer is responsible for ensuring that goods being offered for entry into the United States are in compliance with all applicable laws. For the purposes of this definition, the importer is ordinarily not the custom house broker, the freight forwarder, the carrier, or the steamship representative.

(i) *Monitor* means to conduct a planned sequence of observations or measurements to assess whether a process, point, or procedure is under control and to produce an accurate record for use in verification.

(j)(1) *Processing* means activities that are directly related to the production of juice products.

(2) For purposes of this part, processing does not include:

(i) Harvesting, picking, or transporting raw agricultural ingredients of juice products, without otherwise engaging in processing; and

(ii) The operation of a retail establishment.

(k) Processor means any person engaged in commercial, custom, or institutional processing of juice products, either in the United States or in a foreign country, including any person engaged in the processing of juice products that are intended for use in market or consumer tests.

(l) *Retail establishment* is an operation that provides juice directly to the consumers and does not include an establishment that sells or distributes juice to other business entities as well as directly to consumers. ''Provides'' includes storing, preparing, packaging, serving, and vending.

(m) *Shall* is used to state mandatory requirements.

(n) *Shelf-stable product* means a product that is hermetically sealed and, when stored at room temperature, should not demonstrate any microbial growth.

(o) *Should* is used to state recommended or advisory procedures or to identify recommended equipment.

(p) *Validation* means that element of verification focused on collecting and evaluating scientific and technical information to determine whether the HACCP plan, when properly implemented, will effectively control the identified food hazards.

(q) *Verification* means those activities, other than monitoring, that establish the validity of the HACCP plan and that the system is operating according to the plan.

§ 120.5 Current good manufacturing practice.

Part 110 of this chapter applies in determining whether the facilities, methods, practices, and controls used to process juice are safe, and whether the food has been processed under sanitary conditions.

§ 120.6 Sanitation standard operating procedures.

(a) *Sanitation controls.* Each processor shall have and implement a sanitation standard operating procedure (SSOP) that addresses sanitation conditions and practices before, during, and after processing. The SSOP shall address:

(1) Safety of the water that comes into contact with food or food contact surfaces or that is used in the manufacture of ice;

(2) Condition and cleanliness of food contact surfaces, including utensils, gloves, and outer garments;

(3) Prevention of cross contamination from insanitary objects to food, food packaging material, and other food contact surfaces, including utensils, gloves, and outer garments, and from raw product to processed product;

(4) Maintenance of hand washing, hand sanitizing, and toilet facilities;

(5) Protection of food, food packaging material, and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate, and other chemical, physical, and biological contaminants;

(6) Proper labeling, storage, and use of toxic compounds;

(7) Control of employee health conditions that could result in the microbiological contamination of food, food packaging materials, and food contact surfaces; and

(8) Exclusion of pests from the food plant.

(b) *Monitoring.* The processor shall monitor the conditions and practices during processing with sufficient frequency to ensure, at a minimum, conformance with those conditions and practices specified in part 110 of this chapter that are appropriate both to the plant and to the food being processed. Each processor shall correct, in a timely manner, those conditions and practices that are not met.

(c) *Records.* Each processor shall maintain SSOP records that, at a minimum, document the monitoring and corrections prescribed by paragraph (b) of this section. These records are subject to the recordkeeping requirements of § 120.12.

(d) *Relationship to Hazard Analysis and Critical Control Point (HACCP) plan.* Sanitation standard operating procedure controls may be included in the HACCP plan required under § 120.8(b). However, to the extent that they are implemented in accordance with this section, they need not be included in the HACCP plan.

§ 120.7 Hazard analysis.

(a) Each processor shall develop, or have developed for it, a written hazard analysis to determine whether there are food hazards that are reasonably likely to occur for each type of juice processed by that processor and to identify control measures that the processor can apply to control those hazards. The written hazard analysis shall consist of at least the following:

(1) Identification of food hazards;

(2) An evaluation of each food hazard identified to determine if the hazard is reasonably likely to occur and thus, constitutes a food hazard that must be addressed in the HACCP plan. A food hazard that is reasonably likely to occur is one for which a prudent processor would establish controls because experience, illness data, scientific reports, or other information provide a basis to conclude that there is a reasonable possibility that, in the absence of those controls, the food hazard will occur in the particular type of product being processed. This

evaluation shall include an assessment of the severity of the illness or injury if the food hazard occurs;

(3) Identification of the control measures that the processor can apply to control the food hazards identified as reasonably likely to occur in paragraph (a)(2) of this section;

(4) Review of the current process to determine whether modifications are necessary; and

(5) Identification of critical control points.

(b) The hazard analysis shall include food hazards that can be introduced both within and outside the processing plant environment, including food hazards that can occur before, during, and after harvest. The hazard analysis shall be developed by an individual or individuals who have been trained in accordance with § 120.13 and shall be subject to the recordkeeping requirements of § 120.12.

(c) In evaluating what food hazards are reasonably likely to occur, consideration should be given, at a minimum, to the following:

(1) Microbiological contamination;

(2) Parasites;

(3) Chemical contamination;

(4) Unlawful pesticides residues;

(5) Decomposition in food where a food hazard has been associated with decomposition;

(6) Natural toxins;

(7) Unapproved use of food or color additives;

(8) Presence of undeclared ingredients that may be allergens; and

(9) Physical hazards.

(d) Processors should evaluate product ingredients, processing procedures, packaging, storage, and intended use; facility and equipment function and design; and plant sanitation, including employee hygiene, to determine the potential effect of each on the safety of the finished food for the intended consumer.

(e) HACCP plans for juice need not address the food hazards associated with microorganisms and microbial toxins that are controlled by the requirements of part 113 or part 114 of this chapter. A HACCP plan for such juice shall address any other food hazards that are reasonably likely to occur.

§ 120.8 Hazard Analysis and Critical Control Point (HACCP) plan.

(a) *HACCP plan.* Each processor shall have and implement a written HACCP plan whenever a hazard analysis reveals one or more food hazards that are reasonably likely to occur during processing, as described in § 120.7. The HACCP plan shall be developed by an individual or individuals who have been trained in accordance with § 120.13 and shall be subject to the recordkeeping requirements of § 120.12. A HACCP plan shall be specific to:

(1) Each location where juice is processed by that processor; and

(2) Each type of juice processed by the processor. The plan may group types of juice products together, or group types of production methods together, if the food hazards, critical control points, critical limits, and procedures required to be identified and performed by paragraph (b) of this section are essentially identical, provided that any required features of the plan that are unique to a specific product or method are clearly delineated in the plan and are observed in practice.

(b) *The contents of the HACCP plan.* The HACCP plan shall, at a minimum:

(1) List all food hazards that are reasonably likely to occur as identified in accordance with § 120.7, and that thus must be controlled for each type of product;

(2) List the critical control points for each of the identified food hazards that is reasonably likely to occur, including as appropriate:

(i) Critical control points designed to control food hazards that are reasonably likely to occur and could be introduced inside the processing plant environment; and

(ii) Critical control points designed to control food hazards introduced outside the processing plant environment, including food hazards that occur before, during, and after harvest;

(3) List the critical limits that shall be met at each of the critical control points;

(4) List the procedures, and the frequency with which they are to be performed, that will be used to monitor each of the critical control points to ensure compliance with the critical limits;

(5) Include any corrective action plans that have been developed in accordance with § 120.10(a), and that are to be followed in response to deviations from critical limits at critical control points;

(6) List the validation and verification procedures, and the frequency with which they are to be performed, that the processor will use in accordance with § 120.11; and

(7) Provide for a recordkeeping system that documents the monitoring of the critical control points in accordance with § 120.12. The records shall contain the actual values and observations obtained during monitoring.

(c) *Sanitation.* Sanitation controls may be included in the HACCP plan. However, to the extent that they are monitored in accordance with § 120.6, they are not required to be included in the HACCP plan.

§ 120.9 Legal basis.

Failure of a processor to have and to implement a Hazard Analysis and Critical Control Point (HACCP) system that complies with §§ 120.6, 120.7, and 120.8, or otherwise to operate in accordance with the requirements of this part, shall render the juice products of that processor adulterated under section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. Whether a processor's actions are consistent with ensuring the safety of juice will be determined through an evaluation of the processor's overall implementation of its HACCP system.

§ 120.10 Corrective actions.

Whenever a deviation from a critical limit occurs, a processor shall take corrective action by following the procedures set forth in paragraph (a) or paragraph (b) of this section.

(a) Processors may develop written corrective action plans, which become part of their HACCP plans in accordance with § 120.8(b)(5), by which processors predetermine the corrective actions that they will take whenever there is a deviation from a critical limit. A corrective action plan that is appropriate for a particular deviation is one that describes the steps to be taken and assigns responsibility for taking those steps, to ensure that:

(1) No product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation; and

(2) The cause of the deviation is corrected.

(b) When a deviation from a critical limit occurs, and the processor does not have a corrective action plan that is appropriate for that deviation, the processor shall:

(1) Segregate and hold the affected product, at least until the requirements of paragraphs (b)(2) and (b)(3) of this section are met;

(2) Perform or obtain a review to determine the acceptability of the affected product for distribution. The review shall be performed by an individual or individuals who have adequate training or experience to perform such review;

(3) Take corrective action, when necessary, with respect to the affected product to ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation;

(4) Take corrective action, when necessary, to correct the cause of the deviation; and

(5) Perform or obtain timely verification in accordance with § 120.11, by an individual or individuals who have been trained in accordance with § 120.13, to determine whether modification of the HACCP plan is required to reduce the risk of recurrence of the deviation, and to modify the HACCP plan as necessary.

(c) All corrective actions taken in accordance with this section shall be fully documented in records that are subject to verification in accordance with § 120.11(a)(1)(iv)(B) and the recordkeeping requirements of § 120.12.

§ 120.11 Verification and validation.

(a) *Verification.* Each processor shall verify that the Hazard Analysis and Critical Control Point (HACCP) system is being implemented according to design.

(1) Verification activities shall include:

(i) A review of any consumer complaints that have been received by the processor to determine whether such complaints relate to the performance of the HACCP plan or reveal previously unidentified critical control points;

(ii) The calibration of process monitoring instruments;

(iii) At the option of the processor, the performance of periodic end-product or in-process testing; except that processors of citrus juice that rely in whole or in part on surface treatment of fruit shall perform end-product testing in accordance with § 120.25.

(iv) A review, including signing and dating, by an individual who has been trained in accordance with § 120.13, of the records that document:

(A) The monitoring of critical control points. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that the records document values that are within the critical limits. This review shall occur within 1 week (7 days) of the day that the records are made;

(B) The taking of corrective actions. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that appropriate corrective actions were taken in accordance with § 120.10. This review shall occur within 1 week (7 days) of the day that the records are made; and

(C) The calibrating of any process monitoring instruments used at critical control points and the performance of any periodic end-product or in-process testing that is part of the processor's verification activities. The purpose of these reviews shall be, at a minimum, to ensure that the records are complete and that these activities occurred in accordance with the processor's written procedures. These reviews shall occur within a reasonable time after the records are made; and

(v) The following of procedures in § 120.10 whenever any verification procedure, including the review of consumer complaints, establishes the need to take a corrective action; and

(vi) Additional process verification if required by § 120.25.

(2) Records that document the calibration of process monitoring instruments, in accordance with paragraph (a)(1)(iv)(B) of this section, and the performance of any periodic end-product and in-process testing, in accordance with paragraph (a)(1)(iv)(C) of this section, are subject to the recordkeeping requirements of § 120.12.

(b) *Validation of the HACCP plan.* Each processor shall validate that the HACCP plan is adequate to control food hazards that are reasonably likely to occur; this validation shall occur at least once within 12 months after implementation and at least annually thereafter or whenever any changes in the process occur that could affect the hazard analysis or alter the HACCP plan in any way. Such changes may include changes in the following: Raw materials or source of raw materials; product formulation; processing methods or systems, including computers and their software; packaging; finished product distribution systems; or the intended use or consumers of the finished product. The validation shall be performed by an individual or individuals who have been trained in accordance with § 120.13 and shall be subject to the recordkeeping requirements of § 120.12. The HACCP plan shall be modified immediately whenever a validation reveals that the plan is no longer adequate to fully meet the requirements of this part.

(c) *Validation of the hazard analysis.* Whenever a juice processor has no HACCP plan because a hazard analysis has revealed no food hazards that are reasonably likely to occur, the processor shall reassess the adequacy of that hazard analysis whenever there are any changes in the process that could reasonably affect whether a food hazard exists. Such changes may include changes in the following: Raw materials or source of raw materials; product formulation; processing methods or systems, including computers and their software; packaging; finished product distribution systems; or the intended use or intended consumers of the finished product. The validation of the hazard analysis shall be performed by an individual or individuals who have been trained in accordance with § 120.13, and, records documenting the validation shall be subject to the recordkeeping requirements of § 120.12.

§ 120.12 Records.

(a) *Required records.* Each processor shall maintain the following records documenting the processor's Hazard Analysis and Critical Control Point (HACCP) system:

(1) Records documenting the implementation of the sanitation standard operating procedures (SSOP's) (see § 120.6);

(2) The written hazard analysis required by § 120.7;

(3) The written HACCP plan required by § 120.8;

(4) Records documenting the ongoing application of the HACCP plan that include:

(i) Monitoring of critical control points and their critical limits, including the recording of actual times, temperatures, or other measurements, as prescribed in the HACCP plan; and

(ii) Corrective actions, including all actions taken in response to a deviation; and

(5) Records documenting verification of the HACCP system and validation of the HACCP plan or hazard analysis, as appropriate.

(b) *General requirements.* All records required by this part shall include:

(1) The name of the processor or importer and the location of the processor or importer, if the processor or importer has more than one location;

(2) The date and time of the activity that the record reflects, except that records required by paragraphs (a)(2), (a)(3), and (a)(5) of this section need not include the time;

(3) The signature or initials of the person performing the operation or creating the record; and

(4) Where appropriate, the identity of the product and the production code, if any. Processing and other information shall be entered on records at the time that it is observed. The records shall contain the actual values and observations obtained during monitoring.

(c) *Documentation.* (1) The records in paragraphs (a)(2) and (a)(3) of this section shall be signed and dated by the most responsible individual onsite at the processing facility or by a higher level official of the processor. These signatures shall signify that these records have been accepted by the firm.

(2) The records in paragraphs (a)(2) and (a)(3) of this section shall be signed and dated:

(i) Upon initial acceptance;

(ii) Upon any modification; and

(iii) Upon verification and validation in accordance with § 120.11.

(d) *Record retention.* (1) All records required by this part shall be retained at the processing facility or at the importer's place of business in the United States for, in the case of perishable or refrigerated juices, at least 1 year after the date that such products were prepared, and for, in the case of frozen, preserved, or shelf stable products, 2 years or the shelf life of the product, whichever is greater, after the date that the products were prepared.

(2) Offsite storage of processing records required by paragraphs (a)(1) and (a)(4) of this section is permitted after 6 months following the date that the monitoring occurred, if such records can be retrieved and provided onsite within 24 hours of request for official review. Electronic records are considered to be onsite if they are accessible from an onsite location and comply with paragraph (g) of this section.

(3) If the processing facility is closed for a prolonged period between seasonal packs, the records may be transferred to some other reasonably accessible location at the end of the seasonal pack but shall be immediately returned to the processing facility for official review upon request.

(e) *Official review.* All records required by this part shall be available for review and copying at reasonable times.

(f) *Public disclosure.* (1) All records required by this part are not available for public disclosure unless they have been previously disclosed to the public, as defined in § 20.81 of this chapter, or unless they relate to a product or ingredient that has been abandoned and no longer represent a trade secret or confidential commercial or financial information as defined in § 20.61 of this chapter.

(2) Records required to be maintained by this part are subject to disclosure to the extent that they are otherwise publicly available, or that disclosure could not reasonably be expected to cause a competitive hardship, such as generic type HACCP plans that reflect standard industry practices.

(g) *Records maintained on computers.* The maintenance of computerized records, in accordance with part 11 of this chapter, is acceptable. § 120.13 *Training.*

(a) Only an individual who has met the requirements of paragraph (b) of this section shall be responsible for the following functions:

(1) Developing the hazard analysis, including delineating control measures, as required by § 120.7.

(2) Developing a Hazard Analysis and Critical Control Point (HACCP) plan that is appropriate for a specific processor, in order to meet the requirements of § 120.8;

(3) Verifying and modifying the HACCP plan in accordance with the corrective action procedures specified in § 120.10(b)(5) and the validation activities specified in § 120.11(b) and (c); and § 120.7;

(4) Performing the record review required by § 120.11(a)(1)(iv).

(b) The individual performing the functions listed in paragraph (a) of this section shall have successfully completed training in the application of HACCP principles to juice processing at least equivalent to that received under standardized curriculum recognized as adequate by the Food and Drug Administration, or shall be otherwise qualified through job experience to perform these functions. Job experience may qualify an individual to perform these functions if such experience has provided knowledge at least equivalent to that provided through the standardized curriculum. The trained individual need not be an employee of the processor.

§ 120.14 Application of requirements to imported products.

This section sets forth specific requirements for imported juice.

(a) *Importer requirements.* Every importer of juice shall either:

(1) Obtain the juice from a country that has an active memorandum of understanding (MOU) or similar agreement with the Food and Drug Administration, that covers the food and documents the equivalency or compliance of the inspection system of the foreign country with the U.S. system, accurately reflects the relationship between the signing parties, and is functioning and enforceable in its entirety; or

(2) Have and implement written procedures for ensuring that the juice that such importer receives for import into the United States was processed in accordance with the requirements of this part. The procedures shall provide, at a minimum:

(i) Product specifications that are designed to ensure that the juice is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act because it may be injurious to health or because it may have been processed under insanitary conditions; and

(ii) Affirmative steps to ensure that the products being offered for entry were processed under controls that meet the requirements of this part. These steps may include any of the following:

(A) Obtaining from the foreign processor the Hazard Analysis and Critical Control Point (HACCP) plan and prerequisite program of the standard operating procedure records required by this part that relate to the specific lot of food being offered for import;

(B) Obtaining either a continuing or lot specific certificate from an appropriate foreign government inspection authority or competent third party certifying that the imported food has been processed in accordance with the requirements of this part;

(C) Regularly inspecting the foreign processor's facilities to ensure that the imported food is being processed in accordance with the requirements of this part;

(D) Maintaining on file a copy, in English, of the foreign processor's hazard analysis and HACCP plan, and a written guarantee from the foreign processor that the imported food is processed in accordance with the requirements of this part;

(E) Periodically testing the imported food, and maintaining on file a copy, in English, of a written guarantee from the foreign processor that the imported food is processed in accordance with the requirements of this part; or

(F) Other such verification measures as appropriate that provide an equivalent level of assurance of compliance with the requirements of this part.

(b) *Competent third party.* An importer may hire a competent third party to assist with or perform any or all of the verification activities specified in paragraph (a)(2) of this section, including writing the importer's verification procedures on the importer's behalf.

(c) *Records.* The importer shall maintain records, in English, that document the performance and results of the affirmative steps specified in paragraph (a)(2)(ii) of this section. These records shall be subject to the applicable provisions of § 120.12.

(d) *Determination of compliance.* The importer shall provide evidence that all juice offered for entry into the United States has been processed under conditions that comply with this part. If assurances do not exist that an imported juice has been processed under conditions that are equivalent to those required of domestic processors under this part, the product will appear to be adulterated and will be denied entry.

Subpart B—Pathogen Reduction

§ 120.20 General.

This subpart augments subpart A of this part by setting forth specific requirements for process controls.

§ 120.24 Process controls.

(a) In order to meet the requirements of subpart A of this part, processors of juice products shall include in their Hazard Analysis and Critical Control Point (HACCP) plans control measures that will consistently produce, at a minimum, a 5 log (*i.e.*, 10^5) reduction, for a period at least as long as the shelf life of the product when stored under normal and moderate abuse conditions, in the pertinent microorganism. For the purposes of this regulation, the ''pertinent microorganism'' is the most resistant microorganism of public health significance that is likely to occur in the juice. The following juice processors are exempt from this paragraph:

(1) A juice processor that is subject to the requirements of part 113 or part 114 of this chapter; and

(2) A juice processor using a single thermal processing step sufficient to achieve shelf-stability of the juice or a thermal concentration process that includes thermal treatment of all ingredients, provided that the processor includes a copy of the thermal process used to achieve shelf-stability or concentration in its written hazard analysis required by § 120.7.

(b) All juice processors shall meet the requirements of paragraph (a) of this section through treatments that are applied directly to the juice, except that citrus juice processors may use treatments to fruit surfaces, provided that the 5-log reduction process begins after culling and cleaning as defined in § 120.3(a) and (f) and the reduction is accomplished within a single production facility.

(c) All juice processors shall meet the requirements of paragraphs (a) and (b) of this section and perform final product packaging within a single production facility operating under current good manufacturing practices. Processors claiming an exemption under paragraph (a)(1) or (a)(2) of this section shall also process and perform final product packaging of all juice subject to the claimed exemption within a single production facility operating under current good manufacturing practices.

§ 120.25 Process verification for certain processors.

Each juice processor that relies on treatments that do not come into direct contact with all parts of the juice to achieve the requirements of § 120.24 shall analyze the finished product for biotype I *Escherichia coli* as follows:

(a) One 20 milliliter (mL) sample (consisting of two 10 mL subsamples) for each 1,000 gallons of juice produced shall be sampled each production day. If less than 1,000 gallons of juice is produced per day, the sample must be taken for each 1,000 gallons produced but not less than once every 5 working days that the facility is producing that juice. Each subsample shall be taken by randomly selecting a package of juice ready for distribution to consumers.

(b) If the facility is producing more than one type of juice covered by this section, processors shall take subsamples according to paragraph (a) of this section for each of the covered juice products produced.

(c) Processors shall analyze each subsample for the presence of *E. coli* by the method entitled ''Analysis for *Escherichia coli* in Citrus Juices—Modification of AOAC Official Method 992.30'' or another method that is at least equivalent to this method in terms of accuracy, precision, and sensitivity in detecting *E. coli*. This method is designed to detect the presence or absence of *E. coli* in a 20 mL sample of juice (consisting of two 10 mL subsamples). The method is as follows:

(1) *Sample size.* Total-20 mL of juice; perform analysis using two 10 mL aliquots.

(2) *Media.* Universal Preenrichment Broth (Difco, Detroit, MI), EC Broth (various manufacturers).

(3) *Method.* ColiComplete (AOAC Official Method 992.30—modified).

(4) *Procedure.* Perform the following procedure two times:

(i) Aseptically inoculate 10 mL of juice into 90 mL of Universal Preenrichment Broth (Difco) and incubate at 35 °C for 18 to 24 hours.

(ii) Next day, transfer 1 mL of preenriched sample into 10 mL of EC Broth, without durham gas vials. After inoculation, aseptically add a ColiComplete SSD disc into each tube.

(iii) Incubate at 44.5 °C for 18 to 24 hours.

(iv) Examine the tubes under longwave ultra violet light (366 nm). Fluorescent tubes indicate presence of *E. coli*.

(v) MUG positive and negative controls should be used as reference in interpreting fluorescence reactions. Use an *E. coli* for positive control and 2 negative controls—a MUG negative strain and an uninoculated tube media.

(d) If either 10 mL subsample is positive for *E. coli*, the 20 mL sample is recorded as positive and the processor shall:

(1) Review monitoring records for the control measures to attain the 5-log reduction standard and correct those conditions and practices that are not met. In addition, the processor may choose to test the sample for the presence of pathogens of concern.

(2) If the review of monitoring records or the additional testing indicates that the 5-log reduction standard was not achieved (*e.g.*, a sample is found to be positive for the presence of a pathogen or a deviation in the process or its delivery is identified), the processor shall take corrective action as set forth in § 120.10.

(e) If two samples in a series of seven tests are positive for *E. coli*, the control measures to attain the 5-log reduction standard shall be deemed to be inadequate and the processor shall immediately:

(1) Until corrective actions are completed, use an alternative process or processes that achieve the 5-log reduction after the juice has been expressed;

(2) Perform a review of the monitoring records for control measures to attain the 5-log reduction standard. The review shall be sufficiently extensive to determine that there are no trends towards loss of control;

(i) If the conditions and practices are not being met, correct those that do not conform to the HACCP plan; or

(ii) If the conditions and practices are being met, the processor shall validate the HACCP plan in relation to the 5-log reduction standard; and

(3) Take corrective action as set forth in § 120.10. Corrective actions shall include ensuring no product enters commerce that is injurious to health as set forth in § 120.10(a)(1).

Dated: December 20, 2000.

Jane E. Henny,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

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Part VI

Department of Agriculture

Cooperative State Research, Education and Extension Service

Requests for Proposals (RFP): Food and Agricultural Sciences National Needs Graduate Fellowship Grants Program for Fiscal Years 2001 and 2002; and Special Research Grants Programs, Citrus Tristeza Research; Notice

DEPARTMENT OF AGRICULTURE

Cooperative State Research, Education, and Extension Service

Request for Proposals (RFP): Food and Agricultural Sciences National Needs Graduate Fellowship Grants Program for Fiscal Years 2001 and 2002

AGENCY: Cooperative State Research, Education, and Extension Service, USDA.

ACTION: Notice of request for proposals and request for input.

SUMMARY: The Cooperative State Research, Education, and Extension Service (CSREES) announces the availability of grant funds and requests proposals for the Food and Agricultural Sciences National Needs Graduate Fellowship Grants Program for Fiscal Years (FYs) 2001 and 2002, and for 2001 Supplemental Grants for Special International Study or Thesis/Dissertation Research Travel Allowances. Proposals are hereby requested from eligible institutions as identified herein for competitive consideration for Food and Agricultural Sciences National Needs Graduate Fellowship Grant awards. In addition, CSREES seeks proposals from recipients of currently active Food and Agricultural Sciences National Needs Fellowship Grants for supplemental grants to support special international study or thesis/dissertation research experiences for current Fellows.

CSREES also is soliciting comments regarding this RFP from any interested party. Such comments will be considered in the development of any future requests for proposals for this program. Such comments will be used in meeting the requirements of section 103(c)(2) of the Agricultural Research, Extension, and Education Reform Act of 1998 (AREERA).

DATES: All proposals for Food and Agricultural Sciences National Needs Graduate Fellowship Grants must be received on or before July 10, 2001. Supplemental Grant proposals to support special international study or thesis/dissertation research for current Fellows must be received by October 1, 2001. Proposals not received on or before these dates, as appropriate, will not be considered for funding.

Comments are requested within six months from the issuance of this RFP. Comments received after that date will be considered to the extent practicable.

ADDRESSES: For Food and Agricultural Sciences National Needs Graduate Fellowship Grant proposals, hand-delivered proposals (brought in person by the applicant or through a courier service) must be received on or before July 10, 2001, at the following address: National Needs Graduate Fellowship Grants Program; c/o Proposal Services Unit Office of Extramural Programs Cooperative State Research, Education, and Extension Service; U.S. Department of Agriculture; Room 1307, Waterfront Centre; 800 9th Street, SW.; Washington, DC 20024. The telephone number is (202) 401–5048. Proposals transmitted via facsimile (fax) machine will not be accepted. Proposals submitted by mail must be received on or before July 10, 2001. Proposals submitted by mail should be sent to the following address: National Needs Graduate Fellowship Grants Program; c/o Proposal Services Unit; Office of Extramural Programs; Cooperative State Research, Education, and Extension Service; U.S. Department of Agriculture; STOP 2245; 1400 Independence Avenue, SW.; Washington, DC 20250–2245.

For International Study or Thesis/Dissertation Research Supplemental Grant proposals, hand-delivered proposals (brought in person by the applicant or through a courier service) must be received prior to October 1, 2001, at the following address: Graduate Fellowship (International) Supplemental Grants Program; c/o Proposal Services Unit; Office of Extramural Programs; Cooperative State Research, Education, and Extension Service; U.S. Department of Agriculture; Room 1307, Waterfront Centre; 800 9th Street, SW.; Washington, DC 20024. The telephone number is (202) 401–5048. Proposals transmitted via a facsimile (fax) machine will not be accepted. Proposals submitted by mail must be received prior to October 1, 2001. Proposals submitted by mail should be sent to the following address: Graduate Fellowship (International) Supplemental Grants Program; c/o Proposal Services Unit; Office of Extramural Programs; Cooperative State Research, Education, and Extension Service; U.S. Department of Agriculture; STOP 2245; 1400 Independence Avenue, SW.; Washington, DC 20250–2245.

Written user comments should be submitted by mail to: Policy and Program Liaison Staff; Office of Extramural Programs; USDA–CSREES; STOP 2299; 1400 Independence Avenue, SW.; Washington, DC 20250–2299; or via e-mail to: *RFP–OEP@reeusda.gov.* (This e-mail address is intended only for receiving stakeholder input comments regarding this RFP, and not for requesting information or forms.)

FOR FURTHER INFORMATION CONTACT: Dr. Howard Sandberg; Higher Education Programs; Cooperative State Research, Education, and Extension Service; U.S. Department of Agriculture, STOP 2251; 1400 Independence Avenue, SW.; Washington, DC 20250–2251; Telephone: (202) 720–2193; E-mail: *hsandberg@reeusda.gov.*

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Stakeholder Input

CSREES is requesting comments regarding this FY 2001 RFP from any interested party. In your comments, please include the name of the program and the fiscal year solicitation for applications to which you are responding. These comments will be considered in the development of the next solicitation for applications for the program. Such comments will be used in meeting the requirements of section 103(c)(2) of the Agricultural Research, Extension, and Education Reform Act of 1998, 7 U.S.C. 7613(c). Comments should be submitted as provided for in the **ADDRESSES** and **DATES** portions of this notice.

Catalog of Federal Domestic Assistance

This program is listed in the Catalog of Federal Domestic Assistance under No. 10.210, Food and Agricultural Sciences National Needs Graduate Fellowship Grants.

Part I. Food and Agricultural Sciences National Needs Graduate Fellowship Grants

A. Administrative Provisions and Legislative Authority

This Program is subject to the provisions found at 7 CFR part 3402. 7 CFR part 3402 sets forth procedures to be followed when submitting grant proposals for food and agricultural sciences national needs graduate fellowship grants, rules governing the evaluation of proposals and the awarding of grants, and regulations relating to the post-award administration of such grant projects.

Legislative authority for this program is contained in section 1417(b)(6) of the National Agricultural Research, Extension, and Teaching Policy Act of 1977, as amended (NARETPA) (7 U.S.C. 3152(b)(6)).

In accordance with the statutory authority, subject to the availability of funds, the Secretary of Agriculture, who has delegated the authority to the Administrator of CSREES, may make competitive grants, for periods not to exceed five years, to land-grant colleges and universities, to colleges and universities having significant minority enrollments and a demonstrable capacity to carry out the teaching of food and agricultural sciences, and to other colleges and universities having a demonstrable capacity to carry out the teaching of food and agricultural sciences, to administer and conduct graduate fellowship programs to help meet the Nation's needs for development of scientific and professional expertise in the food and agricultural sciences. For this program, the term ''food and agricultural sciences'' means basic, applied, and developmental research, extension, and teaching activities in food and fiber, agriculture, renewable natural resources, forestry, and physical and social sciences, including activities related to subject areas defined in section 1404(8) of NARETPA, 7 U.S.C. 3103(8).

B. Program Description

1. Purpose of the Program

This program seeks to award grants for training students for a doctoral degree at colleges and universities which have demonstrable teaching and research competencies in the food and agricultural sciences. The grants are specifically intended to support fellowship programs that encourage outstanding students to pursue and complete their degree at such institutions in an area of the food and agricultural sciences for which there is a national need for the development of scientific and professional expertise.

2. Targeted National Need Areas

Food and agricultural science areas appropriate for fellowship grant applications are those which are directly related to one of the following: (1) Animal, microbial, or plant molecular biology including genomics or bioinformatics; (2) natural resources and environment; (3) agricultural systems or natural resource engineering; (4) marketing or management; (5) food science or human nutrition; or (6) human sciences. A proposal is restricted to one national need area.

3. Eligibility

Proposals may be submitted by institutions that confer a doctoral degree in a national need area. For proposals involving more than one institution, all institutions must meet the eligibility requirements. Proposals also may be submitted by a research foundation maintained by an eligible college or university. Eligibility requirements are discussed further in 7 CFR 3402.3.

4. Degree Level Supported

In FYs 2001 and 2002, only the doctoral level of study will be supported.

5. Proposal Submission Limitations

No limitations are placed on the number of proposals which can be submitted by a college or university.

6. Limitations on Number of Fellowships

There is no limit on the number of fellowships in the single national need area which can be requested in the proposal. While proposals must document institution willingness to recruit and train the number of fellows requested, CSREES may fund fewer fellows than requested in a proposal. Also, the maximum total amount of funds from this program that may be awarded to an institution in FYs 2001 and 2002 is limited to $276,000.

7. Available Funding

Subject to the enactment of the appropriations acts that will provide funds to CSREES for this program in FYs 2001 and 2002, CSREES anticipates that approximately $5.6 million will be available for fellowship grants for the FYs 2001 and 2002 combined competition, including approximately $2.8 million in anticipated FY 2001 appropriations and approximately $2.8 million in anticipated FY 2002 appropriations. Contingent on the availability of these funds, approximately $934,000 will be allocated to each of the six national need areas. This program is highly competitive, and it is anticipated that available funding will support approximately 81 doctoral fellows. No-year funds drawn from expired fellowship grants with unspent funds remaining may be used to fund additional fellows. Please note that Congress has not enacted the FY 2002 appropriation bills for the Department. Therefore, the $5.6 million cited for FYs 2001 and 2002 grants is only tentative, and USDA is not bound by this estimate.

8. Stipend Level

Each institution funded will receive $69,000 for each doctoral fellowship awarded. However, it is anticipated that total program funds available will not be evenly divisible by $69,000. Therefore, one fellowship may be supported on a partial basis with a lesser amount of funds, or one fellowship may be supported fully by a combination of FYs 2001 and 2002 funds and unspent funds remaining from expired fellowship grants. Except in the case of a partially funded fellowship, fellowship monies must be used to: (1) Support the same doctoral fellow for three years at $22,000 per year; and (2) provide for an institution annual cost-of-education allowance of $1,000. Total funds awarded to an institution under the program in FYs 2001 and 2002 shall not exceed $276,000.

C. Selection Process and Evaluation Criteria

Section 223 of the Agricultural Research, Extension, and Education Reform Act of 1998, Pub. L. No. 105–185, amended section 1417 of NARETPA to require that priorities be given in awarding grants for certain teaching enhancement projects under section 1417(b) of NARETPA. This program is authorized under section 1417(b). CSREES considers all applications received in response to this solicitation as teaching enhancement project applications. To implement the new priorities for proposals submitted for the FYs 2001 and 2002 competition, the evaluation criteria used to evaluate proposals, as provided in the administrative provisions for this program (7 CFR 3402.19), have been

modified to include new criteria for proposals demonstrating enhanced coordination among eligible institutions and focusing on innovative, multidisciplinary education programs, material, or curricula. The following criteria and weights will be used to evaluate proposals submitted for funding to the FYs 2001 and 2002 competition:

(A) 25 points—The degree to which the proposal establishes clearly that the proposed program of graduate study will result in the development of outstanding scientific/professional expertise related to a national need area and will do so in a reasonable period of time.

(B) 25 points—The degree to which the proposal contains any special features such as a focus on innovative, multidisciplinary education programs, material, or curricula; enhanced coordination among institutions eligible for grants under the Food and Agricultural National Needs Fellowship Grant Program; an inter-disciplinary, multi-disciplinary, or cross-disciplinary approach, an unusual collateral specialization in a related discipline, experiential learning opportunities, unique mentoring programs, seminars, or a multi-university collaborative approach.

(C) 20 points—The degree to which the proposal substantiates clearly that the institution's faculty, facilities and equipment, instructional support resources, and other academic attributes are excellent for providing outstanding graduate study and research at the forefront of science and technology related to the chosen area of national need.

(D) 20 points—The degree to which the institution's plans and procedures for recruiting and selecting academically outstanding Fellows and for advising and guiding Fellows through a program of study reflect excellence as documented in the proposal.

(E) 5 points—The degree to which supplementary summary data substantiate program quality in the targeted need area.

(F) 5 points—The quality of the proposal as reflected by its substantive content, organization, clarity, and accuracy.

D. How To Obtain Application Materials

An Application Kit containing program application materials can be downloaded from the CSREES, Office of Higher Education Programs (HEP) web site at http://www.reeusda.gov/serd/hep/hep.htm or will be made available to eligible institutions upon request. These materials include the administrative provisions, this Request for Proposals, Summary Information, forms, instructions, and other relevant information needed to prepare and submit grant proposals. Copies of the Application Kit may be requested from the Proposal Services Unit; Office of Extramural Programs; Cooperative State Research, Education, and Extension Service; U.S. Department of Agriculture; STOP 2245; 1400 Independence Avenue, SW.; Washington, DC 20250–2245. The telephone number is 202–401–5048. When contacting the Proposal Services Unit, please indicate that you are requesting forms for the FYs 2001 and 2002 National Needs Graduate Fellowship Grants Program.

Application materials also may be requested via Internet by sending a message which states that you want to receive a copy of the application materials for the FY 2001/2002 National Needs Graduate Fellowship Grants Program with your name, mailing address (not e-mail) and phone number to psb@reeusda.gov. The materials will then be mailed to you (not e-mailed) as quickly as possible.

E. Submission of a Proposal

1. Intent To Submit a Proposal

Submission of an Intent to Submit a Proposal (Form CSREES–706) is requested for the FYs 2001 and 2002 competition and is due May 11, 2001. Form CSREES–706 can be sent by FAX to 202–720–2030; by courier to Graduate Fellowship Program; CSREES/SERD/HEP; Waterfront Centre; 3rd Floor, Room 3251; 800 9th Street, SW.; Washington, DC 20024; or by mail to Graduate Fellowship Program, USDA/CSREES/SERD/HEP, 1400 Independence Ave., SW.; STOP 2251; Washington, DC 20250–2251.

2. What To Submit

An original and six (6) copies of a proposal must be submitted. Proposals should contain all requested information when submitted. Each proposal should be typed on 8½″ x 11″ white paper, double-spaced, and on one side of the page only. Please note that the text of the proposal should be prepared using a font no smaller than 12 point and one-inch margins. All copies of the proposal must be submitted in one package. Each copy of the proposal must be stapled securely in the upper left-hand corner (DO NOT BIND).

The proposal should be paginated and a Table of Contents should be included preceding the proposal narrative. Applicants are cautioned to comply with the 20-page limitation for the narrative section of the proposal. Applicants also are cautioned to include *summary* faculty vitae using Summary Vita—Teaching Proposal (Form CSREES–708). More detailed information on the narrative, summary vita, and other portions of a proposal is provided in subpart C of 7 CFR part 3402.

3. Where and When To Submit

Hand-delivered proposals (brought in person by the applicant or through a courier service) must be received on or before July 10, 2001, at the following address: National Needs Graduate Fellowship Grants Program; c/o Proposal Services Unit; Office of Extramural Programs; Cooperative State Research, Education, and Extension Service; U.S. Department of Agriculture; Room 1307, Waterfront Centre; 800 9th Street, SW.; Washington, DC 20024. The telephone number is (202) 401–5048. Proposals transmitted via facsimile (fax) machine will not be accepted.

Proposals submitted through the mail must be received on or before July 10, 2001. Proposals submitted through the mail should be sent to the following address: National Needs Graduate Fellowship Grants Program; c/o Proposal Services Unit; Office of Extramural Programs; Cooperative State Research, Education, and Extension Service; U.S. Department of Agriculture; STOP 2245; 1400 Independence Avenue, SW., Washington, DC 20250–2245.

4. Acknowledgment of Proposals

The receipt of all proposals will be acknowledged via e-mail. Therefore it is important to include an e-mail address on the Proposal Cover Page (Form CSREES–701) when applicable. This acknowledgment will contain a proposal identification number. Once your proposal has been assigned a proposal number, please cite that number in future correspondence.

F. Current Research Information System (CRIS) Reports and Impact Reports

Institutions will be asked to submit annual CRIS Reports in partial fulfillment of the reporting requirements of 7 CFR 3402.25(a). Also, institutions will be asked to submit reports describing significant impacts generated by the activities and accomplishments of the fellows in partial fulfillment of the reporting requirements of 7 CFR 3402.25.

Part II. 2001 Special International Study or Thesis/Dissertation Research Travel Allowances

A. Administrative Provisions and Legislative Authority

This Program is subject to the provisions found at 7 CFR part 3402. 7 CFR 3402.5(e) sets forth procedures to be followed when submitting supplemental grant proposals for special international study or thesis/dissertation research travel allowances. 7 CFR part 3402, subparts E and F set forth rules governing the evaluation of proposals and the awarding of grants, and regulations relating to the post-award administration of such grant projects.

Legislative authority for this program is contained in section 1417(b)(6) of the National Agricultural Research, Extension, and Teaching Policy Act of 1977, as amended (NARETPA) (7 U.S.C. 3152(b)(6)).

B. Program Description

CSREES has determined that a new competition for special international study or thesis/dissertation research travel allowances will be held during FY 2001, and hereby solicits proposals for competitive supplemental grants. Proposals may be submitted by universities or colleges who currently have active Food and Agricultural Sciences National Needs Graduate Fellowship Grants. Eligibility for this opportunity is limited to any current Fellow with sufficient time to complete the international experience before the termination date of the fellowship grant under which he/she is supported. These supplementary grants provide support for a Fellow to conduct thesis/dissertation research or to undertake studies at a site outside of the United States. Before the international study or thesis/dissertation research travel may commence, a Fellow must have completed one academic year of full-time study, as defined by the institution, under the fellowship appointment and arrangements must have been formalized for the Fellow to study and/or conduct research in the foreign location(s).

Estimated funds for supplemental grants in FY 2001 are approximately $60,000. These funds are obtained from no-year funds drawn from expired fellowship grants with unspent funds remaining. CSREES has determined that no FY 2001 appropriations will be targeted to supplemental grants supporting special international study or thesis/dissertation research travel allowances. For each travel allowance, the institution may request up to $10,000. Travel allowance monies may be used only to pay travel and living expenses for the Fellow while the Fellow is on the specific international assignment as proposed in the application for the special international study or thesis/dissertation research travel allowance. No limitation is placed on the number of applications an institution may submit. Awards will be made to the extent possible based on the review of the proposal and subject to the availability of funds.

C. Selection Process and Evaluation Criteria

Applications for the special international travel allowances will be evaluated as they are received until available funds for the supplemental grants are exhausted. Upon receipt of an application, CSREES staff will first determine the eligibility of the Fellow for whom the application was submitted for an international travel experience. Eligible and complete requests then will be reviewed by professional staff from USDA or other Federal agencies, as appropriate. Since awards for supplemental grants will be made as reviews are completed, there is no assurance funds will be available late in the application period for every acceptable proposal.

The six evaluation criteria are:

1. 10 points—Destination and duration—the degree to which the destination and duration of the travel experience is appropriate for enhancing the Fellow's academic program.
2. 30 points—Travel experience activities—the degree to which the specific international experiences contribute to the Fellow's program of study.
3. 20 points—Advance preparations—the degree to which the proposed study or research activities are well-planned, including the likelihood that these activities will come to fruition and that the participation of identified personnel will materialize.
4. 10 points—Budget—the degree to which the budget for the international experience is justified.
5. 20 points—Personnel—the degree to which the personnel, both U.S. and international, involved with the travel experience have the appropriate credentials and experience to direct the Fellow's international experience, and the likelihood that their participation as mentors, trainers, advisors, or teachers will contribute to the educational value of the travel experiences.
6. 10 points—Supporting documentation—the degree to which letters from the dean of the college (or equivalent administrative unit) and the fellowship grant project director support the application.

D. How To Obtain Application Materials

An Application Kit containing program application materials can be downloaded from the HEP web site at *http://www.reeusda.gov/serd/hep/hep.htm* or will be made available to eligible institutions upon request. These materials include the administrative provisions, Request for Proposals, Summary Information, forms, instructions, and other relevant information needed to prepare and submit grant applications. Copies of the Application Kit may be requested from the Proposal Services Unit; Office of Extramural Programs; Cooperative State Research, Education, and Extension Service; U.S. Department of Agriculture; STOP 2245; 1400 Independence Avenue, SW.; Washington, DC 20250–2245. The telephone number is (202) 401–5048. When contacting the Proposal Services Unit, please indicate that you are requesting the Application Kit for the FY 2001 Graduate Fellowship (International) Supplemental Grants Program.

Application materials may also be requested via Internet by sending a message, that states that you wish to receive a copy of the application materials for the 2001 Graduate Fellowship (International) Supplemental Grants Program with your name, mailing address (not e-mail) and telephone number to psb@reeusda.gov. The materials will then be mailed to you (not e-mailed) as quickly as possible.

E. What To Submit

An original plus six (6) copies of each application must be submitted. Proposals should contain all requested information when submitted. Each proposal should be typed on 8½'' × 11″ white paper, double-spaced, and on one side of the page only. Please note that the text of the proposal should be prepared using a font no smaller than 12 point and one-inch margins. Each copy of the application should be stapled securely in the upper left-hand corner (DO NOT BIND). All copies of the application must be submitted in one package. Applications transmitted via a facsimile (FAX) machine will not be accepted.

A separate application must be submitted by a fellowship grant project director at an eligible institution on behalf of each Fellow for which a special international study or thesis/dissertation research travel allowance is requested.

Each application must include an ''Application for Funding,'' Form

CSREES–661, and a ''Budget,'' Form CSREES–55. To provide HEP with sufficient information upon which to evaluate the merits of the requests for a special international study or thesis/dissertation research travel allowance, each application for a supplemental grant must contain a narrative which provides the following: (1) The specific destination(s) and duration of the travel; (2) the specific study or thesis/dissertation research activities in which the Fellow will be engaged; (3) how the international experience will contribute to the Fellow's program of study; (4) a budget narrative specifying and justifying the dollar amount requested for the travel; (5) summary credentials of both the U.S. and international faculty or other professionals with whom the Fellow will be working during the international experience (summary credentials must not exceed three pages per person; ''Summary Vita—Teaching Proposal,'' Form CSREES–708, may be used for this purpose); (6) a letter from the dean of the Fellow's college or equivalent administrative unit supporting the Fellow's travel request and certifying that the travel experience will not jeopardize the Fellow's satisfactory progress toward degree completion; and (7) a letter from the fellowship grant project director certifying the Fellow's eligibility, the accuracy of the Fellow's travel request, and the relevance of the travel to the Fellow's advanced degree objectives.

The narrative portion of the application must not exceed 10 pages, excluding the summary vita/vitae.

F. Where and When To Submit

Applications for the special international study or thesis/dissertation research travel allowance supplemental grants may be submitted at any time prior to October 1, 2001. However, to allow time for CSREES to process the applications, proposals should be submitted at least three months prior to the proposed beginning date of the international research project. Applicants are urged to submit their proposals early.

Note: Proposals for these special supplemental awards should *not* be submitted as part of the application for a FY 2001/2002 Graduate Fellowship grant.)

Hand-delivered proposals (brought in person by the applicant or through a courier service) must be received prior to October 1, 2001, at the following address: Special International Study or Thesis/Dissertation Research Supplemental Grant; c/o Proposal Services Unit; Office of Extramural Programs; Cooperative State Research, Education, and Extension Service; U.S. Department of Agriculture; Room 1307, Waterfront Centre; 800 9th Street, SW.; Washington, DC 20024. The phone number is 202–401–5048. Proposals transmitted via a facsimile (fax) machine will not be accepted.

Proposals submitted through the U.S. mail must be received prior to October 1, 2001. Proposals submitted through the U.S. mail should be sent to the following address: Graduate Fellowship (International) Supplemental Grants Program; c/o Proposal Services Unit; Office of Extramural Programs; Cooperative State Research, Education, and Extension Service; U.S. Department of Agriculture; STOP 2245; 1400 Independence Avenue, SW.; Washington, DC 20250–2245.

G. Impact Reports

Awardees will be asked to submit an impact report at the conclusion of the international research experience. The impact report describes the accomplishments made by the Fellow as a result of the international research experience. This report should be submitted to: Graduate Fellowship Program; CSREES/SERD/HEP, USDA; STOP 2251; 1400 Independence Ave., SW.; Washington, DC 20250–2251.

Done at Washington, DC, this 11th day of January, 2001.

Colien Hefferan,

Administrator, Cooperative State Research, Education, and Extension Service.

[FR Doc. 01–1492 Filed 1–18–01; 8:45 am]

BILLING CODE 3410–22–P

DEPARTMENT OF AGRICULTURE

Cooperative State Research, Education, and Extension Service

Request for Proposals: Special Research Grants Program, Citrus Tristeza Research

AGENCY: Cooperative State Research, Education, and Extension Service, Department of Agriculture.

ACTION: Notice of request for proposals and request for input.

SUMMARY: The Cooperative State Research, Education, and Extension Service (CSREES) announces the availability of grant funds and requests proposals for the Special Research Grants Program, Citrus Tristeza Research for fiscal year (FY) 2001. The purpose of the program is to support research that focuses on problems caused by Citrus Tristeza Virus (CTV) and the Brown Citrus Aphid. This request for proposals (RFP) sets forth procedures to be followed when submitting grant proposals, rules governing the evaluation of proposals, the awarding of grants, and regulations relating to the post-award administration of such grants.

CSREES also is requesting comments regarding this RFP from any interested party. These comments will be considered in the development of the next RFP for this program. Such comments will be used in meeting the requirements of section 103(c)(2) of the Agricultural Research, Extension, and Education Reform Act of 1998.

DATES: All proposals must be received at USDA on or before February 15, 2001. Proposals not received on or before this date will not be considered for funding.

User comments are requested within six months from the issuance of this RFP. Comments received after that date will be considered to the extent practicable.

ADDRESSES: Proposals should be submitted to the following mailing address: Special Research Grants Program, Citrus Tristeza Research; c/o Proposal Services Unit; Cooperative State Research, Education, and Extension Service; U.S. Department of Agriculture; STOP 2245; 1400 Independence Avenue, SW.; Washington, DC 20250–2245.

The address for hand-delivered proposals or proposals submitted using an express mail or overnight courier service is: Special Research Grants Program, Citrus Tristeza Research; c/o Proposal Services Unit; Cooperative State Research, Education, and Extension Service; U.S. Department of Agriculture; Room 1307, Waterfront Centre; 800 9th Street, SW.; Washington, DC 20024. Telephone: (202) 401–5048.

Written user comments should be submitted by mail to: Policy and Program Liaison Staff; Office of Extramural Programs; USDA–CSREES; STOP 2299; 1400 Independence Avenue, SW.; Washington, DC 20250–2299; or via e-mail to: *RFP-OEP@reeusda.gov.* (This e-mail address is intended only for receiving comments regarding this solicitation and not for requesting information or forms.)

FOR FURTHER INFORMATION CONTACT: Dr. Tom Bewick, Manager, Citrus Tristeza Research Program; Cooperative State Research, Education, and Extension Service; U.S. Department of Agriculture; STOP 2220; 1400 Independence Avenue, SW.; Washington, DC 20250–2220; telephone (202) 401–3356; fax (202) 401–6869; e-mail: tbewick@reeusda.gov.

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Stakeholder Input

CSREES is requesting comments regarding the FY 2001 Special Research Grants Program, Citrus Tristeza Research RFP from any interested party. In your comments, please include the name of the program and the fiscal year solicitation for applications to which you are responding. These comments will be considered in the development of the next RFP for the program. Such comments will be used in meeting the requirements of section 103(c)(2) of the Agricultural Research, Extension, and Education Reform Act of 1998, 7 U.S.C. 7613(c). Comments should be submitted as provided for in the **ADDRESSES** and **DATES** portions of this notice.

Part I—General Information

A. Legislative Authority

The authority for this program is contained in section (c)(1)(A) of the Competitive, Special, and Facilities Research Grant Act, section 2 of Pub. L. 89–106, as amended (7 U.S.C. 450i(c)(1)(A)). This program is subject to the administrative regulations found in 7 CFR Part 3400.

In accordance with the statutory authority, the Secretary may make grants for the purpose of conducting research to facilitate or expand promising breakthroughs in areas of the food and agricultural sciences of importance to the United States.

B. Definitions

For the purpose of awarding grants under this program, the following definitions are applicable:

(1) *Administrator* means the Administrator of the Cooperative State Research, Education, and Extension Service and any other officer or employee of the Department to whom the authority involved may be delegated.

(2) *Authorized departmental officer* or *awarding official* means the Secretary or any employee of the Department who has the authority to issue or modify grant instruments on behalf of the Secretary.

(3) *Authorized organizational representative* means the president, director, chief executive officer, or other designated official of the applicant organization who has the authority to commit the resources of the organization.

(4) *Budget period* means the interval of time (usually 12 months) into which the project period is divided for budgetary and reporting purposes.

(5) *Department* or *USDA* means the United States Department of Agriculture.

(6) *Grantee* means the organization or entity designated in the grant award document as the responsible legal entity to which a grant is awarded.

(7) *Peer review panel* or *group* means an assembled group of experts or consultants qualified by training and experience in particular scientific or technical fields to give expert advice on the scientific and technical merit of grant applications in those fields. The panel members will evaluate eligible proposals submitted to this program in their personal and professional area(s) of expertise.

(8) *Prior approval* means written approval evidencing prior consent by an authorized departmental officer as defined in (2) above.

(9) *Project* means the particular activity within the scope of the program supported by a grant award.

(10) *Principal Investigator* means the single individual designated by the grantee in the grant application and approved by the Administrator who is responsible for the scientific and technical direction of the project.

(11) *Project period* means the total length of time that is approved by the Administrator for conducting the research project as outlined in an approved grant application.

(12) *Secretary* means the Secretary of Agriculture and any other officer or employee of the Department to whom the authority involved may be delegated.

C. Eligibility

Proposals may be submitted by State agricultural experiment stations, all colleges and universities, other research institutions and organizations, Federal agencies, private organizations or corporations, and individuals. Although an applicant may be eligible based on its status as one of these entities, other factors may exclude an applicant from receiving Federal assistance under this program (*e.g.,* debarment or suspension, a determination of non-responsibility based on submitted organizational management information).

Part II—Program Description

A. Purpose and Scope of the Program

Proposals are invited for competitive grant awards under the Special Research Grants Program, Citrus Tristeza Research for fiscal year (FY) 2001. The purpose of this grant program is to support research that focuses on problems caused by CTV and the Brown Citrus Aphid. This research should aim to facilitate promising breakthroughs in this important area of the food and agricultural sciences.

CTV is a pathogen of citrus vectored by several aphid species. This disease has been found in all the citrus producing regions of the United States and is of world-wide importance. The virus strain complex can cause a variety of symptoms, from mild to severe, depending upon the host and its environment. A new aphid vector, the Brown Citrus Aphid was introduced in Florida. This vector is capable of transmitting a severe stem-pitting form of the virus. The Brown Citrus Aphid also occurs in Central America and the Caribbean Basin and thus poses a threat to citrus in other citrus producing areas in the United States (*e.g.,* Louisiana, Texas, Arizona, and California).

The research priority areas that have been identified are (1) characterization and detection of CTV strains; (2) biology and control of the Brown Citrus Aphid; (3) host plant resistance, including scion and rootstock development; (4) epidemiology and crop loss assessment; and (5) development of cross-protecting CTV strains.

B. Available Funds and Award Limitations

Funds will be awarded on a competitive basis to support research projects that focus on solving problems caused by the CTV and Brown Citrus Aphid. The total amount of funds available in FY 2001 for support of this program is approximately $595,000. Each proposal submitted in FY 2001 shall request funding for a period not to

exceed two years. FY 2001 awardees must submit new proposals and recompete to receive additional funding at the expiration of their current grant.

C. Applicant Peer Review Requirements

Subsection (c)(5)(A) of the Competitive, Special, and Facilities Research Grant Act, as amended (7 U.S.C. 450i(c)(5)(A)) requires applicants to conduct a scientific peer review of a proposed research project in accordance with regulations promulgated by the Secretary prior to the Secretary making a grant award under this authority. Regulations implementing this requirement are set forth in 7 CFR 3400.20 and 3400.21. The regulations impose the following requirements for scientific peer review by applicants of proposed research projects:

1. Credible and independent. Review arranged by the grantee must provide for a credible and independent assessment of the proposed project. A credible review is one that provides an appraisal of technical quality and relevance sufficient for an organizational representative to make an informed judgment as to whether the proposal is appropriate for submission for Federal support. To provide for an independent review, such review may include USDA employees, but should not be conducted solely by USDA employees.

2. Notice of completion and retention of records. A notice of completion of the review shall be conveyed in writing to CSREES either as part of the submitted proposal or prior to the issuance of an award, at the option of CSREES (see Part III. B.(2)(i). The written notice constitutes certification by the applicant that a review in compliance with these regulations has occurred. Applicants are not required to submit results of the review to CSREES; however, proper documentation of the review process and results should be retained by the applicant.

3. Renewal and supplemental grants. Review by the grantee is not automatically required for renewal or supplemental grants as defined in 7 CFR 3400.6. A subsequent grant award will require a new review if, according to CSREES, either the funded project has changed significantly, other scientific discoveries have affected the project, or the need for the project has changed. Note that a new review is necessary when applying for another standard or continuation grant after expiration of the grant term.

Part III—Preparation of a Proposal

A. Program Application Materials

Program application materials will be made available to interested entities upon request. These materials include information about the purpose of the program, how the program will be conducted, and the required contents of a proposal, as well as the forms needed to prepare and submit grant applications under the program. The application kit can be downloaded from the Internet at the following website: http://www.reeusda.gov/1700/funding/ourfund.htm or may be obtained by writing or calling the following office: Proposal Services Unit; Office of Extramural Programs; Cooperative State Research, Education, and Extension Service; U.S. Department of Agriculture; STOP 2245; 1400 Independence Avenue, SW.; Washington, DC 20250–2245; Telephone: (202) 401–5048. When contacting the Proposal Services Unit, please indicate that you are requesting application materials for the FY 2001 Special Research Grants Program, Citrus Tristeza Research. Application materials also may be requested via Internet by sending a message with your name, mailing address (not e-mail) and telephone number to psb@reeusda.gov that states that you wish to receive a copy of the application materials for the FY 2001 Special Research Grants Program, Citrus Tristeza Research. The materials will then be mailed to you (not e-mailed) as quickly as possible.

B. Content of a Proposal

(1) General

The proposal should follow these guidelines, enabling reviewers to more easily evaluate the merits of each proposal in a systematic, consistent fashion:

(a) The proposal should be prepared on only one side of the page using standard size (8 ½″ x 11″) white paper, one inch margins, typed or word processed using no type smaller than 12 point font regardless of whether it is single or double spaced. Use an easily readable font face (*e.g.,* Geneva, Helvetica, CG Times). Once accepted for review, your proposal will be read by at least three expert reviewers. Thus it is to your advantage to ensure that your proposal is not difficult to read.

(b) Each page of the proposal, including the Project Summary, budget pages, required forms, and appendices, should be numbered sequentially in the upper right-hand corner.

(c) The proposal should be stapled in the upper left-hand corner. Do not bind. An original and 9 copies (10 total) must be submitted in one package, along with 20 copies of the Project Summary as a separate attachment.

(2) Cover Page

Complete Form CSREES–661, Application for Funding, in its entirety. This form is to be utilized as the Cover Page. Form CSREES–661 serves as a source document for the CSREES grant database; it is therefore important that it be completed accurately.

(a) In Block 6, complete the title of the project. The project title must be brief (80-character maximum), yet represent the major thrust of the effort being proposed. Project titles are read by a variety of nonscientific people; therefore, highly technical words or phraseology should be avoided where possible. In addition, introductory phrases such as ''investigation of'' or ''research on'' should not be used.

(b) Blocks 7 and 8 should be completed to read ''Special Research Grants Program, Citrus Tristeza Research.''

(c) In Block 13, the Type of Award Request is ''new.''

(d) In Block 14, note the total amount of Federal dollars being requested.

(e) In Block 15, designate Principal Investigator(s)/Project Directors(s) (PI/PD). Listing multiple co-PIs beyond those required for genuine collaboration is discouraged. Note that providing a Social Security Number is voluntary, but is an integral part of the CSREES information system and will assist in the processing of the proposal.

(f) Type of Performing Organization (Block 18). A check should be placed in the box beside the type of organization which actually will carry out the effort. For example, if the proposal is being submitted by an 1862 Land-Grant institution but the work will be performed in a department, laboratory, or other organizational unit of an agricultural experiment station, box ''03'' should be checked. If portions of the effort are to be performed in several departments, check the box that applies to the individual listed as PI/PD #1 in Block 15.a.

(g) In Block 22 list the names or acronyms of all other public or private sponsors including other agencies within USDA and other programs funded by CSREES to whom your application has been or will be sent. In the event you decide to send your application to another organization or agency at a later date, you must inform the identified CSREES program manager as soon as practicable. Submitting your proposal to other potential sponsors will not prejudice its review by CSREES;

however, duplicate support for the same project will not be provided.

(h) The original copy of the Application for Funding form must contain the pen-and-ink signatures of the PI/PD(s) and authorized organizational representative for the applicant organization.

(i) By signing the Application for Funding form, the AOR of the applicant institution is providing the required certification that the full proposal has received a credible and independent peer review arranged by the institution (see Part II. C.).

(j) Note that by signing the Application for Funding form, the applicant is also providing the required certifications set forth in 7 CFR Part 3017, regarding Debarment and Suspension and Drug-Free Workplace, and 7 CFR Part 3018, regarding Lobbying. The three certification forms are included in this application package for informational purposes only. It is not necessary to sign and submit the forms to USDA as part of the proposal.

(3) Table of Contents

For consistency and ease in locating information, each proposal must contain a detailed Table of Contents just after the Cover Page. The Table of Contents should include page numbers for each component of the proposal. Page numbers, shown in the upper right-hand corner, should begin with the first page of the Project Summary.

(4) Project Summary

The proposal must contain a Project Summary of 250 words or less on a separate page. The summary must be self-contained and describe the overall goals and relevance of the project. The summary should also contain a listing of the major organizations participating in the project. The Project Summary should immediately follow the Table of Contents. In addition to the summary, this page must include the title of the project, the name of the applicant organization, the authorized organizational representative, and the PI(s), followed by the summary.

(5) Project Narrative

Note: The Project Narrative shall not exceed 10 pages. To ensure fair and equitable competition, reviewers are instructed that they need to read only the first 10 pages of the Project Narrative and to ignore information on additional pages. The Project Narrative should contain the following items:

(a) Objectives—Clear, concise, complete, and logically arranged statement(s) of the specific aims of the proposed effort must be included in all proposals.

(b) Procedures—The procedures or methodology to be applied to the proposed effort should be explicitly stated. This section should include but not necessarily be limited to a description of the proposed investigations and/or experiments in the sequence in which it is planned to carry them out; techniques to be employed, including their feasibility; kinds of results expected; means by which data will be analyzed or interpreted; pitfalls which might be encountered; and limitations to proposed procedures.

(c) Justification—This section should include in-depth information on the magnitude of the problem and its relevance to ongoing food and agricultural research programs; the importance of starting the work during the current fiscal year, and reasons for having the work performed by the proposing institution.

(d) Cooperation and Institutional Units Involved—Cooperative and multi-State applications are encouraged. Identify each institutional unit contributing to the project. Identify each State in a multiple-State proposal and designate the lead State. When appropriate, the project should be coordinated with the efforts of other State and/or national programs. Clearly define the roles and responsibilities of each institutional unit of the project team, if applicable.

If it will be necessary to enter into formal consulting or collaborative arrangements with other individuals or organizations, such arrangements should be fully explained and justified. For purposes of proposal development, informal day-to-day contacts between key project personnel and outside experts are not considered to be collaborative arrangements and thus do not need to be detailed.

All anticipated subcontractual arrangements also should be explained and justified in this section. A proposed statement of work, budget, and budget narrative for each arrangement involving the transfer of substantive programmatic work or the providing of financial assistance to a third party must be provided. Agreements between departments or other units of your own institution and minor arrangements with entities outside of your institution (*e.g.,* requests for outside laboratory analyses) are excluded from this requirement. If you expect to enter into subcontractual arrangements, please note that the provisions contained in 7 CFR Part 3019, USDA Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations, and the general provisions contained in 7 CFR 3015.205, USDA Uniform Federal Assistance Regulations, flow down to subcontractors. In addition, when applicable, required clauses from 7 CFR 3019.40 through 3019.48 (''Procurement Standards'') and appendix A (''Contract Provisions'') should be included in final contractual documents, and it is necessary for the subcontractor to make a certification relating to debarment/suspension.

(e) Literature Review—A summary of pertinent publications with emphasis on their relationship to the effort being proposed should be provided and should include all important and recent publications from other institutions, as well as those from the applicant institution. The citations themselves should be accurate, complete, and written in an acceptable journal format.

(f) Current Work—Current unpublished institutional activities to date in the program area under which the proposal is being submitted should be described.

(g) Facilities and Equipment—All facilities which are available for use or assignment to the project during the requested period of support should be reported and described briefly. Any potentially hazardous materials, procedures, situations, or activities, whether or not directly related to a particular phase of the effort, must be explained fully, along with an outline of precautions to be exercised. Examples include work with toxic chemicals and experiments that may put human subjects or animals at risk.

All items of major instrumentation available for use or assignment to the proposed project should be itemized. In addition, items of nonexpendable equipment not currently accessible and needed to conduct and bring the project to a successful conclusion should be listed, including dollar amounts and, if funds are requested for their acquisition, justified.

(h) Project Timetable—The proposal should outline all important phases as a function of time, year by year, for the entire project, including periods beyond the grant funding period.

(6) Key Personnel

All senior personnel who are expected to be involved in the effort must be clearly identified. For each person, the following should be included:

(a) An estimate of the time commitment involved; and

(b) vitae of all key persons who are expected to work on the project,

whether or not CSREES funds are sought for their support. Each vitae should be limited to two (2) pages in length, excluding publications listings. A chronological list of the most representative publications during the past five (5) years must be provided for each professional project member for whom a vitae appears. Authors should be listed in the same order as they appear on each paper cited, along with the title and complete reference as these usually appear in journals.

(7) Conflict-of-Interest List

A separate Conflict-of Interest List form (Form CSREES–1233) must be submitted for each investigator for whom a curriculum vitae is required. This form is necessary to assist program staff in excluding from proposal review those individuals who have conflicts-of-interest with the project personnel in the grant proposal. The Program Manager must be informed of additional conflicts-of-interest that arise after the proposal has been submitted.

(8) Budget

A detailed budget for each year of requested support must be submitted. In addition, a cumulative budget is required detailing requested support for the overall project period. The budget form may be reproduced as needed by applicants. Funds may be requested under any of the categories listed on the form, provided that the item or service for which support is requested is allowable under the authorizing legislation, the applicable Federal cost principles, and these program guidelines, and can be justified as necessary for the successful conduct of the proposed project. Applicants must also include a budget narrative to explain and justify their budgets. The following guidelines should be used in developing the proposal budget(s):

(a) Salaries and Wages—Salaries and wages are allowable charges and may be requested for personnel who will be working on the project in proportion to the time such personnel will devote to the project. If salary funds are requested, the number of Senior and Other Personnel and the number of CSREES Funded Work Months must be shown in the spaces provided. Grant funds may not be used to augment the total salary or rate of salary of project personnel or to reimburse them for time in addition to a regular full-time salary covering the same general period of employment. Salary funds requested must be consistent with the normal policies of the institution and with the applicable OMB Cost Principles. Administrative and clerical salaries are normally classified as indirect costs. (See Item i. below.) However, if requested under A.2.e., they must be fully justified.

(b) Fringe Benefits—Funds may be requested for fringe benefit costs if the usual accounting practices of your institution provide that institutional contributions to employee benefits (social security, retirement, etc.) be treated as direct costs. Fringe benefit costs may be included only for those personnel whose salaries are charged as a direct cost to the project. See, *e.g.,* OMB Circular No. A–21, Cost Principles for Educational Institutions, for further guidance in this area.

(c) Nonexpendable Equipment—Nonexpendable equipment means tangible nonexpendable personal property including exempt property charged directly to the award having a useful life of more than one year and an acquisition cost of $5,000 or more per unit. (However, institutions may establish lower limits.) As such, items of necessary instrumentation or other nonexpendable equipment should be listed individually by description and estimated cost in the budget narrative. This applies to revised budgets as well, as the equipment item(s) and amount(s) may change.

Note: For projects awarded under the authority of subsection (c)(1)(A) of the Competitive, Special, and Facilities Research Grant Act, no funds will be awarded for the renovation or refurbishment of research spaces; the purchase or installation of fixed equipment in such spaces; or for the planning, repair, rehabilitation, acquisition, or construction of a building or facility.

(d) Materials and Supplies—The types of expendable materials and supplies which are required to carry out the project should be indicated in general terms with estimated costs in the budget narrative.

(e) Travel—The type and extent of travel and its relationship to project objectives should be described briefly and justified. If travel is proposed, provide the purpose, the destination, method of travel, number of persons traveling, number of days, and estimated cost for each trip. If details of a trip are not known at the time of proposal submission, provide a basis for determining the amount requested. Airfare allowances normally will not exceed round-trip jet economy air accommodations. U.S. flag carriers must be used when available. See 7 CFR 3015.205(b)(4) for further guidance.

(f) Publication Costs/Page Charges—Anticipated costs of preparing and publishing results of the research being proposed (including page charges, necessary illustrations, and the cost of a reasonable number of coverless reprints) may be estimated and charged against the grant.

(g) Computer (ADPE) Costs—Reimbursement for the costs of using specialized facilities (such as a university or department-controlled computer mainframe or data processing center) may be requested if such services are required for completion of the work.

(h) All Other Direct Costs—Anticipated direct project charges not included in other budget categories must be itemized with estimated costs and justified in the budget narrative. This applies to revised budgets as well, as the item(s) and dollar amount(s) may change. Examples include space rental at remote locations, subcontractual costs, charges for consulting services, telephone, facsimile, e-mail, shipping costs, and fees for necessary laboratory analyses. You are encouraged to consult the ''Instructions for Completing Form CSREES–55, Budget,'' of the Application Kit for detailed guidance relating to this budget category.

(i) Indirect Costs—The recovery of indirect costs under this program may not exceed the lesser of the grantee institution's official negotiated indirect cost rate or pursuant to section 1462 of National Agricultural Research, Extension, and Teaching Policy Act, 7 U.S.C. 3310, the equivalent of 19 percent of total Federal funds awarded. (An alternative method to calculate this limitation is to multiply total direct costs by 23.456 percent.) This limitation also applies to any subcontractor, and should be reflected in the subcontractor's budget.

(j) Cost-sharing—Cost-sharing is encouraged; however, cost-sharing is not required.

(9) Budget Narrative

All budget categories for which support is requested, must be individually listed (with costs) and justified on a separate sheet of paper and placed immediately behind the Budget Form.

(10) Current and Pending Support

All proposals must list any other current public or private support (including in-house support) to which key personnel identified in the proposal have committed portions of their time, whether or not salary support for person(s) involved is included in the budget for each project. Analogous information must be provided for any pending proposals that are being considered by, or that will be submitted in the near future to, other possible sponsors, including other USDA programs or agencies. Concurrent

submission of identical or similar proposals to other possible sponsors will not prejudice proposal review or evaluation by the Administrator for this purpose. However, a proposal that duplicates or overlaps substantially with a proposal already reviewed and funded (or that will be funded) by another organization or agency will not be funded under this program. The application material includes Form CSREES–663, Current and Pending Support, which should be used for listing current and pending support. Note that the project being proposed should be included in the pending section of the form.

(11) Assurance Statement(s) (Form CSREES–662)

A number of situations encountered in the conduct of projects require special assurance, supporting documentation, etc., before funding can be approved for the project. In addition to any other situation that may exist with regard to a particular project, it is expected that some applications submitted in response to these guidelines will include the following:

(a) Recombinant DNA or RNA Research. As stated in 7 CFR 3015.205(b)(3), all key personnel identified in the proposal and all endorsing officials of the proposing organization are required to comply with the guidelines established by the National Institutes of Health entitled, ''Guidelines for Research Involving Recombinant DNA Molecules,'' as revised. If your project proposes to use recombinant DNA or RNA techniques, the application must so indicate by checking the ''yes'' box in Block 19 of Form CSREES–661 and by completing Section A of Form CSREES–662. For applicable proposals recommended for funding, Institutional Biosafety Committee approval is required before CSREES funds will be released.

(b) Animal Care. Responsibility for the humane care and treatment of live vertebrate animals used in any grant project supported with funds provided by CSREES rests with the performing organization. Where a project involves the use of living vertebrate animals for experimental purposes, all key project personnel and all endorsing officials of the proposing organization are required to comply with the applicable provisions of the Animal Welfare Act, as amended (7 U.S.C. 2131 *et seq.*) and the regulations promulgated thereunder by the Secretary in 9 CFR parts 1, 2, 3, and 4 pertaining to the care, handling, and treatment of these animals. If your project will involve these animals or activities, you must check the ''yes'' box in Block 20 of Form CSREES–661 and complete Section B of Form CSREES–662. In the event a project involving the use of live vertebrate animals results in a grant award, funds will be released only after the Institutional Animal Care and Use Committee has approved the project.

(c) Protection of Human Subjects. Responsibility for safeguarding the rights and welfare of human subjects used in any grant project supported with funds provided by CSREES rests with the performing organization. Guidance on this issue is contained in the National Research Act, Pub. L. 93–348, as amended, and implementing regulations established by the Department under 7 CFR part 1c. If you propose to use human subjects for experimental purposes in your project, you should check the ''yes'' box in Block 21 of Form CSREES–661 and complete Section C of Form CSREES–662. In the event a project involving human subjects results in a grant award, funds will be released only after the appropriate Institutional Review Board has approved the project.

(12) Compliance With the National Environmental Policy Act (NEPA)

As outlined in 7 CFR part 3407 (the Cooperative State Research, Education, and Extension Service regulations implementing NEPA), the environmental data for any proposed project is to be provided to CSREES so that CSREES may determine whether any further action is needed. In most cases, based on previously funded projects, the preparation of environmental data is not usually required. Certain categories of actions are excluded from the requirements of NEPA.

In order for CSREES to determine whether any further action is needed with respect to NEPA, pertinent information regarding the possible environmental impacts of a particular project is necessary; therefore, Form CSREES–1234, NEPA Exclusions Form, must be included in the proposal indicating whether the applicant is of the opinion that the project falls within a categorical exclusion and the reasons therefor. If it is the applicant's opinion that the proposed project falls within the categorical exclusions, the specific exclusion must be identified. Form CSREES–1234 and supporting documentation should be the last page of the proposal.

Even though a project may fall within the categorical exclusions, CSREES may determine that an Environmental Assessment or an Environmental Impact Statement is necessary for an activity. This will be the case if substantial controversy on environmental grounds exists or if other extraordinary conditions or circumstances are present which may cause such activity to have a significant environmental effect. However, this rarely occurs.

Part IV—Submission of a Proposal

A. What To Submit

An original and nine copies of the complete proposal must be submitted. Each copy of the proposal must be stapled in the upper left-hand corner. DO NOT BIND. In addition, submit 20 copies of the proposal's Project Summary. All copies of the proposal and Project Summary must be submitted in one package.

B. Where and When To Submit

Proposals must be received on or before February 15, 2001. Proposals that are hand-delivered, delivered by courier, or sent via overnight delivery services must be sent or delivered to: Special Research Grants Program, Citrus Tristeza Research; c/o Proposal Services Unit; Office of Extramural Programs; USDA/CSREES; Room 1307, Waterfront Centre; 800 9th Street, SW.; Washington, DC 20024; Telephone: (202) 401–5048.

Note: Applicants are strongly encouraged to submit their completed proposals via overnight mail or delivery services to ensure timely receipt by the USDA.

Proposals sent via the U.S. Postal Service must be sent to the following address: Special Research Grants Program, Citrus Tristeza Research; c/o Proposal Services Unit; Office of Extramural Programs; USDA/CSREES; STOP 2245; 1400 Independence Avenue, SW.; Washington, DC 20250–2245; Telephone: (202) 401–5048.

C. Acknowledgment of Proposals

The receipt of all proposals will be acknowledged by e-mail, therefore applicants are encouraged to provide e-mail addresses, where designated, on the Form CSREES–661. The acknowledgment will contain an identifying proposal number. Once your proposal has been assigned a proposal number, please cite that number in future correspondence.

Part V—Selection Process and Evaluation Criteria

A. Selection Process

Applicants should submit fully developed proposals that meet all the requirements set forth in this RFP.

Each proposal will be evaluated in a two-part process. First, each proposal will be screened to ensure it meets the

requirements as set forth in this RFP. Proposals not meeting the requirements as set forth in this RFP will not be considered for funding. However, USDA retains the right to conduct discussions with applicants to resolve technical and/or budget issues as it deems necessary. Second, each proposal that meets the requirements will be technically evaluated by a peer review panel.

The individual peer panel members will be selected from among those recognized as specialists who are uniquely qualified by training and experience in their respective fields to render expert advice on the merit of proposals being reviewed. The individual reviews of the panel members will be used to determine which proposals should be recommended to the Administrator (or his designee) for final funding decisions.

There is no commitment by USDA to fund any particular proposal or to make a specific number of awards. Care will be taken to avoid actual, potential, and/or the appearance of conflicts of interest among reviewers. Evaluations will be confidential to USDA staff members, peer reviewers, and the principal investigator(s), to the extent permitted by law.

The specificity of these organisms and their host limits the areas in which relevant research can be carried out. The brown citrus aphid has recently been introduced into the citrus growing areas of Florida. Research on both the virus/aphid and on field biology of the aphid is largely conducted in the areas of Florida and Puerto Rico where it is established. CSREES anticipates that the expertise necessary to review proposals will be found at organizations in these geographic areas. Therefore, conflict-of-interest rules will be amended to allow reviewers to evaluate submitted proposals from their own university as long as the applicant and reviewer do not work on the same campus. Thus, for this program, the scientists from the University of Florida but from other campuses (*i.e.,* Research and Education Centers) are not considered to be in conflict.

B. Evaluation Criteria

The evaluation of proposals will be based on the following criteria, weighted relative to each other as noted in the parentheses following each criterion listed.

(1) Overall scientific and technical quality of the proposal (15 points);

(2) Scientific and technical quality of the approach (10 points);

(3) Relevance and importance of proposed research to solution of specific areas of inquiry, and application of expected results for States in which the grantee resides and will perform the work (30 points);

(4) Feasibility of attaining objectives; adequacy of professional training and experience, facilities and equipment (40 points);

(5) The appropriateness of the level of funding requested (5 points).

Part VI—Supplementary Information

A. Access To Review Information

Copies of summary reviews will be sent to the applicant principle investigator automatically, as soon as possible after the review process has been completed. The identity of the individual peer reviewers will not be provided.

B. Grant Awards

(1) General

Within the limit of funds available for such purpose, the awarding official of CSREES shall make grants to those responsible, eligible applicants whose proposals are judged most meritorious under the procedures set forth in this RFP. The date specified by the Administrator as the effective date of the grant shall be no later than September 30 of the Federal fiscal year in which the project is approved for support and funds are appropriated for such purpose, unless otherwise permitted by law. It should be noted that the project need not be initiated on the grant effective date, but as soon thereafter as practical so that project goals may be attained within the funded project period. All funds granted by CSREES under this RFP shall be expended solely for the purpose for which the funds are granted in accordance with the approved application and budget, the regulations, the terms and conditions of the award, the applicable Federal cost principles, and the Department's assistance regulations (parts 3015, 3016, and 3019 of 7 CFR).

(2) Organizational Management Information

Specific management information relating to an applicant shall be submitted on a one-time basis as part of the responsibility determination prior to the award of a grant identified under this part if such information has not been provided previously under this or another program for which the sponsoring agency is responsible. Copies of forms recommended for use in fulfilling the requirements contained in this section will be provided by the sponsoring agency as part of the preaward process.

(3) Grant Award Document and Notice of Grant Award

The grant award document shall include at a minimum the following:

(a) Legal name and address of performing organization or institution to whom the Administrator has awarded a grant under the terms of this RFP;

(b) Title of project;

(c) Name(s) and address(es) of principal investigator(s) chosen to direct and control approved activities;

(d) Identifying grant number assigned by the Department;

(e) Project period, specifying the amount of time the Department intends to support the project without requiring recompetition for funds;

(f) Total amount of Departmental financial assistance approved by the Administrator during the project period;

(g) Legal authority(ies) under which the grant is awarded;

(h) Approved budget plan for categorizing allocable project funds to accomplish the stated purpose of the grant award; and

(i) Other information or provisions deemed necessary by CSREES to carry out its respective granting activities or to accomplish the purpose of a particular grant.

The notice of grant award, in the form of a letter, will be prepared and will provide pertinent instructions or information to the grantee that is not included in the grant award document.

CSREES will award standard grants to carry out this program. A standard grant is a funding mechanism whereby CSREES agrees to support a specified level of effort for a predetermined time period without additional support at a future date.

C. Use of Funds; Changes

(1) Delegation of Fiscal Responsibility

Unless the terms and conditions of the grant state otherwise, the grantee may not in whole or in part delegate or transfer to another person, institution, or organization the responsibility for use or expenditure of grant funds.

(2) Changes in Project Plans

(a) The permissible changes by the grantee, principal investigator(s), or other key project personnel in the approved project grant shall be limited to changes in methodology, techniques, or other aspects of the project to expedite achievement of the project's approved goals. If the grantee and/or the principal investigator(s) are uncertain as

to whether a change complies with this provision, the question must be referred to the CSREES Authorized Departmental Officer (ADO) for a final determination.

(b) Changes in approved goals or objectives shall be requested by the grantee and approved in writing by the CSREES ADO prior to effecting such changes. In no event shall requests for such changes be approved which are outside the scope of the original approved project.

(c) Changes in approved project leadership or the replacement or reassignment of other key project personnel shall be requested by the grantee and approved in writing by the awarding official of CSREES prior to effecting such changes.

D. Applicable Federal Statutes and Regulations

This program is subject to the administrative provisions for the Special Research Grants Program found in 7 CFR part 3400, which set forth procedures to be followed when submitting grant proposals, the processes regarding the awarding of grants, and regulations relating to the post-award administration of such grants. However, where there are differences between this RFP and the administrative provisions, this RFP shall take precedence to the extent that the administrative provisions authorize such deviations.

Several other Federal statutes and regulations apply to grant proposals considered for review and to project grants awarded under this program. These include but are not limited to:

7 CFR part 3019—USDA implementation of OMB Circular A–110, Uniform Administrative Requirements for Grants and Agreements With Institutions of Higher Education, Hospitals, and Other Nonprofit Organizations.

7 CFR part 3052—USDA implementation of OMB Circular No. A–133, Audits of States, Local Governments, and Non-profit Organizations.

E. Confidential Aspects of Proposals and Awards

When a proposal results in a grant, it becomes a part of the record of the Agency's transactions, available to the public upon specific request. Information that the Secretary determines to be of a privileged nature will be held in confidence to the extent permitted by law. Therefore, any information that the applicant wishes to have considered as privileged should be clearly marked as such and sent in a separate statement, two copies of which should accompany the proposal. The original copy of a proposal that does not result in a grant will be retained by the Agency for a period of one year. Other copies will be destroyed. Such a proposal will be released only with the consent of the applicant or to the extent required by law. A proposal may be withdrawn at any time prior to the final action thereon.

F. Regulatory Information

For the reasons set forth in the final Rule-related Notice to 7 CFR part 3015, subpart V (48 FR 29115, June 24, 1983), this program is excluded from the scope of the Executive Order 12372 which requires intergovernmental consultation with State and local officials. Under the provisions of the Paperwork Reduction Act of 1995, as amended (44 U.S.C. chapter 35), the collection of information requirements contained in this Notice have been approved under OMB Document No. 0524–0022.

Done at Washington, DC, this 11th day of January 2001.

Colien Hefferan,

Administrator, Cooperative State Research, Education, and Extension Service.

[FR Doc. 01–1493 Filed 1–18–01; 8:45 am]

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Part VII

Department of Housing and Urban Development

24 CFR Parts 5, 92, et al.

Determining Adjusted Income in HUD Programs Serving Persons with Disabilities: Requiring Mandatory Deductions for Certain Expenses; and Disallowance for Earned Income; Final Rule

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Parts 5, 92, 200, 236, 574, 582, 583, 891, 982

[Docket No. FR–4608–F–02]

RIN 2501–AC72

Determining Adjusted Income in HUD Programs Serving Persons with Disabilities: Requiring Mandatory Deductions for Certain Expenses; and Disallowance for Earned Income

AGENCY: Office of the Secretary, HUD.

ACTION: Final rule.

SUMMARY: This final rule amends HUD's regulations in part 5, subpart F, to include additional HUD programs in the list of programs that must make certain deductions in calculating a family's adjusted income. These deductions primarily address expenses related to a person's disability, for example medical expenses or attendant care expenses. The purpose of this amendment is to expand the benefits of these deductions to persons with disabilities served by HUD programs not currently covered by part 5, subpart F. Second, this rule adds a new regulatory section to part 5 to require for some but not all of these same programs the disallowance of increases in income as a result of earnings by persons with disabilities. HUD believes that making these deductions and disallowance available to persons with disabilities through as many HUD programs as possible will assist persons with disabilities in obtaining and retaining employment, which is an important step toward economic self-sufficiency.

This rule follows publication of a August 21, 2000 proposed rule, and takes into consideration public comments received on the rule.

DATES: Effective Date: February 20, 2001.

FOR FURTHER INFORMATION CONTACT: For the HOME Investment Partnerships Program, contact Mary Kolesar, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410, telephone (202) 708–2470.

For the Housing Choice Voucher Program, contact Patricia Arnaudo, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410, telephone (202) 708–0744.

For the Housing Opportunities for Persons with AIDS Program, contact David Vos, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410, telephone (202) 708–1934.

For the Rent Supplement Program, contact, Willie Spearmon, Office of Housing, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410; telephone (202) 708–3000.

For the Rental Assistance Payment (RAP) Program, contact Willie Spearmon, Office of Housing, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410; telephone (202) 708–3000.

For the Section 202 Supportive Housing Program for the Elderly (including Section 202 Direct Loans for Housing for the Elderly and Persons with Disabilities), contact Aretha Williams, Office of Housing, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410, telephone (202) 708–2866.

For Section 8 Project-Based, contact Willie Spearmon, Office of Housing, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410; telephone (202) 708–3000.

For the Section 811 Supportive Housing Program for Persons with Disabilities, contact Gail Williamson, Office of Housing, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410, telephone (202) 708–2866.

For the Shelter Plus Care Program, contact the State Assistance Division, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410, telephone (202) 708–2140.

For the Supportive Housing Program (McKinney-Vento Act Homeless Assistance), contact Clifford Taffet, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410, telephone (202) 708–1234.

For all of the above telephone numbers, persons with hearing or speech-impairments may call 1–800–877–8339 (Federal Information Relay Service TTY). (Other than the ''800'' number, the telephone numbers are not toll-free numbers.)

SUPPLEMENTARY INFORMATION:

I. Background

HUD's FY 1999 Appropriations Act, which included the Quality Housing and Work Responsibility Act of 1998 (as title V of the FY 1999 HUD Appropriations Act) (the entire FY 1999 Appropriations Act, including title V, is Public Law 105–276, approved October 21, 1998, and frequently referred to as the ''Public Housing Reform Act'') enacted landmark measures in HUD programs, including many of the reforms sought by Secretary Cuomo, such as transforming public housing, creating additional housing assistance vouchers, merging the Section 8 certificate and voucher programs, and enabling more families to obtain FHA mortgages to become homeowners. Since the Public Housing Reform Act became law, HUD has published many rules and notices implementing the important changes in HUD programs required by the Act. While the majority of these changes are applicable to HUD's public housing and Section 8 programs, HUD has been able to extend, administratively at times, the benefits of some of these landmark measures to HUD programs not specifically identified by the statute.

On August 21, 2000 (65 FR 50842), HUD published a proposed rule that proposed to extend the benefits of (1) deducting certain expenses as provided by the Public Housing Reform Act (currently applicable only to public housing and Section 8 housing (tenant-based and project-based)); and (2) disregarding certain increases in earned income as provided by the Public Housing Reform Act (currently applicable only to public housing) to persons with disabilities served by the following HUD programs—HOME Investment Partnerships, Housing Opportunities for Persons with AIDS, Supportive Housing, and Housing Choice Voucher.

HUD proposed these benefit extensions to persons with disabilities because HUD believes that these deductions and the disregard of earned income constitute an important step in helping persons with disabilities find employment and retain employment. HUD is aware that the lack of accessible, affordable housing continues to be a barrier to the ability of persons with disabilities to take advantage of economic opportunities in many communities across the country. The availability of accessible, affordable housing and the location of that housing can be the key to persons with disabilities in obtaining employment. The August 21, 2000 proposed rule provides more detailed information on the two amendments made by the proposed rule (the extension of certain mandatory deductions of expenses, and the disregard of earned income) and HUD refers the reader to the earlier

rulemaking for more detailed information.

II. Discussion of Public Comments on the Proposed Rule

The public comment period for the August 21, 2000, proposed rule closed on October 20, 2000. HUD received 26 comments. The commenters represented a broad cross-section of affected entities. Commenters included a wide spectrum of individuals and entities affected by or interested in this rulemaking. The majority of the commenters expressed support for the rule's proposals. Notwithstanding widespread support of the rule's proposals, commenters raised certain concerns about the rule, primarily with respect to HUD's proposal to expand the earned income disregard. The following presents a discussion of the significant comments and questions raised by the commenters and HUD's responses to these comments and questions.

A. Mandatory Expense Deduction From Gross Income

Comment: This proposal is a positive step in helping persons with disabilities become economically self sufficient. The following comments reflect the types of comments submitted in support for this proposal.

The expense deduction will help people with disabilities to obtain and keep employment.

The expense deduction will increase the opportunity for persons with disabilities to access many HUD programs.

The expense deduction will have a positive effect on persons with disabilities.

The expense deduction creates incentives for residents in HUD-assisted programs to return to the work force by adjusting their rent to reflect increased expenses.

Many poor people must spend a large portion of their income on required services. The rule represents a positive step by ensuring that money spent on care for persons with disabilities and child care expenses is not counted as income.

The more uniform standard of income deductions as proposed by the rule will simplify program administration at the local level.

HUD Response. HUD appreciates the comments in support of the proposal to deduct certain expenses from gross income.

Comment. The rule should allow for the deduction of expenses incurred to prevent institutionalization of a person with disabilities.

HUD Response. The rule provides for deduction of unreimbursed reasonable attendant care expenses. (See § 5.611(a)(3)(ii).)

Comment. Since the intention of the rule is self-sufficiency, the rule should not limit the exclusion of certain expenses only to the extent they exceed three percent of gross income. The rule would better serve families if it allows for a complete exclusion of the listed expenses.

HUD Response. The three percent cap is imposed by statute, and therefore cannot be revised by HUD through regulation. (See 42 U.S.C. 1437a(b)(5).)

Comment. The definition of ''adjusted income'' in § 5.611 provides the basis for determining the amount of rent to be charged to an eligible household *after* the initial determination of eligibility is made. As amended by the proposed rule, § 5.611 ensures that adjustments to income for persons with disabilities would be taken into account in determining rent. However, if § 5.609 is not similarly amended, some persons with disabilities whose gross incomes slightly exceed the program limits, but who would be eligible for substantial deductions for expenses of care, would be excluded from program eligibility.

HUD Response. The statutory provision for these deductions relates to adjusted income, not income for eligibility purposes. There is no indication of Congressional intent to adjust eligibility limits, which most applicants are considerably below in any event, for such purposes.

B. Mandatory Earned Income Disregard

Comment: This proposal is a positive step in helping persons with disabilities become economically self sufficient. The following comments reflect the types of comments submitted in support for this proposal.

Persons with disabilities often have difficulty transitioning to employment. The earned income disregard will support these families in their quest for independence, and ease the transition to self-sufficiency.

The earned income disregard concept has worked well in conjunction with the Temporary Assistance for Needy Families (TANF) program. It should be equally valuable in helping persons with disabilities residing in HUD-assisted housing move toward self-sufficiency.

Counting all income from earnings is tantamount to removing any incentive to work and be a contributing citizen when it would result in the loss or significant reduction in housing assistance benefits.

The more residents who work, the greater the income to HUD and those involved in operating HUD assisted housing.

The earned income disregard helps qualified families negotiate the transition from public assistance to employment. Any negative budget impacts caused by the disregard will be short-term in nature and will be offset by increased rental income (or lower subsidy levels) as families are able to stay successfully employed.

HUD Response. HUD appreciates the comments in support of this proposal.

Comment. Broader application of the earned income disregard may diminish funds available for other programs. A mandatory earned income disregard will, in some cases, limit housing choice. It will force agencies to disallow earned income that would otherwise enable families to qualify for better housing under the Section 8 voucher program. The impact of this proposed policy on the Housing Choice Voucher Program must be considered before finalizing the rule. The final rule needs to address all these concerns.

HUD Response. HUD took these concerns into consideration in developing the proposed rule, and determined that any fiscal impact will not be significant and will be short-term. HUD believes that the long term benefits of this proposal—helping persons with disabilities obtain and retain employment—outweigh any initial short term impact. As several commenters pointed out, this proposal will help persons with disabilities move toward self-sufficiency, which will increase available funds for other families.

Comment. The earned income disregard should be coordinated with other federal agencies (*e.g.,* SSA, HHS, DOL) to ensure that there are no overlaps or inconsistencies with other applicable programs. The rule does not take into account the way the earned income disregard interfaces other federal programs affecting persons with disabilities.

HUD Response. HUD undertook this coordination when developing its proposed and final rules on ''Changes in Admissions and Occupancy Requirements,'' published on April 30, 1999 (64 FR 23460) and March 29, 2000 (61 FR 16692), which implemented the earned income disregard for public housing (see 24 CFR 960.255). The earned income disregard in § 5.617 is modeled on § 960.255.

Comment. HUD should evaluate the effectiveness of the earned income disregard as an incentive for employment based on the historical

experience of the public housing program before extending it to additional programs. Empirical studies are needed to validate the effectiveness of rent-based work incentives such as the mandatory earned income disregard.

HUD Response. HUD believes that at this time the expansion of earned income disregard to persons with disabilities is an appropriate incentive for employment, and has determined that the costs of implementation of this expanded benefit to persons with disabilities are not significant.

Comment. The Public Housing Reform Act specifically directs that the earned income disregard be applied to public housing. HUD must articulate in the final rule a sufficient justification for interpreting the statute so broadly as to allow extension of the earned income disregard to other programs as contemplated by the rule. The proposed rule did not provide this justification.

HUD Response. Section 3(b) of the U.S. Housing Act of 1937 gives the Secretary the authority to define ''income'' and therefore through this definition of income allows the Secretary to apply the earned income disregard to HUD's housing voucher program. For the HOME Program, section 104(9) and (1) of the Cranston-Gonzalez National Affordable Housing Act (42 U.S.C. 12704) states that the varying median income definitions of low-and very low-income families shall be determined by the Secretary. For the HOPWA program, Section 859(a) of the Cranston-Gonzalez National Affordable Housing Act (42 U.S.C. 12908) cites to section 8 of the U.S. Housing Act of 1937 to the end that rental assistance ''shall be provided to the extent practicable in the manner provided for under section.'' This provision refers to rental assistance, not income, and vests in the administrator discretion whether it would be practicable to follow the temporary ineligibility of section 8 income disregards. For the Supportive Housing for the Homeless program, the authorizing statute contains no income limitations. Section 426(d) of the McKinney-Vento Homeless Assistance Act (42 U.S.C. 11386) states that assisted tenants may be required to pay an occupancy charge in an amount determined by the recipient providing the project, which may not exceed the amount determined under section 3(a) of the U.S. Housing of Act of 1937. Therefore, HUD can amend the regulations for this program to provide for use by the housing provider of earned income disregards in establishing its occupancy charges.

Comment. Several commenters requested that HUD extend the earned income disregard to programs other than the four programs provided in the August 21, 2000 proposed rule. Their comments included the following:

The earned income disregard should be extended to all Section 8 participants, including those receiving Moderate Rehabilitation and Project Based assistance.

The earned income disregard should be extended to all Section 8 program participants, regardless of how the actual program title is styled. Program administration will be much easier if the earned income disregard is made applicable to all Section 8 programs.

The earned income disregard should be extended to persons participating in the Section 811 program.

The earned income disregard should be extended to all households served under Section 202.

The earned income disregard should be extended to Shelter Plus Care recipients.

The earned income disregard should be extended to all persons with disabilities, regardless of the program under which they are participating.

The income disregard should be extended to all persons with disabilities in all types of HUD housing.

HUD Response. As discussed in the preamble to the August 21, 2000, proposed rule, HUD extended the earned income disregard to persons with disabilities in four programs (the HOME Investment Partnerships Program, the Housing Opportunities for Persons with AIDS, Supportive Housing Program, and the Housing Choice Voucher Program) because HUD had the requisite statutory authority to do so. At this time, HUD does not have the statutory authority to extend the earned income disregard to other programs but is seeking such authority.

Comment. The rule does not contain a suitable implementation strategy. There are many questions with regard to implementation of the earned income disregard. HUD should postpone the effective date of any proposed extension of the earned income disregard until HUD can provide additional guidance to PHAs.

HUD Response. As is appropriate for rules, the rule establishes the requirements for application of the earned income disregard. The specifics of how this is to be implemented by public housing agencies (PHAs) will be set out in guidance issued by HUD. HUD issued guidance to PHAs on this subject in connection with the publication of the final rule on Admissions and Occupancy. HUD expects to issue further guidance.

Comment. The Federal government should not substitute its own judgment for that of local housing providers since only at the local level can the costs and benefits of the mandatory income disregard be effectively weighed. Whether or not to incorporate the income disregard into specific programs is a matter best reserved to local discretion.

HUD Response. Consistent with the Public Housing Reform Act, HUD has left considerable discretion to PHAs on the manner of implementation of various requirements imposed by the statute. However, it is primarily the responsibility of Congress and HUD to determine which categories of families will be eligible for certain benefits. Determining whether persons with disabilities will be eligible for the earned income disregard is a determination that should be made by HUD to ensure consistency and fairness in application across the nation, and not a decision that should be made solely at the local level.

Comment. Notwithstanding its beneficial effect on program participants, an expanded earned income disregard will have a negative fiscal impact on local housing providers. HUD should raise administrative allowances to compensate agencies for the increased cost of managing earned income disregard provisions. The expanded earned income disregard will force housing providers to incur greater administrative costs. HUD should therefore include provisions in the rule to ''make them whole.'' Additionally, the use of a selective earned income disregard based on disability and specific program participation status places an undue administrative burden on housing providers since they must compute the earned income disregard in some cases, but not in others. Agencies that administer both Section 8 and Public Housing Programs will find it very difficult to train staff to compute rent one way for Section 8 and another way for Public Housing.

HUD Response. HUD believes that any negative fiscal impact on local housing providers will not be significant. HUD recognizes that with the start-up of implementation of any new requirement or responsibility, there is an increase in administrative burden, but as the processes for implementation are established and once those processes are underway, the administrative burden lessens.

Comment. The proposed earned income disregard will likely result in some individuals in a building receiving a benefit while others do not. This will

lead to friction between tenants and increase management difficulty.

HUD Response. HUD believes that any friction that may be voiced by tenants will be minimal. As HUD noted in the preamble to the August 21, 2000 proposed rule, estimates concerning unemployment indicate that the unemployment rate among persons with significant disabilities is in the range of 70% to 75%, among the highest of disadvantaged groups in the nation. HUD believes that the amendments made by this rule may help to lower this rate for persons residing in HUD assisted housing.

Comment. HUD's earned income disregard policy needs to go further by expanding the amount of income that is excluded and graduating the level of the disregard to allow for a transitional period. The earned income disregard should incorporate a transition period and be applicable to other forms of public assistance. The time period under which earned income may be disregarded is too short since many persons with disabilities cycle in and out of employment. The 48 month, once in a lifetime exclusion contained in the rule should be modified to address the cyclical employment pattern of many persons with disabilities.

HUD Response. The amount of income that is eligible for exclusion is established by statute (see 42 U.S.C. 1437a(b)(5)). The 48 month period arose from considerable public comment on the comparable regulatory provision for public housing (§ 960.255) in the rule on Admissions and Occupancy (see 61 FR 16704). Given the considerable public comment on the period of time in which earned income may be disregarded, HUD declines to modify that period at this time.

Comment. The rule should allow child support paid by a non-custodial parent who earns income or is engaged in educational activities to be excluded from income.

HUD Response. The commenter makes a valid point, but such a change is outside the scope of this rulemaking and needs to be addressed in separate rulemaking.

Comment. While the earned income disregard is an incentive for persons to become employed who are not working, the rule is a disincentive for persons working part-time to become employed full-time. Social Security payment restrictions also compound this problem. More needs to be done to provide income disallowances to help part-time workers become employed full-time.

HUD Response. HUD recognizes that the earned income disregard provided by statute will not serve as an incentive to all families in all situations. The statutory earned income disregard is limited to income increases as a result of employment of a member of the family who was previously unemployed for one or more years. (See section 3(d) of the U.S. Housing Act of 1937; 42 U.S.C. 1437a(d).) HUD, however, recognizes that some part-time employment should not be considered ''previous employment'' and has defined by regulation the term ''previously unemployed'' to include a person who has earned, in the twelve months previous to employment no more than would be received for 10 hours of work per week for 50 weeks at the established minimum wage. (See § 5.617 of this rule, and § 960.255 of the public housing regulations.)

Comment. In determining if a person with a disability is previously unemployed for the mandatory period prior to beginning employment, the rule should specifically include time during which the person received public assistance.

HUD Response. Consistent with the statutory language, the rule includes increases in annual incomes resulting during or within six months after receiving assistance, benefits or services under any state program for temporary assistance for needy families funded under part A of title IV of the Social Security Act, as determined by the responsible entity in consultation with the local agencies administering temporary assistance for needy families (TANF) and welfare-to-work programs. (See § 5.617 of this rule, and § 960.255 of the public housing regulations.)

Comment. The earned income disregard should contain a grandfather clause to allow individuals that are employed at the time of their admission to subsidized housing to take advantage of the offset. The earned income disregard should not be available to persons who are employed at the time they enter assisted housing.

HUD Response. The statute establishes the requirements for eligibility of the earned income disregard and the rule in defining ''qualified family'' and ''previously unemployed'' reflects the statutory eligibility requirements. (See § 5.617(a).)

Comment. The definition of ''qualified family'' in the rule is inconsistent with other regulatory provisions. Section 5.617(b) should be changed to make clear that it includes a family with any adult member with a disability, not just the head of household or spouse, as eligible for the income disregard.

HUD Response. HUD believes that there is no ambiguity here. The definition of ''qualified family'' in § 5.617 makes no reference to the head of household or spouse, but simply ''a family member.'' Section 960.255, upon which § 5.617 is modeled, also does not refer to the head of household or spouse. HUD believes both regulations are clear and no further modification is needed.

Comment. HUD's income disregard program should dovetail with the Plan to Achieve Self-Sufficiency (PASS) program so that persons with disabilities continue to receive the disregard benefit even after they are no longer participating in PASS. The income disregard should apply to all families with a member participating in the PASS program. The earned income disregard should apply as long as any household member, not just a family member with a disability, is receiving TANF benefits. The earned income disregard should specifically allow eligibility when any family member receives any type of government support, not limited to TANF. The earned income disregard should be applicable to those families receiving ''welfare to work'' funds.

HUD Response. The contours of the earned income disregard are established by statute. The statute, however, includes as eligible for the earned income disregard a family whose annual income increases, during or within six months, after receiving assistance, benefits or services under any state program for temporary assistance for needy families funded under part A of title IV of the Social Security Act, as determined by the responsible entity in consultation with the local agencies administering temporary assistance for needy families (TANF) and welfare-to-work programs.

C. Specific Issue for Comment

Expansion of the earned income disregard to all families. In the August 21, 2000 proposed rule, HUD advised that although this rule limited the extension of the earned income disregard to persons with disabilities, HUD is analyzing the extension of the earned income disregard to all families served by HUD and HUD specifically solicited comment on this issue. (See 65 FR 50844, column one.)

Comment. A few commenters submitted comments on this issue and their comments were as follows:

The Public Housing Reform Act does not limit the earned income disregard strictly to persons with disabilities. If HUD is going to extend the income disregard to other programs, it should

not be restricted solely to persons with disabilities.

The earned income disregard should be extended to all families not only families with persons with disabilities. However, application of the earned income disregard to all families may diminish the availability of funds for expanding the number of families participating in the Section 8 or other HUD programs. For this reason, we urge HUD to seek the necessary appropriations from Congress to ensure the expansion of this disregard to all programs.

The earned income disregard should be extended to all households served under HOPWA.

HUD Response. HUD appreciates the comments on this issue, and is continuing to study this matter.

III. Findings and Certifications

Environmental Impact

In accordance with 24 CFR 50.19(c)(1) of HUD's regulations, this rule does not direct, provide for assistance or loan and mortgage insurance for, or otherwise govern or regulate, real property acquisition, disposition, leasing, rehabilitation, alteration, demolition, or new construction, or establish, revise, or provide for standards for construction or construction materials, or manufactured housing. Therefore, this rule is categorically excluded from the requirements of the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*).

Regulatory Planning and Review

The Office of Management and Budget has reviewed this proposed rule under Executive Order 12866 (captioned ''Regulatory Planning and Review'') and determined that this rule is a ''significant regulatory action'' as defined in section 3(f) of the Order (although not an economically significant regulatory action under the Order). Any changes made to this rule as a result of that review are identified in the docket file, which is available for public inspection during regular business hours (7:30 a.m. to 5:30 p.m.) at the Office of the General Counsel, Rules Docket Clerk, Room 10276, U.S. Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410–0500.

Regulatory Flexibility Act

The Secretary has reviewed this rule before publication and by approving it certifies, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), that this rule would not have a significant economic impact on a substantial number of small entities. This rule is limited to expanding existing mandatory expense deductions and earned income disregard to the calculation of income for persons with disabilities in other HUD programs by which the program participants will benefit, and the owners of the housing assisted by these programs will benefit from the uniformity in the program administration this rule presents.

Executive Order 13132, Federalism

This rule does not have federalism implications and does not impose substantial direct compliance costs on State and local governments or preempt State law within the meaning of Executive Order 13132 (entitled ''Federalism'').

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) (UMRA) requires Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and on the private sector. This rule does not impose, within the meaning of the UMRA, any Federal mandates on any State, local, or tribal governments or on the private sector.

List of Subjects

24 CFR Part 5

Administrative practice and procedure, Aged, Claims, Drug abuse, Drug traffic control, Grant programs—housing and community development, Grant programs—Indians, Individuals with disabilities, Loan programs—housing and community development, Low and moderate income housing, Mortgage insurance, Pets, Public housing, Rent subsidies, Reporting and recordkeeping requirements.

24 CFR Part 92

Administrative practice and procedure, Grant programs—housing and community development, Grant programs—Indians, Low and moderate income housing, Manufactured homes, Rent subsidies, Reporting and recordkeeping requirements.

24 CFR Part 200

Administrative practice and procedure, Claims, Equal employment opportunity, Fair housing, Home improvement, Housing standards, Lead poisoning, Loan programs—housing and community development, Mortgage insurance, Organization and functions (Government agencies), Penalties, Reporting and recordkeeping requirements, Social security, Unemployment compensation, Wages.

24 CFR Part 236

Grant programs—housing and community development, Low and moderate income housing, Mortgage insurance, Rent subsidies, Reporting and recordkeeping requirements.

24 CFR Part 574

AIDS/HIV, Community facilities, Disabled, Grant programs—health programs, Grant programs—housing and community development, Grant programs—social programs, Homeless, Housing, Low and moderate income housing, Nonprofit organizations, Rent subsidies, Reporting and recordkeeping requirements, Technical assistance.

24 CFR Part 582

Homeless, Rent subsidies, Reporting and recordkeeping requirements.

24 CFR Part 583

Homeless, Rent subsidies, Reporting and recordkeeping requirements.

4 CFR Part 891

Aged, Civil rights, Grant programs—housing and community development, Individuals with disabilities, Loan programs—housing and community development, Low and moderate income housing, Mental health programs, Rent subsidies, Reporting and recordkeeping requirements.

24 CFR Part 982

Grant programs—Housing and community development, Housing, Rent subsidies.

Accordingly, HUD amends parts 5, 92, 200, 236, 574, 582, 583, 891 and 982 of title 24 of the Code of Federal Regulations as follows:

PART 5—GENERAL HUD PROGRAM REQUIREMENTS; WAIVERS

1. The authority citation for part 5 continues to read as follows:

Authority: 42 U.S.C. 3535(d), unless otherwise noted.

2. The heading for subpart F is revised to read as follows:

Subpart F—Section 8 and Public Housing, and Other HUD Assisted Housing Serving Persons with Disabilities: Family Income and Family Payment; Occupancy Requirements for Section 8 Project-Based Assistance

3. Section 5.601 is revised to read as follows:

§ 5.601 Purpose and applicability.

This subpart states HUD requirements on the following subjects:

(a) Determining annual and adjusted income of families who apply for or

receive assistance in the Section 8 (tenant-based and project-based) and public housing programs;

(b) Determining payments by and utility reimbursements to families assisted in these programs;

(c) Additional occupancy requirements that apply to the Section 8 project-based assistance programs. These additional requirements concern:

(1) Income-eligibility and income-targeting when a Section 8 owner admits families to a Section 8 project or unit;

(2) Owner selection preferences; and

(3) Owner reexamination of family income and composition;

(d) Determining adjusted income, as provided in § 5.611(a) and (b), for families who apply for or receive assistance under the following programs: HOME Investment Partnerships Program (24 CFR part 92); Rent Supplement Payments Program (24 CFR part 200, subpart W); Rental Assistance Payments Program (24 CFR part 236, subpart D); Housing Opportunities for Persons with AIDS (24 CFR part 574); Shelter Plus Care Program (24 CFR part 582); Supportive Housing Program (McKinney Act Homeless Assistance) (24 CFR part 583); Section 202 Supportive Housing Program for the Elderly (24 CFR 891, subpart B); Section 202 Direct Loans for Housing for the Elderly and Persons with Disabilities (24 CFR part 891, subpart E) and the Section 811 Supportive Housing for Persons with Disabilities (24 CFR part 891, subpart C). Unless specified in the regulations for each of the programs listed in paragraph (d) of this section or in another regulatory section of this part 5, subpart F, the regulations in part 5, subpart F, generally are not applicable to these programs; and

(e) Determining earned income disregard for persons with disabilities, as provided in § 5.617, for the following programs: HOME Investment Partnerships Program (24 CFR part 92); Housing Opportunities for Persons with AIDS (24 CFR part 574); Supportive Housing Program (McKinney Act Homeless Assistance) (24 CFR part 583); and the Housing Choice Voucher Program (24 CFR part 982).

4. In § 5.603, paragraph (a)(1) is revised and a new definition of ''responsible entity'' is added to paragraph (b) to read as follows:

§ 5.603 Definitions.

* * * * *

(a) *Terms found elsewhere in part 5.*

(1) *Subpart A.* The terms *1937 Act, elderly person, public housing, public housing agency (PHA), responsible entity* and *Section 8* are defined in § 5.100.

* * * * *

(b) * * *

Responsible entity. For § 5.611, in addition to the definition of ''responsible entity'' in § 5.100, and for § 5.617, in addition to only that part of the definition of ''responsible entity'' in § 5.100 which addresses the Section 8 program covered by § 5.617 (public housing is not covered by § 5.617), ''responsible entity'' means:

(1) For the HOME Investment Partnerships Program, the participating jurisdiction, as defined in 24 CFR 92.2;

(2) For the Rent Supplement Payments Program, the owner of the multifamily project;

(3) For the Rental Assistance Payments Program, the owner of the Section 236 project;

(4) For the Housing Opportunities for Persons with AIDS (HOPWA) program, the applicable ''State'' or ''unit of general local government'' or ''nonprofit organization'' as these terms are defined in 24 CFR 574.3, that administers the HOPWA Program;

(5) For the Shelter Plus Care Program, the ''Recipient'' as defined in 24 CFR 582.5;

(6) For the Supportive Housing Program, the ''recipient'' as defined in 24 CFR 583.5;

(7) For the Section 202 Supportive Housing Program for the Elderly, the ''Owner'' as defined in 24 CFR 891.205;

(8) For the Section 202 Direct Loans for Housing for the Elderly and Persons with Disabilities), the ''Borrower'' as defined in 24 CFR 891.505; and

(9) For the Section 811 Supportive Housing Program for Persons with Disabilities, the ''owner'' as defined in 24 CFR 891.305.

* * * * *

5. Revise § 5.611 to read as follows:

§ 5.611 Adjusted income.

Adjusted income means annual income (as determined by the responsible entity, defined in § 5.100 and § 5.603) of the members of the family residing or intending to reside in the dwelling unit, after making the following deductions:

(a) *Mandatory deductions.* In determining adjusted income, the responsible entity must deduct the following amounts from annual income:

(1) $480 for each dependent;

(2) $400 for any elderly family or disabled family;

(3) The sum of the following, to the extent the sum exceeds three percent of annual income:

(i) Unreimbursed medical expenses of any elderly family or disabled family; and

(ii) Unreimbursed reasonable attendant care and auxiliary apparatus expenses for each member of the family who is a person with disabilities, to the extent necessary to enable any member of the family (including the member who is a person with disabilities) to be employed. This deduction may not exceed the earned income received by family members who are 18 years of age or older and who are able to work because of such attendant care or auxiliary apparatus; and

(4) Any reasonable child care expenses necessary to enable a member of the family to be employed or to further his or her education.

(b) *Additional deductions.* (1) For public housing, a PHA may adopt additional deductions from annual income. The PHA must establish a written policy for such deductions.

(2) For the HUD programs listed in § 5.601(d), the responsible entity shall calculate such other deductions as required and permitted by the applicable program regulations.

6. A new § 5.617 is added to read as follows:

§ 5.617 Self-sufficiency incentives for persons with disabilities—Disallowance of increase in annual income.

(a) *Applicable programs.* The disallowance of increase in annual income provided by this section is applicable only to the following programs: HOME Investment Partnerships Program (24 CFR part 92); Housing Opportunities for Persons with AIDS (24 CFR part 574); Supportive Housing Program (24 CFR part 583); and the Housing Choice Voucher Program (24 CFR part 982).

(b) *Definitions.* The following definitions apply for purposes of this section.

Disallowance. Exclusion from annual income.

Previously unemployed includes a person with disabilities who has earned, in the twelve months previous to employment, no more than would be received for 10 hours of work per week for 50 weeks at the established minimum wage.

Qualified family. A disabled family residing in housing assisted under one of the programs listed in paragraph (a) of this section or receiving tenant-based rental assistance under one of the programs listed in paragraph (a) of this section:

(1) Whose annual income increases as a result of employment of a family member who is a person with

disabilities and who was previously unemployed for one or more years prior to employment;

(2) Whose annual income increases as a result of increased earnings by a family member who is a person with disabilities during participation in any economic self-sufficiency or other job training program; or

(3) Whose annual income increases, as a result of new employment or increased earnings of a family member who is a person with disabilities, during or within six months after receiving assistance, benefits or services under any state program for temporary assistance for needy families funded under Part A of Title IV of the Social Security Act, as determined by the responsible entity in consultation with the local agencies administering temporary assistance for needy families (TANF) and Welfare-to-Work (WTW) programs. The TANF program is not limited to monthly income maintenance, but also includes such benefits and services as one-time payments, wage subsidies and transportation assistance—provided that the total amount over a six-month period is at least $500.

(c) *Disallowance of increase in annual income.*—(1) *Initial twelve month exclusion.* During the cumulative twelve month period beginning on the date a member who is a person with disabilities of a qualified family is first employed or the family first experiences an increase in annual income attributable to employment, the responsible entity must exclude from annual income (as defined in the regulations governing the applicable program listed in paragraph (a) of this section) of a qualified family any increase in income of the family member who is a person with disabilities as a result of employment over prior income of that family member.

(2) *Second twelve month exclusion and phase-in.* During the second cumulative twelve month period after the date a member who is a person with disabilities of a qualified family is first employed or the family first experiences an increase in annual income attributable to employment, the responsible entity must exclude from annual income of a qualified family fifty percent of any increase in income of such family member as a result of employment over income of that family member prior to the beginning of such employment.

(3) *Maximum four year disallowance.* The disallowance of increased income of an individual family member who is a person with disabilities as provided in paragraph (c)(1) or (c)(2) is limited to a lifetime 48 month period. The disallowance only applies for a maximum of twelve months for disallowance under paragraph (c)(1) and a maximum of twelve months for disallowance under paragraph (c)(2), during the 48 month period starting from the initial exclusion under paragraph (c)(1) of this section.

(d) *Inapplicability to admission.* The disallowance of increases in income as a result of employment of persons with disabilities under this section does not apply for purposes of admission to the program (including the determination of income eligibility or any income targeting that may be applicable).

PART 92—HOME INVESTMENT PARTNERSHIPS PROGRAM

7. The authority citation for part 92 continues to read as follows:

Authority: 42 U.S.C. 3535(d) and 12701–12839.

8. In § 92.203, a new paragraph (d)(3) is added to read as follows:

§ 92.203 Income determinations.

* * * * *

(d) * * *

(3) The participating jurisdiction must follow the requirements in § 5.617 when making subsequent income determinations of persons with disabilities who are tenants in HOME-assisted rental housing or who receive tenant-based rental assistance.

PART 200—INTRODUCTION TO FHA PROGRAMS

9. The authority citation for part 200 continues to read as follows:

Authority: 12 U.S.C. 1701–1715z–18; 42 U.S.C. 3535(d).

10. Section 200.1303 is revised to read as follows;

§ 200.1303 Annual income exclusions for the Rent Supplement Program.

(a) The exclusions to annual income described in 24 CFR 5.609(c) apply to those rent supplement contracts governed by the regulations at 24 CFR part 215 in effect immediately before May 1, 1996 (contained in the April 1, 1995 edition of 24 CFR, parts 200 to 219), in lieu of the annual income exclusions described in 24 CFR 215.21(c) (contained in the April 1, 1995 edition of 24 CFR, parts 200 to 219).

(b) The mandatory deductions described in 24 CFR 5.611(a) also apply to the rent supplement contracts described in paragraph (a) of this section in lieu of the deductions provided in the definition of ''adjusted income'' in 24 CFR 215.1 (as contained in the April 1, 1995 edition of 24 CFR, parts 200 to 219).

(c) The definition of ''persons with disabilities'' in paragraph (c) of this section replaces the terms ''disabled person'' and ''handicapped person'' used in the regulations in 24 CFR part 215, subpart A (as contained in the April 1, 1995 edition of 24 CFR, parts 200 to 219). *Person with disabilities,* as used in this part, has the same meaning as provided in 24 CFR 891.305.

PART 236—MORTGAGE INSURANCE AND INTEREST REDUCTION PAYMENT FOR RENTAL PROJECTS

11. The authority citation for part 236 continues to read as follows:

Authority: 12 U.S.C. 1701–1715z–1; 42 U.S.C. 3535(d).

Subpart D—Rental Assistance Payments

12. Section 236.710 is revised to read as follows;

§ 236.710 Qualified tenant.

(a) The benefits of rental assistance payments are available only to an individual or a family who is renting a dwelling unit in a project that is subject to a contract entered into under the requirements of this subpart or who is occupying such a dwelling unit as a cooperative member. To qualify for the benefits of rental assistance payments, the individual or family must satisfy the definition of Qualified Tenant found in § 236.2 of subpart A (contained in the April 1, 1995 edition of 24 CFR, parts 220 to 499; see the Savings clause at § 236.1(c)).

(b) To receive rental assistance under this subpart, the income of the individual or family must be determined to be too low to permit the individual or family to pay the approved Gross Rent with 30 percent of the individual's or family's Adjusted Monthly Income, as defined in § 236.2 of subpart A (contained in the April 1, 1995 edition of 24 CFR, parts 220 to 499). Determination of the Adjusted Monthly Income must include the deductions required for adjusted income in 24 CFR 5.611(a) in lieu of the deductions provided in the definition of ''adjusted income'' in 24 CFR 236.2 (contained in the April 1, 1995 edition of 24 CFR, parts 220 to 499; see the Savings clause at § 236.1(c)).

(c) For requirements concerning the disclosure and certification of Social Security Numbers, see 24 CFR part 5, subpart B. For requirements regarding

the signing and submitting of consent forms for the obtaining of wage and claim information from State Wage Information Collection Agencies, see 24 CFR part 5, subpart B. For restrictions on financial assistance to noncitizens with ineligible immigration status, see 24 CFR part 5, subpart E.

(d) The definition of ''persons with disabilities'' in paragraph (d) of this section replaces the terms ''disabled person'' and ''handicapped person'' used in the regulations in 24 CFR part 236, subpart A (contained in the April 1, 1995 edition of 24 CFR, parts 220 to 499; see the Savings clause at § 236.1(c)). *Person with disabilities,* as used in this part, has the same meaning as provided in 24 CFR 891.305.

PART 574—HOUSING OPPORTUNITIES FOR PERSONS WITH AIDS

13. The authority citation for part 574 continues to read as follows:

Authority: 42 U.S.C. 3535(d) and 12901–12912.

14. Paragraphs (d)(1) and (d)(3) of § 574.310 are revised to read as follows:

§ 574.310 General standards for eligible housing activities.

* * * * *

(d) *Resident rent payment.* * * *

(1) 30 percent of the family's monthly adjusted income (adjustment factors include the age of the individual, medical expenses, size of family and child care expenses and are described in detail in 24 CFR 5.609). The calculation of the family's monthly adjusted income must include the expense deductions provided in 24 CFR 5.611(a), and for eligible persons, the calculation of monthly adjusted income also must include the disallowance of earned income as provided in 24 CFR 5.617, if applicable;

* * * * *

(3) If the family is receiving payments for welfare assistance from a public agency and a part of the payments, adjusted in accordance with the family's actual housing costs, is specifically designated by the agency to meet the family's housing costs, the portion of the payment that is designated for housing costs.

* * * * *

PART 582—SHELTER PLUS CARE

15. The authority citation for part 582 continues to read as follows:

Authority: 42 U.S.C. 3535(d) and 11403–11407b.

16. Section 582.310 is revised to read as follows:

§ 582.310 Resident rent.

(a) *Amount of rent.* Each participant must pay rent in accordance with section 3(a)(1) of the U.S. Housing Act of 1937 (42 U.S.C. 1437a(a)(1)), except that in determining the rent of a person occupying an intermediate care facility assisted under title XIX of the Social Security Act, the gross income of this person is the same as if the person were being assisted under title XVI of the Social Security Act.

(b) *Calculating income.* (1) Income of participants must be calculated in accordance with 24 CFR 5.609 and 24 CFR 5.611(a).

(2) Recipients must examine a participant's income initially, and at least annually thereafter, to determine the amount of rent payable by the participant. Adjustments to a participant's rental payment must be made as necessary.

(3) As a condition of participation in the program, each participant must agree to supply the information or documentation necessary to verify the participant's income. Participants must provide the recipient information at any time regarding changes in income or other circumstances that may result in changes to a participant's rental payment.

PART 583—SUPPORTIVE HOUSING PROGRAM

17. The authority citation for part 583 continues to read as follows:

Authority: 42 U.S.C. 3535(d) and 11389.

18. In § 583.315, paragraph (a) is revised to read as follows:

§ 583.315 Resident rent.

(a) *Calculation of resident rent.* Each resident of supportive housing may be required to pay as rent an amount determined by the recipient which may not exceed the highest of:

(1) 30 percent of the family's monthly adjusted income (adjustment factors include the number of people in the family, age of family members, medical expenses and child care expenses). The calculation of the family's monthly adjusted income must include the expense deductions provided in 24 CFR 5.611(a), and for persons with disabilities, the calculation of the family's monthly adjusted income also must include the disallowance of earned income as provided in 24 CFR 5.617, if applicable;

(2) 10 percent of the family's monthly gross income; or

(3) If the family is receiving payments for welfare assistance from a public agency and a part of the payments, adjusted in accordance with the family's actual housing costs, is specifically designated by the agency to meet the family's housing costs, the portion of the payment that is designated for housing costs.

* * * * *

PART 891—SUPPORTIVE HOUSING FOR THE ELDERLY AND PERSONS WITH DISABILITIES

19. The authority citation for part 891 continues to read as follows:

Authority: 12 U.S.C. 1701q, 42 U.S.C. 1437f, 3535(d) and 8013.

20. In § 891.105, the definitions of *Annual Income, Total Tenant Payment,* and *Utility Allowance* are revised and a new definition of *Adjusted Income* is added to read as follows:

§ 891.105 Definitions.

* * * * *

Adjusted income as defined in part 5, subpart F of subtitle A of this title.

Annual income as defined in part 5, subpart F of subtitle A of this title. In the case of an individual residing in an intermediate care facility for the developmentally disabled that is assisted under title XIX of the Social Security Act and this part, the annual income of the individual shall exclude protected personal income as provided under that Act. For purposes of determining the total tenant payment, the income of such individuals shall be imputed to be the amount that the household would receive if assisted under title XVI of the Social Security Act.

* * * * *

Total tenant payment means the monthly amount defined in, and determined in accordance with part 5, subpart F of subtitle A of this title.

Utility allowance is defined in part 5, subpart F of this subtitle A of this title and is determined or approved by HUD.

* * * * *

21. In part 891, revise the heading of subpart E to read as follows:

Subpart E—Loans for Housing for the Elderly and Persons with Disabilities

22. In § 891.520, the definitions of *Gross Rent, Tenant Rent, Total Tenant Payment, Utility Allowance,* and *Utility Reimbursement* are revised and a new definition of *Adjusted Income* is added to read as follows:

§ 891.520 Definitions applicable to 202/8 projects.

* * * * *

Adjusted income as defined in part 5, subpart F of subtitle A of this title.

* * * * *

Gross rent is defined in part 5, subpart F of subtitle A of this title.

* * * * *

Tenant rent means the monthly amount defined in, and determined in accordance with part 5, subpart F of subtitle A of this title.

Total tenant payment means the monthly amount defined in, and determined in accordance with part 5, subpart F of subtitle A of this title.

Utility allowance is defined in part 5, subpart F of subtitle A of this title and is determined or approved by HUD.

Utility reimbursement is defined in part 5, subpart F of subtitle A of this title.

* * * * *

PART 982—SECTION 8 TENANT BASED ASSISTANCE: HOUSING CHOICE VOUCHER PROGRAM

23. The authority citation for part 982 continues to read as follows:

Authority: 42 U.S.C. 1437f and 3535(d).

24. In § 982.201, paragraph (b)(3) is revised to read as follows:

§ 982.201 Eligibility and targeting.

* * * * *

(b) * * *

(3) The annual income (gross income) of an applicant family is used both for determination of income-eligibility under paragraph (b)(1) of this section and for targeting under paragraph (b)(2)(i) of this section. In determining annual income of an applicant family which includes persons with disabilities, the determination must include the disallowance of increase in annual income as provided in 24 CFR 5.617, if applicable.

* * * * *

Dated: January 10, 2001.

Andrew Cuomo,

Secretary.

[FR Doc. 01–1536 Filed 1–18–01; 8:45 am]

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Federal Register

Friday,
January 19, 2001

Part VIII

Department of Health and Human Services

Health Care Financing Administration

42 CFR Part 400, et al.

Medicaid Program; Medicaid Managed Care; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Part 400, 430, 431,434, 435, 438, 440, and 447

[HCFA–2001–FC]

RIN 0938–AI70

Medicaid Program; Medicaid Managed Care

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule with comment period.

SUMMARY: This final rule with comment period amends the Medicaid regulations to implement provisions of the Balanced Budget Act of 1997 (BBA) that allow the States greater flexibility by permitting them to amend their State plan to require certain categories of Medicaid beneficiaries to enroll in managed care entities without obtaining waivers if beneficiary choice is provided; establish new beneficiary protections in areas such as quality assurance, grievance rights, and coverage of emergency services; eliminate certain requirements viewed by State agencies as impediments to the growth of managed care programs, such as the enrollment composition requirement, the right to disenroll without cause at any time, and the prohibition against enrollee cost-sharing. In addition, this final rule expands on regulatory beneficiary protections provided to enrollees of prepaid health plans (PHPs) by requiring that PHPs comply with specified BBA requirements that would not otherwise apply to PHPs.

DATES: Effective Date: These regulations are effective on April 19, 2001. Provisions that must be implemented thorough contracts with managed care organizations, prepaid health plans, health insuring organizations, or enrollment brokers are effective with respect to contracts that are up for renewal or renegotiation on or after April 19, 2001, but no longer than April 19, 2002.

Comment Date: We will consider comments on the upper payment limits in § 438.(c) if we receive them at the appropriate address, as provided below, no later than 5 p.m. on March 20, 2001.

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: HCFA–2001–FC, P.O. Box 8010, Baltimore, MD 21244–8010 .

To ensure that mailed comments are received in time for us to consider them, please allow for possible delays in delivering them.

If you prefer, you may deliver your written comments (1 original and 3 copies) to one of the following addresses: Room 443–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C5–16–03, 7500 Security Boulevard, Baltimore, MD 21244–8010.

Comments mailed to the above addresses may be delayed and received too late for us to consider them.

Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA–2001–FC. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 443–G of the Department's office at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 to 5 p.m. (phone: (202) 690–7890).

FOR FURTHER INFORMATION CONTACT:

Subparts A and B—Bruce Johnson: (410) 786–0615
Subpart C—Tim Roe: (410) 786–6647
Subpart D—Ann Page: (410) 786–0083
Subpart F—Tim Roe: (410) 786–2006
Subpart H—Tim Roe: (410) 786–2006
Subpart I—Tim Roe: (410) 786–2006
Subpart J—Bruce Johnson: (410) 786–0615

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I. Background

Title XIX of the Social Security Act (the Act) established the Medicaid program, under which matching Federal funds are provided to State agencies to pay for coverage of health care services to low-income pregnant women, families and aged, blind, and disabled individuals. The Medicaid program is administered by States according to Federal statutory and regulatory requirements, under the aegis of a ''State plan'' that must be approved by the Health Care Financing Administration (HCFA). At the program' s inception, most health coverage under the Medicaid program was provided by reimbursing health care providers on a fee-for-service basis for services furnished to Medicaid beneficiaries. (Note: The term ''beneficiaries'' is used throughout the preamble to refer to individuals eligible for and receiving Medicaid benefits. The term ''recipients'' is used in the text of the regulation and is synonymous with ''beneficiary'').

Increasingly, however, State agencies have provided Medicaid coverage through managed care contracts, under which a managed care organization (MCO) or other similar entity is paid a fixed monthly capitation payment for each beneficiary enrolled with the entity for health coverage. Enrolled beneficiaries are required to receive the majority of health care services through the managed care entity. In most States, enrollment in these managed care arrangements is currently mandatory for at least certain categories of beneficiaries. Prior to the enactment of the Balanced Budget Act of 1997 (BBA), State agencies were required to obtain a waiver of a statutory ''freedom of choice requirement'' in order to operate these mandatory managed care programs. No such waiver was required for arrangements involving voluntary enrollment in managed care.

The Balanced Budget Act of 1997

Chapter One of the Medicaid provisions (Subtitle H) of the BBA significantly strengthens Medicaid managed care programs by modifying prior law to: (1) reflect the more widespread use of managed care by State agencies to serve Medicaid beneficiaries; (2) build on the increased expertise acquired by HCFA and the State agencies in the administration of managed care programs; (3) incorporate the knowledge that has been learned from Medicaid, Medicare and private sector managed care programs and their oversight organizations; and (4) provide a framework that will allow HCFA and

State agencies to continue to incorporate further advances in the oversight of managed care, particularly as it pertains to the protection of beneficiaries and the quality of care delivered to Medicaid enrollees. This final rule with comment period implements most of the provisions of that chapter (that is, sections 4701 through 4710). It addresses BBA provisions that reduce the need for State agencies to obtain waivers to implement certain managed care programs; eliminate enrollment composition requirements for managed care contracts; increase beneficiary protections for enrollees in Medicaid managed care entities; improve quality assurance; establish solvency standards; protect against fraud and abuse; permit a period of guaranteed eligibility for Medicaid beneficiaries; and improve certain administrative features of State managed care programs. It also strengthens existing regulatory requirements that apply to prepaid health plans (PHPs) by applying to PHPs certain requirements that the BBA imposes on MCOs.

Several principles guided the development of the final rule. First, the rule was developed with a clear emphasis on consumer protections. We have addressed the issues identified by advocates regarding the rights of Medicaid beneficiaries, particularly vulnerable populations, and how they can be protected as State agencies increasingly replace fee-for-service Medicaid delivery systems with managed care programs. In doing so, we have been guided by the Consumers Bill of Rights and Responsibilities (CBRR) issued in November 1997 by the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry. A Presidential directive ordered the Medicaid program to comply, to the extent permitted by law, with the recommendations in the CBRR. As a result, when writing this regulation, we incorporated the CBRR recommendations whenever authorized by law.

Second, we attempted to provide State agencies with sufficient flexibility to continue to be innovative in the development and improvement of their State Medicaid managed care programs. We recognized that uniform, national standards were not always appropriate in all instances and tried to identify areas where States needed flexibility to develop their own standards, unless an overriding beneficiary interest needed to be taken into account. The regulations were also written to support State agencies in their role as ''health care purchasers,'' in addition to their role as ''health care regulators.'' State agencies, like group purchasers in the private sector, are continuing to seek better value for their health care dollars, when ''value'' means the best possible combination of both quality and price. Relevant subparts of this final rule attempt to provide State agencies with the tools needed to become better purchasers.

Third, wherever we determined it was appropriate to develop Medicaid regulatory language that is parallel to the language used in the final Medicare+Choice (M+C) regulations published on June 9, 2000 (65 FR 40170), we did so. The latter M+C final rule implements Medicare managed care provisions in the BBA, many of which are similar to the Medicaid provisions implemented in this final rule.

Fourth, with respect to the quality-related provisions, we opted to take a more conservative approach and not impose greater regulatory burden without a strong evidence base.

Finally, the BBA directed the Secretary of the Department of Health and Human Services to:

> conduct a study concerning the safeguards (if any) that may be needed to ensure that the health care needs of individuals with special health care needs and chronic conditions who are enrolled with Medicaid managed care organizations are adequately met. (Section 4705(c)(2) of the Balanced Budget Act of 1997.)

In response to this charge from the Congress, during October 1998 to August 1999, HCFA conducted a study of existing research, data, and other information in a variety of areas related to the needs of special populations. HCFA has already taken steps to address many of these recommendations through revisions to the 1915(b) waiver process and provision of technical assistance and training activities to States. HCFA's responses in this final rule with comment period to comments on the proposed rule pertaining to safeguards for populations with special health care needs have been informed by our analysis of information gathered for the report to Congress. The final rule reflects revisions in response to comments based on this analysis.

This final rule with comment period creates a new part 438 in title 42 of the Code of Federal Regulations. All new managed care regulations created under the authority of the BBA, other sections of existing Medicaid regulations pertaining to managed care, and appropriate cross references appear in the new part 438. By creating this new part, we are attempting to help users of the regulations to better comprehend the overall regulatory framework for Medicaid managed care. More detailed discussions of the content of each of the subparts of this final rule are found at the beginning of the section of the preamble discussing each subpart.

Statutory Basis

Section 4701 of the BBA creates section 1932 of the Act, changes terminology in title XIX of the Act (most significantly, the BBA uses the term ''managed care organization'' to refer to entities previously labeled ''health maintenance organizations''), and amends section 1903(m) of the Act to require that contracts under that section and contracting MCOs comply with applicable requirements in new section 1932. Among other things, section 1932 of the Act permits State agencies to require most groups of Medicaid beneficiaries to enroll in managed care arrangements without waiver authority under sections 1915(b) or 1115 of the Act. Under the law prior to the BBA, a State agency was required to request Federal waiver authority under section 1915(b) or pursuant to a demonstration authority under section 1115 in order to restrict beneficiaries' Medicaid coverage to managed care arrangements. Section 1932 of the Act also defines the term ''managed care entity'' (MCE) to include MCOs and primary care case managers meeting a new definition in section 1905(t) of the Act; establishes new requirements for managed care enrollment and choice of coverage; and requires MCOs, primary care case managers (PCCMs), and State agencies to provide specified information to enrollees and potential enrollees.

Section 4702 of the BBA amends section 1905 of the Act to permit State agencies to provide primary care case management services without waiver authority. Instead, primary care case management services may be made available under a State's Medicaid plan as an optional service.

Section 4703 of the BBA eliminates a former statutory requirement that no more than 75 percent of the enrollees in an MCO be Medicaid or Medicare beneficiaries.

Section 4704 of the BBA creates section 1932(b) of the Act to add increased protections for those enrolled in managed care arrangements. These include, among others, the application of a ''prudent layperson's'' standard to determine whether emergency room use by a beneficiary was appropriate and must be covered; criteria for showing adequate capacity and services; grievance procedures; and protections for enrollees against liability for payment of an organization's or provider's debts in the case of insolvency.

Section 4705 of the BBA creates section 1932(c) of the Act, which requires State agencies to develop and implement quality assessment and improvement strategies for their managed care arrangements and to provide for external, independent review of managed care activities.

Section 4706 of the BBA provides that, with limited exceptions, an MCO must meet the same solvency standards set by State agencies for private HMOs or be licensed or certified by the State as a risk-bearing entity.

Section 4707 of the BBA creates section 1932(d) of the Act to add protections against fraud and abuse, such as restrictions on marketing and sanctions for noncompliance.

Section 4708 of the BBA adds a number of provisions to improve the administration of managed care arrangements. These include, among others, provisions raising the threshold value of managed care contracts that require the Secretary's prior approval, and permitting the same copayments in MCOs as apply to fee-for-service arrangements.

Section 4709 of the BBA allows State agencies the option to provide 6 months of guaranteed eligibility for all individuals enrolled in an MCE.

Section 4710 of the BBA specifies the effective dates for all the provisions identified in sections 4701 through 4709.

Proposed Rule

On September 29, 1998, we published a proposed rule setting forth proposed regulations implementing the above statutory provisions, as well as proposing to strengthen regulatory PHP requirements by incorporating by regulation requirements that would otherwise apply only to MCOs. (63 FR 52022) A summary of the specific provisions of the proposed regulations upon which we received public comments is set forth at the beginning of the discussion below of the comments we received. For a fuller discussion of our basis and purpose for the approach taken in the September 29, 1998 proposed rule, see the preamble to that document, at 63 FR 52022 through 52074.

We received 305 comments on the September 29, 1998 proposed rule. The comments were extensive and generally pertained to all the sections contained in the proposed rule. We carefully reviewed all of the comments and revisited the policies contained in the proposed rule that related to the comments.

II. Analysis of and Response to Public Comments on the Proposed Rule

A. General Provisions of the Proposed Rule (Subpart A)

1. Basis and Scope (Proposed § 438.1)

Section 438.1 of the proposed regulation set forth the basis and scope of part 438 including the fact that regulations in this part implement authority in sections 1902(a)(4), 1903(m), 1905(t), and 1932 of the Act. Proposed § 438.1 also briefly described these statutory provisions.

2. Definitions (Proposed §§ 438.2, 430.5)

Section 438.2 of the proposed rule included definitions of terms that would apply for purposes of proposed part 438. The proposed definitions and relevant comments and our responses are provided below. As used in this part—

Authorized representative means an individual authorized by an enrollee to act on his or her behalf in any dealings with an MCE or the State. The rules for appointment of representatives set forth in 20 CFR part 404, subpart R apply unless otherwise provided in this subpart.

Managed care entity (MCE) means—

(1) A Medicaid managed care organization (MCO) that has a comprehensive risk contract under section 1903(m) of the Act; or

(2) A primary care case manager.

Managed care organization (MCO) means—

(1) A Federally qualified HMO that meets the advance directives requirements of subpart I of part 489 of this chapter; or

(2) Any public or private entity that meets the advance directives requirements and is determined to also meet the following conditions:

(i) Is organized primarily for the purpose of providing health care services.

(ii) Makes the services it provides to its Medicaid enrollees as accessible (in terms of timeliness, amount, duration, and scope) as those services are to other Medicaid recipients within the area served by the entity.

(iii) Meets the solvency standards of § 438.116.

Prepaid health plan (PHP) means an entity that provides medical services to enrolled recipients under contract with the State agency, and on the basis of prepaid capitation fees, but does not have a comprehensive risk contract.

Primary care means all health care services and laboratory services customarily provided by or through a general practitioner, family physician, internal medicine physician, obstetrician/gynecologist, or pediatrician, in accordance with State licensure and certification laws and regulations.

Primary care case management means a system under which a primary care case manager contracts with the State to furnish case management services (which include the location, coordination and monitoring of primary health care services) to Medicaid recipients.

Primary care case manager means a physician, a physician group practice, an entity that employs or arranges with physicians to furnish primary care case management services or, at State option, one of the following:

(1) A physician assistant.

(2) A nurse practitioner.

(3) A certified nurse-midwife.

Provider means—

(1) Any individual who is engaged in the delivery of health care services in a State and is licensed or certified by the State to carry out that activity in the State; and

(2) Any entity that is engaged in the delivery of health care services in a State and is licensed or certified by the State to deliver those services if licensing or certification is required by State law or regulation.

We also received comments on definitions of ''comprehensive risk contract'' in § 430.5, which defines a ''Comprehensive risk contract'' as a contract that covers comprehensive services, that is, inpatient hospital services and any of the following services, or any three or more of the following services: (1) outpatient hospital services; (2) rural health clinic services; (3) FQHC services; (4) other laboratory and X-ray services; (5) nursing facility (NF) services; (6) early and periodic screening, diagnostic, and treatment (EPSDT) services; (7) family planning services; (8) physician services; and (9) home health services. We have moved this definition, along with the following other managed care-related definitions, from part 430 to § 438.2. In addition, we have clarified the definition of health insuring organization so that it does not appear to require that the health insuring organization's (HIO's) providers be capitated.

Capitation payment means a payment the State agency makes periodically to a contractor on behalf of each recipient enrolled under a contract for the provision of medical services under the State plan. The State agency makes the payment regardless of whether the particular recipient receives services during the period covered by the payment.

Federally qualified HMO means an HMO that HCFA has determined to be a qualified HMO under section 1310(d) of the PHS Act.

Health insuring organization means an entity that, in exchange for capitation payments, covers services for recipients—

(1) Through payments to, or arrangements with, providers;

(2) Under a risk contract.

Nonrisk contract means a contract under which the contractor—

(1) Is not at financial risk for changes in utilization or for costs incurred under the contract that do not exceed the upper payment limits specified in § 447.362 of this chapter; and

(2) May be reimbursed by the State at the end of the contract period on the basis of the incurred costs, subject to the specified limits.

Comments on Definitions

Comment: Several commenters believe that we should delete the reference to 20 CFR part 404, subpart R in the definition of authorized representative. The commenters believe that these rules, which generally govern representative payees for Social Security programs, have little, if any, relevance to the Medicaid program and that these requirements would limit assistance to beneficiaries in the Medicaid managed care enrollment process. They indicated that current rules recognize that beneficiaries may require assistance in a variety of circumstances and provide that applicants and recipients may obtain that assistance from a variety of sources. For example, commenters pointed out that in formal proceedings such as fair hearings, Medicaid beneficiaries enjoy the right to ''represent themselves, use legal counsel, a relative, friend or other spokesman.'' (§ 431.206.) If the applicant is incompetent or incapacitated, anyone acting responsibly for the applicant can make application on the applicant's behalf (§ 435.907). People with disabilities who are incompetent or incapacitated can currently be represented by anyone acting responsibly on their behalf. Commenters indicated that State law is available and is used to step in when a person cannot make medical decisions on his or her behalf.

Response: We concur with the commenters and have deleted the reference to 20 CFR part 404. We have also deleted the reference to ''authorized,'' using only the term ''representative'' to allow for a broad range of representatives, consistent with existing policies and practices. The definition, which has been moved to § 430.5, now reads ''Representative has the meaning given the term by each State consistent with its laws, regulations, and policies.''

We agree with the commenters that the appropriateness of a representative depends on the significance of the activity for which he or she is acting as representative, so that States should have the flexibility to determine who may represent the beneficiary in various activities. The State may establish various criteria depending upon the situation (for example, disenrollment requests, choice of health plans, receiving notices, filing grievance and appeals (including requests for expedited review, being included as a party to the appeal and the State fair hearing, receiving marketing materials, being provided opportunity to review records, etc.) In determining who may represent beneficiaries, we anticipate that States will provide special consideration for individuals with cognitive impairments, who are unable to appoint their own representatives but who may be especially vulnerable and require assistance in accessing the protections offered in these regulations.

Comment: One commenter found the definition of PHP to be too vague. Specifically, the commenter was not aware of what was meant by ''comprehensive'' and that it was confusing to use the words ''capitation'' and ''fee'' to describe a capitation payment. The commenter recommended that we not use the word ''fee'' in conjunction with capitation and that we define ''comprehensive.''

Another commenter believes the proposed regulations should include a new definition of a prepaid health plan (PHP) to include primary care case managers that are paid on a capitated basis for primary care services only. A commenter recommended that any entity meeting the definition of primary care case manager in section 1905(t) of the Act should be treated the same, whether capitated or paid on a fee-for-service (FFS) basis under State plan payment rates.

Response: Normally, we use the phrase ''capitation payment'' or ''capitation rate'' to describe the capitation method of payment rather than use ''capitation fee.'' As such, we agree with the commenter that the word ''fee,'' which is associated with ''fee-for-service'' payment, does not fit well with the word ''capitation.'' We therefore are revising the definition of PHP by replacing the word ''fee'' with the word ''payment'' after ''capitation.''

With respect to the commenter's request that ''comprehensive'' be defined, the September 29, 1998 proposed regulations contained a definition of ''comprehensive risk contract'' that would apply for purposes of the definition of PHP. In the September 29, 1998 proposed rule, it was proposed that this definition be included in § 430.5. Since the commenter apparently did not see this definition, and was not aware that it pertains only to part 438, we are moving the definition of ''comprehensive risk contract'' from § 430.5 to § 438.2.

We disagree that a primary care case manager paid on a capitation basis should be treated the same as one paid on a fee-for-service basis based on State plan payment rates. The definition of primary care case manager in section 1905(t)(2) of the Act does not preclude payment on a capitation basis. Thus, an entity that meets this definition is subject to the rules and requirements that apply to a primary care case manager, whether the entity is paid on a fee-for-service basis, a risk capitation basis, or some other basis. To the extent that a primary care case manager is paid on a capitation basis for providing less than a comprehensive array of services, it would also meet the definition of a PHP and be subject to the requirements in § 438.8. In this case, the primary care case manager would be both a PHP and a PCCM. When the MCO rules that apply to PHPs are stricter than the rules that apply to all primary care case managers, a primary care case manager paid on a capitation basis would have to follow the MCO rules by virtue of its status as a PHP.

Comment: One commenter noted that the proposed definition of primary care refers to service customarily furnished by various types of physicians but does not mention nurse midwives, nurse practitioners, and physician assistants. The commenter asked us to define primary care to describe the functions of a primary care provider to allow inclusion of those classes of providers who are permitted under State law to practice as primary care providers. A second commenter requested that nurse practitioners and certified nurse midwives be expressly referenced in the definition of primary care.

A few commenters asked us to specifically include Federally qualified health centers (FQHCs) and rural health centers (RHCs) within the definition of primary care case manager, which the commenters appear to believe would be necessary in order for FQHCs and RHCs to have the option of serving as a primary care case manager (and as a result be eligible for automatic reenrollment). One commenter noted that the rule failed to identify obstetricians and gynecologists (Ob-

Gyns) as primary care case managers and recommended their inclusion in that definition of primary care case manager.

One commenter urged that the definitions of primary care and primary care case manager include licensure or certification imposed by tribal governments in the case of individuals, groups, or entities that deliver health care services on a reservation. This commenter believes that this would be needed in order for some Tribes to implement tribal MCOs or PCCMs. A second commenter also noted that the definition of primary care case manager assumed State licensure and noted that the concept of tribal sovereignty generally precludes State licensing and certification of tribally operated programs. In order to implement an Indian Health Services (IHS) or tribally operated MCE, this commenter asked that language be added exempting tribes and the IHS from State license or certification requirements.

Finally, one commenter requested that the definitions of primary care and primary care case manager be more clear in order to distinguish between a PCCM system and a capitated program. The commenter urged that the language make clear that States have the option of offering a PCCM option as a form of noncapitated managed care. This commenter urged HCFA to require the PCCM option as an element of mandatory managed care at least for people with severe disabilities.

Response: Our definitions of primary care and primary care case manager mirror the statutory language in section 1905(t) of the Act. We believe that the Congress intended to limit the kinds of health care and laboratory services considered to be primary care to those ''customarily provided'' by the providers listed in the statute (and in the September 29, 1998 proposed rule). Contrary to the apparent belief of the first commenter discussed above, we believe this approach does focus on the ''functions'' performed, not on who is performing these functions. If the definition had been intended to limit primary care to services actually furnished by the physicians referenced, it would have said services ''provided by'' these providers, not services that are ''customarily provided by'' these providers. We thus believe the intent of the definition of primary care is to specify the health care and laboratory services considered to be ''primary care.'' This means that under the proposed rule, the types of practitioners mentioned by the commenters could provide ''primary care services'' if they are ''provided in accordance with State licensure and certification laws and regulations.''

The definition of primary care case manager specifies those practitioners who may provide primary care case management services (for example, locating, coordinating and monitoring health care), which may also include the provision of ''primary care'' if permitted under State law. Nurse practitioners, certified nurse midwives, and physician assistants are included in that definition at State option. Ob-Gyns are already included in the term ''physicians'' as individuals who the statute specifies may be primary care case managers, and a separate mention is not necessary (particularly since Ob-Gyns are specifically mentioned in the definition of primary care. In addition, the definition of primary care case manager allows for ''an entity employing or having other arrangements with physicians to . . .'' serve as a primary care case manager. This would include both RHC and FQHCs, which thus similarly do not need to be mentioned by name. This policy is consistent with what we have allowed under the section 1915(b) of the Act waiver authority.

From the comments received, it is clear that there was confusion between the definition for ''primary care case manager'' and that for ''provider.'' There is also confusion over the term PCCM, which has been used both to identify a managed care system established by the State and type of provider who participates in that system. We are using PCCM to mean ''primary care case manager''—a specific term used to describe those providers who qualify to provide primary care case management services. Conversely, the term ''provider'' is a general term we use in this rule to identify health care professionals who meet the definition; this includes but is not limited to primary care case managers.

The definition of ''provider'' as published in our September 29, 1998 proposed rule, mirrors the definition of provider published in the June 29, 2000 M+C regulation. However, to further clarify the definition and to be consistent with the definition of ''physician'' used in section 1861(r)(1) of the Act, we are revising the definition of ''provider'' (which we are moving to § 400.203 in this final rule) to be ''any individual or entity that is engaged in the delivery of health care services in a State and is legally authorized by the State to engage in that activity in the State.'' We have substituted the words ''licensed or certified'' with ''legally authorized.'' The revised definition allows States, at their option, to include licensure or certification requirements imposed by Tribal governments. It also provides States the flexibility to determine what State requirements any provider must meet (for example, licensure and certification requirements) in order to provide services under managed care arrangements.

In response to the comments about the provision of primary care by providers certified by Tribes, we believe that a change to the definition of primary care incorporating the above language used in the definition of provider would permit states to allow Tribal-certified providers to furnish primary care as primary care case managers. Accordingly, in response to these comments, in the definition of ''primary care,'' we are changing ''in accordance with State licensure and certification laws and regulations'' to ''to the extent the provision of these services is legally authorized in the State in which they are provided.'' As in the case of our definition of ''provider,'' we believe that this change is consistent with the Congress' intent that States have the discretion to regulate and authorize these services, while permitting the State flexibility in the approach it uses to do so. We disagree with the commenters that the definition of ''primary care case manager'' necessarily assumes certification by the State and therefore believe that no changes to this definition are necessary in order for States to permit Tribe-certified providers to serve as primary care case managers.

The primary care and primary care case management definitions do not address the type of payment provided for these services. As stated previously, the definitions related to primary care case manager services generally mirror section 1905(t) of the Act, which does not address payment for these services. These services are usually reimbursed on a fee-for-service (FFS) basis. However, some States do contract with providers or entities on a capitated basis for primary care services. Our definition allows for this practice to continue.

States now have more flexibility to offer Medicaid beneficiaries access to primary care case management services; section 1915(b) of the Act and section 1115 of the Act waiver authority are no longer the only options for States. Section 4702 of the BBA not only provides the definition of primary care case management services in section 1905(t) of the Act (along with definitions of ''primary care case manager,'' ''primary care case management contract'' and ''primary care'') and sets forth the contracting

requirements for providing these services, it also allows States to add primary care case management services as an optional State plan service. Moreover, section 4701 of the BBA allows States to enroll specified beneficiaries into a PCCM program under a mandatory managed care program without the need to obtain a waiver authority. The BBA does not, however, require States to have PCCM as an option when implementing mandatory managed care programs. As specified in § 438.52 of the September 29, 1998 proposed rule, the final rule continues to require States to provide a choice of at least two MCOs, PHPs, or PCCMs to beneficiaries required to enroll in a managed care program; but States can choose whether to offer a PCCM program or simply offer a choice of two or more MCOs.

Comment: One commenter believes the definition of ''comprehensive risk contract'' (now in § 438.2) should include language that makes explicit HCFA's longstanding interpretation that contracts covering specialty care only, such as behavior health contracts, are not comprehensive risk contracts. The commenter suggested that we include this clarification in the definition of comprehensive risk contract. In addition, the commenter suggested that MCO and MCE be defined in § 430.5 because the terms are used several times throughout the Medicaid regulations set forth in subchapter C before they are fully defined in § 438.2.

Response: We do not believe it is necessary to include language expressly reflecting our longstanding position that the provision of only a limited package of inpatient services related to behavioral health problems (or other similarly narrow area) does not constitute the coverage of ''inpatient services'' as used in the introductory clause in section 1903(m)(2)(A) of the Act, and in the definition of ''comprehensive risk contract'' that implements this statutory language. Under this interpretation, the reference to ''inpatient'' services is to coverage of the full range of these services, not a narrow subset. There does not appear to be any confusion regarding this interpretation, and we do not believe that any change in regulations text is justified.

We agree with the commenter that the terms MCO and MCE are used in part 430 before they are defined in § 438.2. Therefore, we are moving all of the relevant managed care definitions from § 430.5 to § 438.2, which will place all managed care definitions in one section. This will also eliminate duplicate definitions (such as PHP) in both sections.

Comment: One commenter believes that ''partial'' risk arrangements (for example, withhold or bonus arrangements that involve risk without traditional capitation) are not addressed in the definitions of nonrisk contract, PHP, and risk contract. This commenter also found that these arrangements are omitted in the reference in the parenthetical in proposed § 438.50(a) to ''whether fee-for-service or capitation'' payment will be used. The commenter recommended that to allow for States to adopt partial risk-sharing arrangements, the regulations should specify the regulatory requirements that apply if the State chooses to enter into partial risk arrangements.

Response: To the extent a partial risk arrangement puts an entity at ''financial risk for changes in utilization,'' it would not qualify as a ''nonrisk contract'' under our definition. It would, however, fall within the definition of ''risk contract'' since the entity would ''assume risk for the costs of services'' and could incur losses if the costs exceed payment. In other words, when funds are put at risk, the contract is a risk contract that would be subject to MCO requirements if it were comprehensive. We agree with the commenter, however, that a partial risk contract that is less than comprehensive and does not involve prepaid capitation, arguably would not technically fall within the existing definition of PHP. This could create an unintended loophole. We therefore are revising the definition of PHP to include these payment arrangements by adding the phrase ''or on other payment arrangements that do not employ State plan payment rates.'' This language would continue to exempt entities paid on a fee-for-service basis based on State plan payment rates from the PHP (and thus MCO) requirements, even if they were paid a ''case management fee'' as a primary care case manager. In this latter situation, there is no financial incentive to deny services.

We also agree with the commenter that the parenthetical in proposed § 438.50(a) (which has been moved to § 438.50(b) as part of a reorganization of that section) excludes partial risk payment arrangements that do not involve capitation. We therefore are adding a ''for example'' at the beginning of the parenthetical to indicate that these are just examples of what might be specified.

Comment: One commenter suggested that we add the sentence, ''An entity must be found to meet the definition of an MCO to enter into Medicaid's comprehensive risk contract'' under the definition of MCO. Other commenters were concerned that the requirement that an MCO is ''organized primarily for the purposes of providing health care services'' could be read to preclude from participation a legal entity that is not necessarily organized primarily to provide health care, such as a county government.

Another commenter noted that although it appears clear from the discussion of the purpose of the definitions in this section and the provisions of § 438.8 that the definition of an MCO is not intended to include PHPs, it would be clearer if this was explicitly stated. The commenter suggested that we include in our definition of an MCO, a statement that specifies PHPs are not considered MCOs. The commenter also suggested that we add language to the definition of PHP to address the potential for risk arrangements with PHPs other than capitation by adding the phrase ''or other risk arrangements'' after the words ''prepaid capitation fees'' because some waivers do not make capitation payments. Another commenter requested that we clarify if MCE includes PCCM programs.

One commenter thought that we interchangeably used the terms MCO and MCE, and used MCE when PCCM was intended, and therefore suggested that we further define the term MCE. The commenter recommended changing MCE to PCCM when appropriate and also revising text to indicate the conditions under which regulations apply to both MCOs and MCEs.

Response: We believe that it would be inaccurate to add the sentence ''an entity must be found to meet the definition of an MCO to enter into Medicaid's comprehensive risk contract'' because certain statutory exemptions allow for other entities to enter into these contracts. We also believe that § 438.6(a) makes clear the entities with which a State agency may enter into a comprehensive risk contract, and makes clear that this includes an MCO. We agree that a county is not organized ''primarily'' for the purpose of providing health care services and that counties should be permitted to contract as MCOs if all of the requirements in sections 1903(m) and 1932 of the Act are otherwise satisfied. In our proposed definition of MCO, we retained the requirement that the entity be organized ''primarily for the purpose'' of providing health care services from our pre-BBA definition of HMO. Since this requirement is not included in the statutory definition of MCO in section 1903(m)(1)(A) of the Act

and could potentially provide an impediment to the availability of county-sponsored managed care arrangements, we are deleting this requirement in response to this comment.

While we do not agree with the commenter's suggestion that it be specified in the definition of MCO that PHPs are excluded, we agree that it would not be clear from the current definition of MCO that an entity that otherwise meets the definition would be excluded if it does not have a comprehensive risk contract. While the definition of MCE refers to an MCO that has a comprehensive risk contract under section 1903(m) of the Act, the MCO definition itself does not include this restriction. Since the regulations use ''MCO requirements'' as a shorthand for requirements that apply to comprehensive risk contractors, we agree that it would be a good idea to include this concept in the definition of MCO. Because an entity is required to meet the definition of MCO as a condition for qualifying for a comprehensive risk contract, we are revising the definition of MCO to provide that it is an entity ''that has, or is seeking to qualify for, a comprehensive risk contract under this part.'' With this qualification, it should be clear that a PHP would not be included since a PHP is by definition an entity that ''does not have a comprehensive risk contract.'' With respect to the commenter's suggestion that ''or other risk arrangements'' be added to the definition of PHP after ''prepaid capitation basis,'' we believe that the commenter's concern has been addressed by the revision we have made in response to the previous comment. The alternative arrangements to capitation suggested by the commenter would be included in the phrase ''other payment arrangements that do not employ State plan payment rates.'' The reason we did not adopt the commenter's specific suggestion of ''other risk arrangements'' is that this would imply that the reference to ''prepaid capitation basis'' was exclusively a risk arrangement, when in fact there have been nonrisk PHPs. (In these cases, capitation payments have been subject to a cost-reconciliation process.) Our alternative approach continues to accommodate nonrisk contracts as PHPs.

With respect to comments on the use of the terms MCO, MCE and PCCM, we do not believe that the terms are used interchangeably in the September 29, 1998 proposed rule, but we understand that the application of these terms to various provisions of the regulation has caused confusion. There is a significant difference between an MCO and MCE. An MCE is either an MCO with a risk comprehensive contract or a primary care case manager. The terms MCO and MCE are used in the statute and in the rule to identify when different requirements apply.

However, in the interest of clarity, we are changing the regulations text to indicate when regulations apply to MCOs, PCCMs, or both. We are also deleting the definition of MCE since the term will no longer be necessary as a result of this change.

3. Contract Requirements (Proposed § 438.6)

Proposed § 438.6 set forth rules governing contracts with MCOs, PHPs, or PCCMs. Paragraph (a) of proposed § 438.6 set forth the entities with which a State may enter into a comprehensive risk contract. Paragraph (b) provided that the actuarial basis for capitation payments must be specified in the contract and that the capitation payments could not exceed the upper payment limit in § 447.361. Paragraph (c) contained requirements regarding enrollment, that enrollments be accepted in the order of application up to capacity limits, that enrollment be voluntary unless specified exceptions apply, and that beneficiaries not be discriminated against based on health status. Paragraph (d) provided that MCEs can cover services for enrollees not covered for nonenrolled individuals. Paragraph (e) required that contracts must meet the requirements in § 438.6. Paragraph (f) required that risk contracts provide the State and HHS access to financial records of MCEs. Paragraph (g) required compliance with physician incentive plan requirements in §§ 422.208 and 422.210. Paragraph (h) required compliance with advance directive requirements. Paragraph (i) provided that with certain exceptions, HIOs are subject to MCO requirements. Paragraph (j) set forth the new rules in section 1905(t) (3) of the Act that apply to contracts with primary care case managers.

Computation of Capitation Payments (Proposed §§ 438.6(b), 438.64)

The September 29, 1998 proposed rule proposed that two provisions addressing capitation rates be moved from part 434 to the new part 438 but proposed to retain the existing requirements governing capitation payments, which are incorporated in a new proposed §§ 438.6(b) and 438.64. Proposed § 438.6(b) required that contracts specify the actuarial basis for capitation and that ''the capitation payments and any other payments provided for in the contract do not exceed the payment limits set forth in § 447.361.'' Proposed § 438.64 reflected the requirement in section 1903(m)(2)(A)(iii) of the Act that rates be computed on an ''actuarially sound basis.''

Comment: A large number of comments from States, provider associations, and advocates objected to the requirement in proposed § 438.6(b)(2) that capitation payments and other payments to the provider cannot exceed the upper payment limit (UPL) set forth at § 447.361. The commenters stated that many States no longer have a fee-for-service base to use in computing the UPL and that it was no longer a valid measure of costs, since it did not recognize or include: (1) additional costs resulting from new regulatory requirements in the September 29, 1998 proposed rule; (2) the costs of required expanded or mandated benefits; (3) overall administrative costs of MCOs; (4) MCO start-up costs; or the decline in MCO profits (in commercial, Medicare, and Medicaid plans). Several commenters indicated that this requirement potentially contradicted the requirement in § 438.64 that rates be computed on an actuarially sound basis since rates that are truly actuarially sound could in some cases exceed the UPL. Commenters recommended that HCFA revise or eliminate the UPL requirement and replace it with new rules on rate setting.

Two commenters stated that there were no good arguments for changing the current UPL provisions.

Response: We agree with the commenters that problems are presented by our decision in the September 29, 1998 proposed rule to retain the current UPL requirement in proposed § 438.6(b)(2). We acknowledge that many States no longer have fee-for-service base year data recent enough to use as a reasonable comparison to the costs of a current capitated managed care system. We therefore are accepting the recommendations of the commenters and are in this final rule deleting § 447.361 and revising § 438.6 by creating a new § 438.6(c), Payments under risk contracts, which (1) does not include a UPL; (2) requires actuarial certification of capitation rates; (3) specifies data elements that must be included in the methodology used to set capitation rates; (4) requires States to consider the costs for individuals with chronic illness, disability, ongoing health care needs or catastrophic claims in developing rates; (5) requires States to provide explanations of risk sharing

or incentive methodologies; and (6) imposes special rules, including a limitation on the amount that can be paid under FFP in some of these arrangements. While these changes are being included in this final rule in response to comments on the September 29, 1998 proposed rule, because they involve a new approach to regulating capitation payments, we are providing for a 60-day comment period limited to our decision to replace the existing UPL with new § 438.6(c).

In making these changes, we are moving from a review that compares capitation rates in risk contracts to the historical fee-for-service cost of the services under contract for an actuarially equivalent nonenrolled population to a review of the utilization and cost assumptions and methodology used by the State to set the actual capitation rates. We believe that this change will result in a more appropriate review of capitation rates by examining how the rates have been established rather than how they compare to an increasingly difficult to establish fee-for-service equivalent.

This change does not affect the rules governing UPLs for other types of providers or services including the currently applicable provisions in § 447.272, § 447.304, § 447.321 or those in a proposed rule on payments to hospitals, nursing facilities, intermediate care facilities for the mentally retarded, and clinics published on October 10, 2000 (65 FR 60151). Nor will this change affect the UPL for nonrisk contracts in § 447.362, which remains in effect.

While comments are solicited on all aspects of this change, we are specifically requesting comments and suggestions on the provisions in § 438.6(c) and § 438.814 that impose special rules on contracts with incentive arrangements or risk-sharing mechanisms. As set forth above, FFP is only available for risk contracts to the extent that payments are determined on an actuarially sound basis. ''Under these provisions, we have determined that where total payments exceed 105 percent of the capitation payments paid under the contract, these payments are no longer actuarially sound. Thus, no FFP would be available for payments resulting from risk corridors or incentive arrangements for amounts that exceed 105 percent of the capitation payments made under the contract. If the risk corridor or incentive arrangement does not apply to all enrollees or services under the contract, the 105 percent limit is based only on that portion of total capitation payments for the enrollees or services covered by the arrangement.'' States could make payments under these arrangements with their own funds but would be precluded from claiming FFP for these payments.

This limitation protects the Federal government against potentially unlimited exposure under risk corridor or bonus arrangements. This is particularly important since the ''cost-effectiveness'' requirement in section 1915(b) of the Act and the ''budget neutrality'' standard imposed under section 1115(a) of the Act demonstrations generally do not contain an outright limit on the Federal share of expenditures under the contract. And, neither of these limits apply to voluntary managed care contracts under section 1915(a) of the Act or contracts for mandatory enrollment under section 1932(a)(1)(A) of the Act using State plan authority.

Without any upper limit on the amount that can be paid in incentive arrangements or risk-sharing mechanisms, the potential exists for inefficiency or inappropriate actions by the contractor to maximize funding, resulting in rates that bear no relationship to those certified by actuaries and which thus are no longer ''actuarially sound.'' We have provided for the limitations in §§ 438.6(c)(5)(ii) and 438.814 as a workable alternative to the current UPL, which meets the following criteria: (1) it provides a clear, consistent rule that can be applied to all risk contracts, regardless of the authority under which the contract operates (waiver or otherwise); (2) it should not discourage the use of any of these arrangements; (3) it explicitly conditions Federal matching funds on the imposition of these limits under any of these arrangements to prevent any potential abuses; and (4) it can be easily administered.

Although not part of this final rule, we also are revising the policies governing cost effectiveness for section 1915(b) of the Act waiver programs. The current regulations at § 431.55, which require waiver programs to be cost-effective and efficient and require States to document this cost-effectiveness of their waiver programs, will remain unchanged. However, HCFA is modifying the process by which States document this cost-effectiveness through re-issuance of State Medicaid Manual provisions and revision of the section 1915(b) of the Act Medicaid waiver applications. The revised waiver cost-effectiveness test will apply to all section 1915(b) of the Act waivers, regardless of the payment system (for example, FFS, capitation) in the State's waiver program.

Comment: Several commenters stated that the current UPL limit does not recognize the cost of providing care to particularly vulnerable populations and that States should be required to use risk-adjusted capitation rates for homeless and other populations with special health care needs. Some of these commenters added that HCFA should encourage States to reimburse MCOs their actual costs for these populations until sufficient data is developed to apply the risk adjustors.

Response: HCFA encourages States to develop capitation rates that are as accurate as possible in predicting the costs of any population enrolled in managed care. To this end, most States already use rates that are risk-adjusted for demographic factors such as age, gender, locality, and adjusted for category of eligibility, all of which will now be required under § 438.6(c)(3)(iii). Only a few States use diagnosis-based risk adjustors, which under § 438.6(c)(3)(iii)(E) of this final rule would be optional. We are not mandating the use of risk adjustment as suggested by the commenter because risk adjustors (both health status and demographic risk adjustors) can only be used when the population falling into any one category is both readily identifiable and large enough to be a statistically valid-sized group. When States have the capability to identify and separate the costs of any individuals with chronic illness, disability, or extensive ongoing health care needs, we would encourage the State to take this into account in its rate-setting methodology. Because the ability to apply these methodologies will vary from State to State, we are not willing to impose this requirement.

However, we are requiring States to utilize risk adjustment, risk sharing, or other mechanisms or assumptions to account for the cost of services for individuals with chronic illness, disability, ongoing health care needs, or catastrophic claims when setting the capitation rate. Other identifiable factors, which may have impact on the expected health care costs of an individual, may also be used in setting more accurate capitation rates.

Further, we believe that moving from the UPL requirement to an enhanced documentation of the assumptions and methodology used to develop capitation rates will result in rates that are determined on a more reasonable and predictable basis specific to the population enrolled than the UPL requirement's comparison to fee-for-service costs.

Current regulations provide authority for States to contract with MCOs on a

nonrisk basis. This type of contract reduces the contractor's risk for changes in enrollee utilization of services under the contract. This provision permits payment to the contractor based on the contractor's costs, subject to the nonrisk upper payment limit in § 447.362 (which is based on FFS costs of the services actually provided, plus an adjustment for administrative costs). However, currently there are very few States with nonrisk contacts. Given our new model of rate review, and the requirement in § 438.6(c)(3)(iv) that ''individuals with chronic illness, disability, ongoing health care needs or catastrophic claims'' be taken into account, we do not believe it is necessary or appropriate to encourage the greater use of nonrisk contracts as suggested by the commenters.

Comment: Several commenters contended that States' rate-setting processes can be inconsistent, arbitrary, and secretive, and recommended that HCFA require a public process in which States would have to disclose the actuarial information and assumptions in the rate setting process. One commenter wanted HCFA assurance that it would continue to review capitation rates in contracts.

Response: We do not believe that requiring a public process in State rate setting would be conducive to more effective rate setting by States. There are currently 19 States that use some form of competitive bidding and 35 States that use a negotiation process to set rates (including some that use a combination of these methods). Imposing a public participation process outside of the requirements for competitive procurement, or in the midst of negotiations between the State and potential contractors, would not be helpful to these processes. We believe that these methods for establishing payment rates differ significantly from FFS under which States establish fee schedules for Medicaid provider payments, such as with institutional payments when a public process is required. Further, we believe that the new rate-setting process set forth at § 438.6(c) will help to make all parties aware of the elements required and assumptions that must be taken into account in establishing capitation rates.

Comment: Several commenters stated that HCFA should define ''actuarially sound.''

Response: In discussions with actuaries, we have found that there is no universally accepted definition of the term actuarially sound. In the past, we have intended this provision to mean a reflection of past costs and prediction of the future costs of specific services for a specific population based upon concepts of predictability and reasonableness. In § 438.6(c)(1)(i), we have defined the term actuarially sound capitation rates. We have used this term in order to reflect that the emphasis in our review of rates is on the State's assumptions and process used in determining capitation rates, rather than payment amounts. These are defined as rates that are certified by an actuary, developed in accordance with generally accepted actuarial principles and practices, and appropriate for the population and services covered under the contract. The American Academy of Actuaries defines generally accepted actuarial principles and practices as:

> * * * those derived from the professional actuarial literature from their common use by actuaries. Actuarial principles and practices are generally accepted when they are consistent with practices described in the actuarial standards of practice adopted by the actuarial Standards Board and to the degrees that they are established by precedent or common usage. (From Section 2, Second Exposure Draft, Proposed Actuarial Standard of Practice, Utilization of Generally Accepted Actuarial Principle and Practices, American Academy of Actuaries.)

The required certification by the State's actuary should include the actuary's determination of the range of soundness for the proposed rates (or specific rate cells). This would be helpful in resolving any disputes that could arise over the soundness of the rates and would supplement the required documentation of the elements and process used to set the capitation rates.

We believe that our definition of actuarially sound capitation rates and new rate setting review requirements provide HCFA's interpretation of actuarial soundness as set forth in section 1903(m)(2)(A)(iii) of the Act.

Comment: One commenter wanted HCFA to apply the actuarial soundness requirement to MCO payments to providers.

Response: We do not have the authority to impose these requirements on rates paid by MCOs to their subcontractors. The only instances in which the statute provides authority to regulate payments by MCOs to subcontractors are the physician incentive plan requirements imposed under section 1903(m)(2)(A)(x) of the Act, and the requirement in section 1903(m)(2)(A)(ix) of the Act that payments by MCOs to FQHCs and RHCs be no less than rates paid to similar subcontractors providing a similar range of services.

Comment: Several commenters stated that HCFA should develop an administrative process for the resolution of rate issues between MCOs and States when potential contractors do not believe that their payment rates are sufficient .

Response: We do not believe it would be appropriate for us to mandate a specific administrative review process for MCO disputes with States over payment rates. It is a State's decision whether to utilize a managed care delivery system in its Medicaid program, and part of that decision may be based upon the rates it believes it can afford to offer prospective MCOs or PHPs. If the rates are not high enough to obtain a sufficient number of contractors, the State must make a decision whether to raise its rates or discontinue its managed care program. HCFA has no authority to require a state to continue or begin a managed care program. We note, however, that under the new procedures in § 438.6(c), HCFA will be reviewing rates for actuarial soundness, so this review provides certain protections to MCOs as to the adequacy of payment rates and should at least in part address the commenters' concerns.

Comment: HCFA should offer technical assistance to States in setting capitation rates.

Response: Section 1903(k) of the Act specifically authorizes us to provide this assistance at no cost to the State, and we have done so in the past. Currently, however, most States have elected to contract with actuarial firms for this assistance.

Comment: One commenter was concerned that language in the September 29, 1998 proposed rule implied that HCFA would no longer review capitation rates and wanted HCFA assurance that it would continue to review capitation rates in contracts.

Response: HCFA will continue to review rates established between states and MCOs or PHPs. In fact, new § 438.6(c) applies these rate-setting requirements to all risk contracts, and we have created a new § 438.6(a) that provides that the HCFA Regional Office must review and approve all MCO and PHP contracts.

Prohibition of Enrollment Discrimination (Proposed § 438.6(c))

Proposed § 438.6(c) (recodified as § 438.6(d) in this final rule) established rules for enrollment and set forth prohibitions against discrimination in the enrollment process. Specifically, proposed § 438.6(c) required that enrollees be accepted in the order in which they applied up to specified capacity limits, provided that with specified exceptions enrollment must be

voluntary, and prohibited discrimination based on health status.

Comment: Several commenters noted that the September 29, 1998 proposed rule appropriately prohibits health plans from ''cherry picking,'' which is the concept of discriminating against persons who may have high health care needs. However, they noted that the requirement only applies during open enrollment. The commenters believe that the requirement should not apply only to ''official'' open enrollment periods, since enrollment can occur at any time during the year as individuals become Medicaid-eligible. The commenters suggested that we revise the September 29, 1998 proposed rule to include the following: ''MCE contracts must provide that MCEs will not discriminate on the basis of race, color, or national origin. In addition, the MCE must not use any policy or practice that has the effect of discriminating on the basis of race, color, or national origin.'' This is required under Title VI of the Civil Rights Act and implementing regulations.

Response: We agree with the commenter that there is no reason for limiting the requirement that the MCE accept individuals for enrollment in the order in which they apply only to open enrollment periods. Therefore, we are revising § 438.6(d)(1) to specify that ''The MCO, PHP, or PCCM accepts individuals eligible for enrollment in the order in which they apply without restriction (unless authorized by the Regional Administrator) up to the limits set under contract.''

We also agree that MCOs, PHPs, or PCCMs should not discriminate based on health status, race, color, or national origin and that MCO contracts should contain assurances of compliance with Title VI of the Civil Rights Act and other applicable civil rights and other Federal and State statutes. Thus, we are revising § 438.6(d)(4) to include this provision.

Comment: A commenter noted that the September 29, 1998 proposed rule provides that the contract must prohibit MCEs from discriminating in its enrollment process based on health status or need for health care. The commenter further noted that its State controls the enrollment process and requires the MCO to accept individuals who choose or are assigned the MCO. Thus, the MCO is incapable of discrimination. The commenter suggested that we require that States comply with this requirement without necessarily requiring language in MCO contracts.

Response: Section 438.6(d) implements sections 1903(m)(2)(A)(v) and 1905(t)(3)(D) of the Act, which prohibit discrimination on the basis of health status by an MCO or PCCM, not the State. We believe that this is because the Congress presumed that the State would engage in no such discrimination, since it would have no incentive to do so. Indeed, in the case of an MCO, PHP, or PCCM paid on a risk basis, it would be in the State's financial interests for beneficiaries with higher health care costs to be enrolled. To the extent a State does not permit an MCO to make enrollment decisions, this would ensure compliance with section 1903(m)(2)(A)(v) of the Act and § 438.6(d). We believe that requiring this provision in the contracts is the best approach to ensure that all MCOs, PHPs, and PCCMs consistently comply with this requirement.

Comment: One commenter contended that requiring MCOs, PHPs, and PCCMs to accept individuals eligible for enrollment in the order in which they apply without restriction contradicts the requirement in § 438.50(f)(2) that MCOs, PHPs, and PCCMs seek to preserve the established relationship that an individual has with his or her primary care provider.

Response: We do not believe that the enrollment requirement under § 438.6(d)(1) contradicts the continuity of patient and physician relationships, since it affects only the effective date of enrollments and not the extent to which provider relationships can be maintained once enrollment is effective. We also note that the requirement in § 438.6(d)(1) refers to individuals who ''apply'' for enrollment, while § 438.50(f)(2) applies in the context of ''default'' enrollments under a State plan mandatory enrollment program.

Additional Services Under MCO Contracts (Proposed § 438.6(d))

Proposed § 438.6(d) (recodified in this final rule at § 438.6(e)) provided that an MCE is permitted to cover services for enrollees that are not covered under the State plan for beneficiaries not enrolled.

Comment: One commenter noted that the discussion of the purpose of proposed § 438.6(d) in the preamble identifies the provision as applicable to MCO contracts, but the text of the September 29, 1998 proposed rule references MCE and not MCO. The commenter suggested that we change the reference from MCE to MCO. The commenter believes that this change would also have the effect of applying this provision to PHPs, which the commenter thought was appropriate.

Response: The commenter was correct that the text of the preamble to the September 29, 1998 proposed rule identifies this provision as applicable to MCOs and that the text of the section references MCEs. Typically, only an MCO (which by definition is paid on a risk basis) or a primary care case manager paid on a risk basis (which would make it a PHP) would offer additional services not covered under the State plan for nonenrollees. This is because these entities would typically use ''savings'' (a portion of the risk payment not needed to cover State plan services) to cover the additional services in question. This is why the preamble to the September 29, 1998 proposed rule spoke only of MCOs (which, as the commenter pointed out, would extend to PHPs as well). However, this provision of the regulations is based on the fact that under a voluntary enrollment situation, section 1915(a) of the Act permits contracts with an organization ''which has agreed to provide care and services in addition to those offered under the State plan'' only to individuals ''who elect to obtain such care and services from such organization.'' Under section 1915(a) of the Act, States are deemed to be in compliance with statewideness and comparability requirements in this situation. There is nothing in section 1915(a) of the Act that limits this result to an MCO (or to MCOs and PHPs) or even requires the organization offering additional services to those who choose to enroll to be paid on a risk basis. In the case of mandatory enrollment under section 1932(a) of the Act, an exemption from Statewideness and comparability requirements permitting additional services for enrollees is similarly provided without regard to whether the entity is an MCO or a primary care case manager. Finally, there is nothing in section 1915(b) or section 1115(a) of the Act that would limit the applicability of the waivers of Statewideness and comparability provided for thereunder to MCOs and PHPs. For these reasons, even though it is unlikely that a nonrisk PHP or PCCM would offer additional services, we are clarifying the reference in what is now § 438.6(e) to apply to MCOs, PHPs, and PCCMs.

Comment: While several commenters recognized that the language in proposed § 438.6(d) exists in the current regulation, they believe that the current regulation has been subject to varied interpretation over the years. The commenters suggested that we clarify whether or not these additional services are included in the base used to determine the upper payment limit (UPL). In other words, if the MCO provides additional services, the commenters believe we should clarify whether or not the State is free to

increase the capitation rates to reflect the costs of those services, even if the costs did not occur in FFS.

Response: Under the former UPL requirement, the costs of additional services would not have been included in the FFS base in computing the UPL. However, as indicated above, we are eliminating the UPL requirement and substituting a requirement that rates be actuarially sound, certified by an actuary to this effect, and developed in accordance with generally accepted actuarial principles upon the projected cost of services contained in the State plan. Section 438.6(c)(4) requires States to base their capitation rates *only* upon the costs of services covered under the State plan. Thus, even in the absence of the UPL requirement, capitation rates may not reflect the cost of these additional services.

Comment: One commenter wanted us to clarify what additional services could be offered under proposed § 438.6(d) and whether these services would be eligible for FFP.

Response: The additional services that can be offered may be optional services described in section 1905 of the Act or any other medically related services, that are not covered under the State plan. However, as noted in the previous response, the provision of the additional services authorized here is not to be recognized in the capitation rate paid to an MCO or in the FFP available to the State.

Comment: One commenter disagreed with the position that these additional services should not be subject to the statewideness and comparability requirements. This commenter believes that waiving these requirements could potentially lead to discrimination on the basis of health status or disability.

Response: Additional services have been provided by HMOs and PHPs under § 434.20(d) for many years prior to the enactment of the BBA, and we do not believe that this has led to enrollment discrimination. Further, the prohibition on enrollment discrimination in § 438.6(d) requires that MCOs, PHPs, or PCCMs accept individuals in the order in which they apply without restrictions, which will protect enrollees from discrimination on the basis of health status or disability.

Compliance With Contracting Rules (Proposed § 438.6(e))

Proposed § 438.6(e) (recodified in this final rule at § 438.6(f)) required contracts with MCOs and primary care case managers to comply with the requirements in § 438.6.

While we received no comments on this provision, the comment discussed above suggesting that the discrimination provision include language requiring compliance with civil rights laws has prompted us to include a general provision that contracts comply with all applicable State and Federal laws in what is now § 438.6(f). This provision merely recognizes obligations that already exist as a matter of law, and does not impose any new obligations or alter any existing ones. It essentially is a statement that HCFA expects contractors to comply with the law. The revised text now reads as follows:

(f) *Compliance with applicable statutes and contracting rules.* All contracts under this subpart must—

(1) Comply with all applicable State and Federal laws; and

(2) Meet all the requirements of this section.

Inspection and Audit of Records (Proposed § 438.6(f))

Proposed § 438.6(f) (codified in this final rule at § 438.6(g)) required risk contracts to include provisions allowing State and Federal inspection and audit of MCE and MCE subcontractors' financial records. We received no comments on this provision.

Physician Incentive Plan (Proposed § 438.6(g))

Proposed § 438.6(g) (codified in this final rule at § 438.6(h)) required that contracts provide for compliance with the rules governing physician incentive plans that apply to Medicare+Choice organization contracts. These rules require that stop loss protection be provided when a physician incentive plan puts a physician at ''substantial financial risk'' (defined in the June 29, 2000 Medicare+Choice regulations) for the costs of services he or she does not provide.

Comment: One commenter supported requiring Medicaid MCOs and nonexempt HIOs to comply with Physician Incentive Plan requirements.

Response: The requirement is maintained as set forth in the September 29, 1998 proposed rule.

Advance Directives (Proposed § 438.6(h))

Proposed § 438.6(h) (recodified in this final rule at § 438.6(i)) required that MCOs comply with the advance directive requirements in subpart I of part 489, provide oral and written information on advance directives, and reflect changes in State law within 90 days.

Comment: One commenter supported requiring MCOs and nonexempt HIOs to comply with advance directive requirements. Several commenters noted that the current advance directive requirement in § 434.28 does not include a requirement to provide adult enrollees with oral information on advance directives. They added that this requirement was not included in the BBA and that written information should suffice. They suggested that we revise proposed § 438.6(h)(2) to eliminate the requirement for oral information, which would permit MCOs to respond orally only to answer questions that arise. Another commenter recommended deleting the entire requirement as excessive and unwarranted, except upon request by enrollees. Another commenter noted that MCE Member Handbooks address advance directives but not in the detail now required and will require possible revisions and reissuance by MCEs.

Response: The commenter is correct that §§ 434.28 and 489.100 do not require MCOs to provide adult enrollees with oral information on advance directives policies. Section 434.28 notes that the requirement in § 489.100 includes provisions to *inform* and distribute written information to adult individuals concerning policies on advance directives. However, § 489.102 does not specify that individuals must be *informed* orally but describes the requirement to provide written information. Therefore, we agree with the commenters that oral information is not required, and we have revised the advanced directive requirement now codified at § 438.6(i)(2) to eliminate the requirement to provide oral information. Because section 1903(m)(1)(A) of the Act requires MCOs to provide information on advance directives to enrollees, we do not have the authority to delete the entire requirement. Since the advance directive policies did not change before the September 29, 1998 proposed regulation, we do not believe Member Handbooks would need revisions, unless they did not comply with § 434.28 before the September 29, 1998 proposed regulation.

Comment: Although proposed § 438.6(h)(2) provided that an MCO must include a description of applicable State law and proposed § 438.6(h)(3) specified that the information must reflect changes in the State law as soon as possible but no later than 90 days after the effective date of the change, several commenters believe that it was too administratively burdensome for MCOs to comply with these requirements and recommended that we remove them from the regulation.

Response: This provision is required by section 1903(m)(1)(A) of the Act, which extends the advance directives requirements of section 1902(w) of the

Act to MCOs. As a statutory requirement, we do not have the authority to remove this requirement from the regulations.

Nonexempt Health Insuring Organizations (Proposed § 438.6(i))

Proposed § 438.6(i) (recodified in this final rule at § 438.6(j)) clarifies that HIOs that began operating on or after January 1, 1986, and are not exempted by statute, are subject to MCO requirements and may not enter into a comprehensive risk contract if they do not meet the definition of MCO. We received no comments on this provision.

Primary Care Case Management Contracts (Proposed § 438.6(j))

Proposed § 438.6(j) (recodified in this final rule at § 438.6(k)) implemented the requirements in section 1905(t)(3) of the Act that apply to ''primary care case management contracts.'' Specifically, proposed § 438.6(j) required that these contracts (1) provide for reasonable and adequate hours of operation, including 24-hour availability of information, referral, and treatment for emergency medical conditions; (2) restrict enrollment to recipients who reside sufficiently near one of the manager's delivery sites to reach that site within a reasonable time using available and affordable modes of transportation; (3) provide for arrangements with, or referrals to, sufficient numbers of physicians and other practitioners to ensure that services under the contract can be furnished to enrollees promptly and without compromise to quality of care; (4) prohibit discrimination in enrollment, disenrollment, and reenrollment based on the recipient's health status and need for health care services; and (5) provide that enrollees have the right to terminate enrollment.

Comment: One commenter contended that the primary care case manager contract standards in proposed § 438.6(j) were minimal at best. The commenter asked that patients have rights of access, coverage, information, and disclosure that are as strong as those that apply to MCOs and PHPs.

Another commenter noted the importance of the primary care case manager contract provision to rural beneficiaries because they are more likely to live greater distances from primary care case manager delivery sites. This commenter asked that we define ''sufficiently'' and ''reasonable'' as used in proposed § 436.8(j)(2) (''sufficiently near . . . to reach . . . within a reasonable time'') and ''sufficient'' in proposed § 436.8(j)(3) (''sufficient number of physicians or other practitioners''). This commenter asked us to adopt a ''lesser of 30 minutes rules'' for rural areas with a defined exception for frontier areas approved by HCFA.

Another commenter believes that in the case of direct contracts with primary care providers, our regulations should take into account that these providers may have small group practices and not impose requirements on these providers that are more appropriate for large organizations. The commenter suggested that there should be a way to distinguish the small group provider from the larger group provider and that we should place fewer requirements on primary care case managers. Specifically, this commenter cited requirements such as specific driving or travel distance or 24-hour availability to services as not practicable for small providers and not always important to beneficiaries willing to travel long distances to be with a doctor they trust. The commenter also contended that recipients who have ongoing satisfactory relationships with personal doctors should be allowed to maintain those relationships and that most of the requirements for MCOs are not appropriate for medical group or individual doctors. The commenter believes that there have not been serious problems of quality and access with PCCM programs; and that the management component has proven cost efficient. The commenter is concerned that managed care has already driven out many small health care providers and that HCFA should ensure that further regulation does not drive out more small providers (who are essential to people with disabilities).

Response: As noted above, the contract requirements for primary care case managers in proposed § 438.6(j) largely mirror the language set forth in section 1905(t)(3) of the Act, which was added by section 4702 of the BBA. The BBA is clear in setting forth which contracting requirements should be placed on PCCMs, which should be placed on MCOs, and which apply to all MCOs and PCCMs. As we discussed in the preamble to the September 29, 1998 proposed rule at 63 FR 52026, PCCM contracts must include those requirements set forth in section 1905(t)(3) of the Act as well as any requirements in section 1932 of the Act that apply to MCEs. For example, a PCCM must meet the information requirements set forth in § 438.10 that apply to it. We also have applied access, coverage, and information requirements to primary care case managers when applicable. When the BBA specifies that requirements apply to MCOs, these requirements are not applicable to primary care contracts as long as the services are reimbursed on a fee-for-service basis based on State plan payment rates. (To the extent that a primary care case manager meets the definition of a PHP, however, it would also be subject, by regulation, to specified MCO requirements.)

The requirement in proposed § 438.6(j)(1) that primary care case manager contracts ensure 24-hour availability of information, referral, and treatment for emergency medical conditions simply reflects the requirement in section 1905(t)(3)(A) of the Act, and therefore cannot be revised. We note, however, that providers have flexibility as to how they meet this requirement. For example, providers can have an employee or an answering service or machine that immediately pages an on-call medical professional. This requirement is essential to allowing referrals to be made for nonemergency services, or information to be given about accessing services, or medical problems to be handled during nonoffice hours.

The requirement in proposed § 438.6(j)(2) that beneficiaries be able to access care within a reasonable time using affordable modes of transportation similarly reflects statutory language in section 1905(t)(3)(B) of the Act that cannot be changed. Again, however, States have the flexibility to determine their own standards to allow for differences based on the needs of the beneficiaries, provider availability, and the geographic uniqueness of the State. HCFA anticipates that State agencies will take responsibility for ensuring that these standards are met. One example, as noted in the preamble of the September 29, 1998 proposed rule, is the 30-minute travel time standard. Many States have adopted this standard and apply it to urban areas. Other State agencies have established 10-mile to 30-mile travel distance depending on the area. HCFA encourages States to develop their PCCM programs so that an enrollee residing in the services areas should not have to travel an unreasonable distance beyond what is customary under FFS arrangements. Due to enrollee-specific needs, types of providers needed to meet enrollee needs, availability of public transportation, etc. HCFA is not proposing a set of standards for each PCCM program.

We encourage States to, and States often do, make exceptions for beneficiaries who request to travel further than the time and distance standards set by the State. We also encourage States, to the extent practical,

to allow beneficiaries who have ongoing successful relationships with providers to maintain those relationships. However, section 1905(t)(3) of the Act does not require this in the case of PCCM contracts.

Section 1905(t)(3) of the Act does not distinguish between small group providers and large group providers and applies its requirements to all primary care case manager contracts. We, therefore, do not have the authority to exempt smaller providers from requirements in section 1905(t)(3) of the Act that are reflected in what is now § 438.6(k), which therefore will remain as written in the September 29, 1998 proposed rule.

4. Provisions That Apply to PHPs (Proposed 438.8)

Proposed § 438.8 provided that specified requirements that apply to MCOs and MCO contracts apply to PHPs and PHP contracts. Specifically, under proposed paragraph (a), the requirements in proposed § 438.6 would apply with the exception of those that pertain to physician incentive plans, advance directives, and HIOs. Proposed paragraphs (b), (c), and (d) incorporated, respectively, the information requirements in proposed § 438.10, the provider discrimination requirement in proposed § 438.12, and the enrollee protections in proposed subpart C of part 438. Proposed paragraph (e) incorporated the quality assurance requirements in proposed subpart E of part 438 to the extent they are applicable to services furnished by the PHP. Proposed paragraph (f) incorporated the requirements in proposed subpart F of part 438 except for proposed § 438.424(b). And proposed paragraph (g) incorporated the enrollment and disenrollment requirements in paragraphs (e) through (h) of proposed § 438.56 and the conflict of interest safeguards in proposed § 438.58.

Physician Incentive/Advance Directives

Comment: Several commenters are concerned that HCFA has not included provisions relating to physician incentive plans and advance directives in its regulations of PHPs. These commenters believe that these two provisions are of vital importance to people with disabilities and chronic illnesses. They believe that to the extent that PHPs perform the same responsibilities as MCOs, they should be subject to the standards comparable to those applied to MCOs.

Some commenters focused on physician incentive plan requirements, agreeing with the above commenters that they should apply when PHPs transfer substantial financial risk to physicians or physician groups. If a State elects to carve out behavioral health, these commenters believe that the same financial arrangement between a PHP and that medical group should be subject to the physician incentive requirements.

The commenters believe that physician incentive plan requirements provide some measure of protection for beneficiaries who might otherwise be under-treated or not treated at all because they have expensive or on-going care needs. They noted that people with chronic and disabling medical or psychiatric disabilities are at high risk for receiving inadequate care because of the high costs often associated with meeting their needs. Moreover, some of the most noted media coverage of treatment cut backs and cut offs has occurred in behavioral health managed care settings when financial incentives are almost always an issue.

These commenters also suggested that enrollees of PHPs should have the same opportunities to execute advance directives prior to the need for this hospitalization, as should enrollees of behavioral health PHPs that cover and provide stabilization and other types of short-term, acute psychiatric interventions in nonhospital settings when psychiatric advance directives might be warranted. Our September 29, 1998 proposed regulations seem to undermine this movement and would likely make acceptance of advance directives by PHPs more difficult. They strongly urged HCFA to make the consumer protections regarding physician incentive plans and advance directives applicable to PHPs.

Another commenter noted that HCFA should give State agencies the discretion to apply advance directives requirements to PHPs. Depending on the nature of the services provided by the PHP, State agencies may believe that it is appropriate for the PHPs to meet the advance directive requirement.

Response: We agree with the commenter that PHPs should provide their enrollees with an opportunity to execute an advance directive to the extent that the PHP performs similar responsibilities as an MCO. So, for example, it may be appropriate for those PHPs that furnish institutional services to provide the opportunity for advance directive. However, there are many PHPs that do not furnish institutional services. Further there are some PHPs that furnish nonclinical services only, such as transportation services. We believe these types of PHPs should not be subject to the advance directive provisions. As a result, we are changing § 438.8(a) to read ''(b) The requirement of § 438.6(h) except for—(1) PHPs that contract for nonclinical services, such as transportation services; and (2) when a State believed it is not appropriate for PHPs to meet the advance directive requirement, such as PHPs that only provide dental coverage.''

With respect to physician incentive plan requirements, we also agree that these provisions represent significant beneficiary protections that should be extended to enrollees in PHPs that transfer substantial financial risk to physicians or physician groups. We have modified § 438.8(a) to reflect this change.

Comment: One commenter recommended that this section be carefully reviewed to ensure that it is clear about the requirements applicable to PHPs. The commenter apparently believes that requirements only apply to PHPs when the term MCO is used in the sections referenced in paragraphs (a) through (g). In a number of these sections, the commenter concluded from this belief that this would exempt PHPs from provisions that the commenter believes should apply. The commenter also believes that § 438.8 does not include references to sections that the commenter believes should be applicable. For example, § 438.802 is not included, although the commenter believes that paragraphs (a) and (c) should apply. The commenter suggested HCFA re-evaluate the use of this mechanism to identify PHP requirements and consider adding specific references to PHPs in each applicable section.

Response: Section 438.802, which discusses the conditions under which FFP is available to MCOs, is based on section 1903(m) of the Act, which does not apply to PHPs. This provision thus does not provide authority to disallow FFP in payments to PHPs. In order to avoid any confusion as to which provisions apply to PHPs, we have added specific references to PHPs in each applicable section. We are also keeping § 438.8, which identifies most of those provisions that apply to PHPs.

Inapplicability of Sanctions Provisions to PHPs

Comment: One commenter noted that the list of MCO provisions that apply to PHPs omitted the sanctions under subpart I. It is unclear whether this sanction authority applies to PHPs through other regulatory provisions. If not, the commenter recommended that HCFA amend the September 29, 1998

proposed rules to apply the subpart I sanction authority to PHPs.

Response: The proposed PHP regulations are based on the authority under section 1902(a)(4) of the Act to provide for methods of administration that are ''found by the Secretary to be necessary for . . . proper and efficient administration.'' While we believe this provides authority to establish requirements that apply to PHPs, we do not believe that would provide authority to promulgate regulations that would authorize a State to impose civil money penalties or other sanctions that are provided for by the Congress only in the case of MCOs. However, States may cover PHP under their own State sanction laws, and we encourage States to do so whenever they believe it is necessary.

PHPs Regulated as MCOs

Comment: Several commenters were pleased that we, relying on our authority under section 1902(a)(4) of the Act, decided to require by regulation that PHPs comply with regulations implementing many consumer protections which the Congress applied to MCOs in the BBA. One commenter believes that it would be a terrible irony for those with these specialized and significant health care needs to be relegated to having fewer rights than other Medicaid recipients. These commenters believe that PHP enrollees should be entitled to the same protections as MCO enrollees since PHPs perform the same responsibilities as MCOs and have similar financial incentives through risk contracts with States.

Several other commenters, however, believe that the BBA did not give the statutory authority in effect to extend statutory MCO requirements by regulation to PHPs. They were concerned that this would be a strong deterrent for some plans and providers who may want to participate but would see meeting the requirements of BBA as too burdensome. The commenters noted that it may be difficult for behavioral health PHPs and dental health PHPs to meet some of the BBA regulatory requirements. These commenters believed that this would create an undue administrative burden on both the State agency and capitated behavioral health providers. The commenters requested that HCFA carefully consider the administrative costs associated with the application of the MCO requirements to risk-bearing providers that provide limited Medicaid services. Particular areas of concern for PHPs included meeting some of the licensing and certification requirements, information requirements, and State plan and contract requirements. Other commenters noted that the enrollment and disenrollment requirements are simply not suitable for capitated behavioral health providers. They believe that this requirement would result in higher cost and less choice because of the negative impact it will have on subcontractors' participation. One commenter suggested that PHPs should not be covered by provisions of the September 29, 1998 proposed rule.

Response: The BBA and the legislative history of the Medicaid managed care provisions in the BBA are silent on the question of how PHPs are to be treated. The BBA did not change the fact that managed care entities regulated as PHPs are only subject to regulatory requirements that we may publish. We agree with the commenter that the BBA does not itself provide us with authority to regulate PHPs, and we are not relying on the BBA as authority for these regulations. Rather, as noted above, we are relying on our authority under section 1902(a)(4) of the Act to establish requirements found by the Secretary to be ''necessary'' for ''proper and efficient administration.'' This has been the basis of PHP regulations from the beginning. The existing PHP regulations in part 434 similarly extended to PHPs by regulation requirements in section 1903(m) of the Act that otherwise only applied to comprehensive risk contractors. For example, under § 434.26(a), both PHPs and HMOs were required to limit their Medicare and Medicaid enrollment to 75 percent of total enrollment. It is true that under § 434.26(b)(4), this requirement could be waived for ''good cause'' in the case of PHPs. Nonetheless, there is longstanding precedent for applying selected requirements in section 1903(m) of the Act by regulation to PHPs. Other longstanding PHP requirements imposed by regulation under the authority in section 1902(a)(4) of the Act include requirements in § 434.27 related to termination of enrollment (for example, a prohibition on termination because of an adverse change in an enrollee's health status), the choice of health professional requirement in § 434.29, requirements in § 434.30 related to emergency medical services, the requirement under § 434.32 that the contract provide for a State-approved grievance procedure, the requirement in § 434.34 that the contract provide for an internal quality assurance system meeting specified standards, and the marketing requirements in § 434.36. We are extending similar requirements in the State responsibilities contained in subpart B of this regulation to PHPs.

All of these requirements were imposed through the same notice and comment rulemaking process being used in this final rule. The only difference between existing requirements and the requirements imposed under this final rule is a matter of degree, not the nature of the requirements in question. We have determined that the BBA contains important beneficiary protections that should be extended by regulation to most PHPs.

It should be noted that not all MCO requirements are being imposed on PHPs and that some PHPs are not required to meet certain specified requirements. For example, as just noted above, we have declined to require that the provisions for sanctions in subpart I be applied to PHPs. Also, some PHPs do not provide the complete set of inpatient hospital services as this term is used in section 1903(m)(2)(A) of the Act, and the exception to the State solvency standards requirement in § 438.116(c)(1) would apply.

Solvency Standards (Proposed § 438.8(d))

Among the beneficiary protections in proposed subpart C that are applied to PHPs under proposed § 438.8(d) are solvency standards in proposed § 438.116. We received several comments on this requirement.

Comment: Several commenters noted that some PHPs would have problems meeting these solvency requirements because not all PHPs, particularly those providing behavioral health services, would fall under one of the exemptions in proposed § 438.116(c). One of the commenters believes it was unclear what a State would have to do to certify a PHP for solvency. The commenter noted that States often use different methodologies than those used for MCOs to determine the solvency standards for PHPs and suggested that States be given more flexibility in this area to set their own PHP solvency standards. Another commenter noted that the solvency requirement is totally inappropriate to PHPs, especially when they serve as subcontractors to an MCO.

Response: Section 438.116(b) requires an MCO, and by operation of § 438.8(d), a PHP, to meet the solvency standards established by the State for private HMOs or to be licensed or certified by the State as a risk-bearing entity. However, § 438.116(c) provides for several possible exceptions to the State solvency standards requirement. If the PHP does not provide the complete set of inpatient hospital services under

section 1903(m)(2)(A) of the Act, the exception to the State solvency standards requirement in § 438.116(c)(1) would apply. Therefore, the exception in § 438.116(c) would normally apply to behavioral health type PHPs. Even though a PHP may be exempt from the solvency standards in § 438.116(b), it still must meet the basic requirements in § 438.116(a), which requires each PHP to provide assurances satisfactory to the State showing that it has adequate provisions against the risk of insolvency to ensure that its Medicaid enrollees will not be liable for the MCO's debts if it becomes insolvent.

5. Information Requirements (Proposed §§ 438.10 and 438.318)

Proposed § 438.10 set forth requirements that apply to States, MCEs or enrollment brokers concerning the provision of information to enrollees and potential enrollees. Paragraph (a) set forth the basic rule that these entities must comply with applicable requirements. Paragraph (b) set forth requirements relating to language and oral interpretation services. Paragraph (c) set forth requirements regarding the format of materials. Paragraph (d) specified to whom information must be provided and when it must be provided. Paragraph (e) specified the information that must be provided, including information on the amount duration and scope of benefits, procedures for obtaining services, names and locations of providers (and which are accepting new patients), any restrictions on freedom of choice, the extent to which out of network providers can be used and after-hours and emergency coverage are provided, policies on referrals for specialty care, cost sharing, the rights and responsibilities of enrollees, and information on complaints, grievances and fair hearings. Paragraph (f) specifies additional information that must be made available upon request. Paragraph (g) required that services not provided under the contract be identified. Paragraph (h) specified information that primary care case managers are required to provide. And paragraph (i) set forth additional information requirements that apply in the case of a mandatory enrollment program under the authority in section 1932(a)(1)(A) of the Act. Proposed § 438.318 (recodified at § 438.218 in this final rule) required that, as a part of the State's ''quality strategy,'' the requirements in proposed § 438.10 must be satisfied, and that contracts must specify that certain information specified in § 438.318(b)(2) be provided.

Comment: Many commenters remarked that proposed § 438.318, ''Enrollee information,'' is redundant with § 438.10 because both require elements of information that a State, MCE, MCO, or PCCM must provide to enrollees and potential enrollees. Commenters recommended combining these sections with a clear distinction between who must provide information. In addition, several commenters also believed that there should be no distinction between mandatory managed care and nonmandatory managed care with respect to information requirements and that requirements should be applicable to both. Further, commenters believe that the regulation exacerbated a problem that exists to some extent in the statute since some requirements apply to MCOs, some to MCEs, and some to States.

Response: Proposed §§ 438.10 and 438.318 have been combined in response to the commenters' concerns; however, the requirements remain essentially the same, since these requirements reflect statutory requirements set forth in section 1932(a)(5) of the Act. Specifically, as the distinction is made in statute, the requirements distinguish between the information that must be provided by MCOs, PHPs, and primary care case managers. There is a further distinction in the statute for mandatory managed care systems under section 1932 of the Act. In specifying in the proposed regulations who had to provide information, States were afforded the maximum flexibility possible since some States have prohibitions regarding distribution of information by MCOs, while some States require MCOs or enrollment brokers to distribute information. Although the specific requirements are now part of § 438.10, in the quality requirements now codified in subpart D, § 438.218 requires that § 438.10 constitute part of the State's quality strategy.

Comment: A commenter indicated that the term ''potential enrollee'' needed to be defined because it was unclear if it meant eligible for Medicaid or eligible for enrollment in a managed care plan.

Response: The term ''potential enrollee'' in this section refers to an individual that has been found eligible for Medicaid and is either required to, or permitted to, join an MCO, PHP, or PCCM. We believe this is clarified with the revised format; therefore, we will not be adding a definition to the regulations text.

Comment: Commenters indicated that the language and format requirements should also apply to member newsletters, health risk appraisal surveys, and health education and preventive care information.

Response: Section 438.10(a)(4) (codified at § 438.10(a)(2) in the September 29, 1998 proposed rule) expressly provides that the provisions of paragraphs (b) (language) and (c) (format) apply to all information furnished to enrollees and potential enrollees, such as enrollment notices, informational, and instructional materials *and* the information specified within the section. HCFA believes that this addresses the commenter's concerns, since the language and format provisions apply to all information furnished to enrollees and potential enrollees, and not just those specified in the § 438.10 itself.

Comment: Many commenters wanted HCFA to require in the regulation that all information and instructional materials (including charts and upon request information) be designated public records and be available to the public.

Response: Assuming that the material the commenters referenced is general information and not specific to an enrollee or potential enrollee, we believe that the information specified in § 438.10 is generally publicly available and therefore may be obtained from the State by following State procedures if the State is in possession of the information. If we are in possession of the information, the information can also be obtained from us under the Freedom of Information Act. We note that States may have procedures to follow for obtaining information.

Comment: A commenter recommended that HCFA encourage States to develop other mediums of notification about managed care options such as public service announcements on radio or TV, posting information on the Internet, and billboards.

Response: While we are not mandating how a State makes individuals aware of their health benefit options, § 438.10 requires that States undertake the activities necessary to fully educate and inform enrollees and potential enrollees about their health care options and how to access benefits.

Comment: Commenters believe that all information provided to enrollees by the State, MCE, or enrollment broker should be developed in consultation with consumers and stakeholder groups.

Response: Although we encourage States to work with consumer and stakeholder groups in the development of material, we do not believe it is necessary to mandate this as part of §§ 438.10 or 438.218. However, many of the elements listed within § 438.10 would be considered marketing material

and would therefore have to be reviewed in accordance with the marketing standards at § 438.104, which require consultation with the Medical Care Advisory Committee (MCAC) established under § 431.12 or a similar entity. The MCAC's or similar entity's membership is required by regulation to include consumer membership. Further, under § 438.218, information standards are part of the overall quality strategy at § 438.304, which includes requirements regarding consumer involvement.

Language Requirements (Proposed § 438.10(b)

Comment: Several commenters found the requirement to make information available in the languages that predominate throughout the State to be problematic; however, commenters offered differing opinions on what they wanted to see in the regulation. Many supported our decision not to include a specific percentage threshold for a language to be considered prevalent in a geographic area but remained concerned that the preamble language referenced a 5 percent figure and that HCFA's Medicaid Managed Care Marketing Guidelines include a 10 percent figure. One commenter suggested that it was too costly for MCOs to meet the costs of printing and distributing materials in other languages at the 5 percent threshold. Another commenter believes that the requirements for language and format were overly prescriptive in light of the absence of any evidence that information is not being given to enrollees in an understandable format. Commenters pointed out that these additional administrative costs are funded out of the same dollar that supports the delivery of care.

In contrast, we also heard from many commenters who understood the need for balance between State flexibility and beneficiary protections but believe that HCFA favored State flexibility too much. Commenters stated that only offering guidance in this area was insufficient. They contended that States should be afforded flexibility in developing methods to provide linguistically and culturally competent services but not in determining whether there is a need for these services in a particular State or service area. Commenters requested that the regulation itself include specifics like those discussed in the preamble. Numerous commenters recommended using a prevalent language threshold as a numerical value rather than a percentage. Several commenters recommended that HCFA adopt the standard employed in California, which calls for translation of written material when there are 3,000 Medicaid beneficiaries in an MCO's service area who have limited English proficiency, or 1,000 such Medicaid beneficiaries residing in one zip code, or 1,500 such beneficiaries in two adjacent zip codes. Some commenters noted that even if an individual was not a member of a prevalent language group, he or she had to have access to information.

Response: We believe that the language and format requirements are essential elements for ensuring that enrollees and potential enrollees receive the information necessary to make an informed choice and access benefits. While we believe they are essential elements, we also continues to believe that the best methodology for determining the prevalent language spoken by a population in a geographic area may differ from State to State and therefore we will not be modifying the regulation to mandate a specific methodology. Further, as we are leaving this methodology for States to determine, the 5 percent rate provided in the preamble should be viewed only as an example and not as a standard. The 10 percent figure in the ''Medicaid Managed Care Marketing Guidelines,'' which also contain suggested guidelines and not mandates, may also be acceptable if it meets the needs of the State. We note, however, that a number of commenters believe that a numeric threshold rather than a percentage was more appropriate because of variations in population density. The commenters believe that percentage thresholds would result in empirically low threshold numbers in low density population areas and unacceptably high threshold numbers in high density populations. We find merit in this argument, which we believe further supports our decision to permit the State to determine the best methodology for its situation. We do note the commenters' suggestions as another example for making this determination. We also note that the HHS Office of Civil Rights (OCR) has issued policy guidance on meeting the language needs of recipients of public funds. (See ''Policy Guidance on the Prohibition Against National Origin Discrimination as it Affects Persons with Limited English Proficiency,'' 65 FR 52762, August 30, 2000.) This guidance gives further examples and guidance on meeting individuals' language needs. Lastly, we agree with the commenter that oral interpretation services must be available free of charge to each potential enrollee and enrollee even if he or she is not a member of a prevalent language group.

Comment: A commenter noted that the oral interpretation requirements in proposed § 438.10(b) apply to MCEs and interpreted this to mean that it would not apply to PHPs. The commenter apparently interpreted § 438.8 to incorporate only requirements for which MCOs are mentioned by name. Under this interpretation of § 438.8, requirements that apply to MCEs (such as the language requirements in § 438.10(b)) would not be incorporated for PHPs. The commenter believes that the language requirements in § 438.10(b) should apply to PHPs.

Response: As noted above, § 438.8 subjects PHPs and PHP contracts to the requirements in paragraphs (a) through (g) that apply to MCOs and MCO contracts. Therefore, since the requirements in § 438.10 are specified in § 438.8(b), these requirements apply to PHPs.

Comment: In addition to requiring that States develop a methodology for determining the prevalence of beneficiaries needing language assistance, some commenters wanted HCFA to recommend a methodology for States to use in determining the prevalence of disabilities in the enrollee population.

Response: While we understand that it may be useful to know the percentage of individuals that may have a disability, we note that the State and MCOs and PHPs must meet the needs of *all* potential enrollees and enrollees and are specifically required under the Americans with Disabilities Act to accommodate the special needs of disabled individuals. We also note that there is a requirement in § 438.206(d) (codified in § 438.306(d) in the September 29, 1998 proposed rule) that States ensure that MCOs maintain a network that is sufficient to provide adequate access, taking into consideration the anticipated enrollment, with ''attention to pregnant women, children, persons with complex and serious medical conditions and persons with special health care needs,'' as well as ''the expected utilization of services, considering enrollee characteristics and health care needs.'' We therefore do not believe that an additional requirement is warranted; however, the State is free to implement such a requirement.

Comment: A commenter recommended that in addition to making oral interpretation services available, HCFA should mandate States to require professional training of interpreters, appropriate accreditation, and appropriate confidential

interpretation services. In addition, the commenter recommended the elimination of family members as translators because of confidentiality issues and sufficient reimbursement for translation services, as well as interpretation services. A commenter further indicated that the State should adjust the capitation rate to reflect reimbursement of interpretation services if the MCO is expected to provide the services.

Response: We believe that it is appropriate and necessary to require that interpretation and translation services be available for all potential enrollees and enrollees and have added this requirement to the regulations text. We also believe that the States should be afforded the flexibility to determine how these translation services are provided and paid for (except that beneficiaries cannot be charged for these services). The Office of Civil Rights has issued policy guidance on the training and use of translators, which may be helpful to States in determining how to meet this requirement.

Format Requirements (Proposed § 438.10(c)(2))

Comment: A commenter noted that proposed § 438.10(c)(2) required that informational material take into consideration people with special needs such as the visually impaired or those with limited reading proficiency. The commenter suggested adding language that specifically states that material in alternative formats will be provided to an enrollee *only upon request*.

Response: While we do not expect a State and MCO, PHP, or PCCM to provide information in alternative formats to all potential enrollees and enrollees, regardless of whether or not they have a special need, we do expect the State and MCO, PHP, or PCCM to provide the information when requested and to fully inform potential enrollees and enrollees about the availability of the information. We have modified § 438.10(c) to provide in § 438.10(c)(1)(ii) that information only need be ''available'' in alternative formats that take into account enrollees with special needs and to make clear in revised § 438.10(c)(2) that enrollees will be informed ''on how to obtain information in the appropriate format.''

Comment: Several commenters were pleased with language in the preamble to the September 29, 1998 proposed rule discussing what constitutes accessible information for people with disabilities and/or limited reading proficiency but believe that this language should be placed in the regulations text. For example, these commenters favored including references in the regulations to 14-point type, a fourth or fifth grade reading level, and the use of focus groups to test cognitive understanding. One commenter suggested that a failure to do so would be a violation of the Americans With Disabilities Act.

Response: Because there is not one commonly accepted standard for providing formats for beneficiaries with special needs, and in light of variances in enrolled population across States, we believe that a State is in the best position to determine the best formats for information. Allowing States to determine the format for information is consistent with the Americans With Disabilities Act, because States have a requirement under § 438.10(c)(1)(i) to present the information in easily understood language and format, and under § 438.6(c)(1)(ii) to take into consideration the special needs of enrollees. Therefore, States are required to meet the information needs of all enrollees; however, we are allowing the States flexibility in determining how they will meet these needs. Additionally, States are required to comply with the Americans with Disabilities Act without regard to the provisions of this regulation

Comment: A commenter objected that the prescriptive nature of the preamble language requiring information to be written at a fourth or fifth grade level could be problematic when providing information on the amount, duration, and scope of benefits.

Response: We do not agree that the preamble language is too prescriptive. While we have recommended that information be provided at a fourth or fifth grade level, the regulation currently affords the flexibility for States to set their own reading level standards, based on the needs of their population.

Comment: Commenters recommended that the requirement in proposed § 438.10(c)(2) that special needs of the visually impaired be taken into account also be applied to persons with hearing impairments and persons with cognitive impairments.

Response: Section 438.10(c)(1)(ii) of this final rule requires that materials take ''into consideration the special needs of those who, *for example,* are visually impaired or who have limited reading proficiency.'' (Emphasis added.) Thus, this list is not intended to be exhaustive, and the special needs listed are just two examples. Individuals with hearing impairments and cognitive impairments would also be considered individuals with special needs that must be considered in material development. We do not believe that it would be possible to have an exhaustive list of special needs as the enrolled populations and needs of enrollees vary by State. In addition, the individuals with special needs vary depending on the circumstance for providing information. For example, an individual with a hearing impairment would not need custom material for mailings but would for educational presentations. We do expect a State and an MCO, PHP, or PCCM to take into consideration the needs of all potential enrollees and enrollees in their State and MCO, respectively.

Comment: A commenter indicated that communications to homeless persons regarding Medicaid Managed Care benefits must take into account a high level of transience, illiteracy, and cognitive impairment in this group.

Response: As stated above, the requirement to take into consideration special needs of individuals applies to all individuals with special needs including people who are homeless.

Comment: Commenters indicated that the regulation should recognize that effective communication may not only require accessible formats but also requires the need for staff training in the managed care plan, health care provider's office, and the Medicaid agency to effectively interact with persons with disabilities, including hearing impairments and cognitive learning problems. Commenters further indicated that to be effective, face-to-face interactions may be required.

Response: We agree with the commenter that effective communication may require more than printed material and have revised the language at § 438.10(c)(1)(ii) to also require that material is provided in an ''appropriate manner' that takes into consideration the special needs of individuals. We have also added a requirement in § 438.10(c)(5) that the State and MCO have mechanisms in place to assist potential enrollees and enrollees with understanding the managed care program and their benefits.

Comment: A commenter believes that the regulations lack the detail needed to assure that States and MCE's understand their obligation to ensure culturally and linguistically appropriate benefits for Medicaid beneficiaries at all levels of the health care delivery system.

Response: We do not agree with the commenter because there are various sections of the regulation that address cultural issues and impose obligations on States to take these issues into account, including the requirements in § 438.10 discussed in this section and requirements in § 438.206 (codified at § 438.306 in the September 29, 1998

proposed rule) discussed below. While we have not provided detailed ''specifications'' in all cases as to *how* States fulfill these obligations, since we believe States should be provided some flexibility in this area, States will be responsible for accomplishing the commenter's desired results, regardless of what methods they use to achieve them.

We have required that oral interpretation services and translation be provided free of charge to beneficiaries and that information on primary care providers include languages spoken.

Comment: Some commenters advocated that all information should be reviewed and approved by the State if not distributed by the State.

Response: Many of the elements listed in § 438.10 are considered marketing material and must therefore be reviewed in accordance with the marketing standards at § 438.104. Paragraph (b)(2) of § 438.104 specifies that each MCO, PHP, or PCCM contract must provide that the entity does not distribute any marketing materials without first obtaining State approval. Further, those that might not be considered marketing materials, such as appointment notices, etc. still must meet the information standards in § 438.10, including understandability.

When Information Must Be Provided (Proposed § 410(d) and (f)).

Comment: Several commenters sought clarification of when complete benefit information was required to be provided to beneficiaries. One commenter recommended that the ''once a year'' requirement of § 438.10(d)(2) be changed to ''at least once a year'' to make it clear that this information need not be provided at a specific anniversary time but rather may be included with other information in the normal course of business during the year.

Response: We agree with the commenter that greater flexibility is needed, and we therefore have provided in a recodified § 438.10(e)(1)(ii) that after the initial provision of information to new enrollees, any significant change in this information must be provided 30 days prior to the effective date of the change. We have also added a requirement in a new § 438.10(f)(4) that all of the information that is ''provided'' pursuant to new paragraphs (d) and (e) (proposed § 438.10(e)) also be available ''upon request'' at any time.

Comment: One commenter expressed concern that the proposed requirement for primary care case managers to provide additional information ''before'' or ''during'' enrollment is confusing as ''before'' or ''during'' can refer to two separate time frames. The commenter recommended that the primary care case manager, or State on behalf of the primary care case manager, be required to provide information ''on'' enrollment.

Response: We agree with the commenter that further clarification is necessary. The regulation has been modified to reflect the same time frames as those required of MCOs, or the State on behalf of the MCO.

Comment: A commenter believes that in addition to annual notification, there should be notification ''as soon as changes occur'' in any of the provisions listed in proposed § 438.10(e) (now in §§ 438.10(d)(2) and (e)(2)).

Response: We agree with the commenter that enrollees should be notified if there is a significant change within the program and have modified the regulations in response to this comment. In the new § 438.10(e)(1)(ii), we are requiring that when there is a significant change (as defined by the State) in the information provided under § 438.10(e)(2), a revised version of the information in paragraph (e)(2) must be provided at least 30 days prior to the effective date of the change. We believe the State is best suited to define what is considered to be a significant change.

Comment: Commenters wanted us to further define when the MCO (or the State) must provide information to enrollees. One commenter suggested that the provision be modified to state that the information should be given within ''a reasonable time after the MCO receives the notice of the recipient's enrollment *or* the effective date of the enrollment, whichever is later.'' Another commenter suggested 7 days after enrollment.

Response: The regulation requires that the information be provided within a ''reasonable time after it receives, from the State or the enrollment broker, notice of the recipient's enrollment.'' We believe that the State is in the best position to define this specific time requirement for providing information.

Comment: Commenters indicated that the dissemination of information is very costly. Additionally, commenters believe that the States were in the best position to provide comparative information. The preference of these commenters was that the State agency assume the administrative responsibility for providing information.

Response: We believe we have provided States with significant flexibility, given the detailed statutory requirements in section 1932(a)(5) of the Act. We agree with the commenter that States should assume responsibility, within the constraints of the requirements in section 1932(a)(5) of the Act, and specifically that States should have the flexibility to decide whether they or MCOs provide comparative information.

Comment: A commenter suggested that the regulations should require States to have a mechanism for notifying their enrollees of their right to request and obtain basic information.

Response: Section 438.10(e)(1)(i) requires that States ensure that enrollees are provided the information at least once a year, rather than just be notified as in the proposed rule.

Comment: A commenter recommended that MCOs provide information directly to enrolled adolescents.

Response: While it is probable that adolescents would receive information directly when enrollment is not linked by family unit, in the case of a family unit we believe that sending one copy of information to each household is sufficient and would constitute providing the information to all ''enrollees'' in that household, provided alternative formats are not necessary for special need reasons. The cost of requiring MCOs to mail directly to multiple family members could be prohibitive. However, this regulation does not prohibit States from imposing this requirement.

Comment: A commenter urged that HCFA ensure that individuals not have to go great lengths to obtain information and that a general request for information should trigger the provision of full information.

Response: We agree with the commenter. Section 438.10(f) includes a requirement that all elements of information be available ''upon request.'' We expect that States and MCOs will not make the process of obtaining information difficult and will provide comprehensive information if any information is requested, since it is in the best interest of all parties that the individuals be as knowledgeable as possible about their health care options, rights, and responsibilities.

Required Information (Proposed § 438.10(e))

Comment: Some commenters argued that proposed §§ 438.10 and 438.318 would impose information requirements upon States or their contracted representatives that go far beyond what is required in statute. Specifically, these commenters pointed out that the statute requires that information on the identity and location of health care providers need only be provided ''upon the request'' of enrollees or potential enrollees, rather than that it be

''provided'' as specified in proposed § 438.10(e)(3). However, there were also a number of commenters who applauded HCFA for requiring that information be ''provided'' and suggested that the provision of additional information on the nature of managed care arrangements would also be appropriate.

Response: Section 1932(a)(5) of the Act spells out information that must be available to all enrollees and potential enrollees. The statute, however, only requires that this information be available ''upon request.'' We believe that the information listed is so basic and fundamental to an enrollee's ability to access services and exercise rights that it is ''necessary for * * * proper and efficient operation'' for this information to be in the hands of all enrollees. For example, an enrollee needs to know about the network of providers in order to access care and about appeal rights to exercise these rights. Therefore, pursuant to our authority under section 1902(a)(4) of the Act to specify what is ''necessary for * * * proper and efficient operation,'' we have required that information such as the names, locations, and telephone numbers of the MCO's network of providers be provided to beneficiaries. We have developed these requirements in keeping with what we believe to be the Congress' general intent that potential enrollees and actual enrollees have this important information. Also, in response to the latter comments that specifically called for information to be given to enrollees on a variety of characteristic features of managed care (for example, prior authorization of services and provider networks), we have added a new type of required information to include ''Description of basic features of managed care'' and ''MCO responsibilities for coordination of enrollee care.'' We have also required the States and MCOs to have in-place mechanisms to assist potential enrollees and enrollees in understanding the managed care system and their benefits. In the BBA-mandated report to the Congress on safeguards for individuals with special health care needs who are enrolled in Medicaid managed care, we noted the extensive evidence that exists on Medicaid, Medicare, and commercial MCO enrollees that demonstrates their lack of knowledge of the characteristic features of managed care and the implications of their enrollment in an MCO. Similarly, evidence exists that there is widespread confusion about MCO responsibilities for care coordination. The nature of comments received support these additional requirements.

Comment: Commenters believe that the elements of information that the MCO (or State) must provide are often elements that are currently included in the member handbook that is supplied by the MCO or by an enrollment broker. A commenter expressed concern that too much information could be overwhelming, causing people to ignore all of it.

Response: We agree with the commenter that the information that must be provided under the September 29, 1998 proposed regulation generally is already provided to enrollees as a common practice. To the extent this is the case, these existing practices could satisfy the requirements in § 438.10(e) with respect to enrollees. It is not our intent that this information be duplicative of what is currently provided. Section 438.10 allows States to continue their current practice of including information as part of an enrollee handbook or requiring that the MCO or (in the case of potential enrollees) that an enrollment broker provide the information. Therefore, HCFA does not believe that the regulation is duplicative or burdensome. We have modified the regulation to specify in § 438.10(d)(1) that the ''State, or its contracted representative'' may provide the information in § 438.10(d)(2) to potential enrollees. Because this information is generally currently provided, we also do not believe that the requirements in § 438.10 would result in ''information overload.''

Comment: Commenters suggested that information on service authorization requirements and provision of transportation to services should be included as elements of the basic information about procedures for obtaining benefits.

Response: Section 438.10(e)(2)(iii) expressly requires that information containing the procedures for obtaining benefits be provided, including any authorization requirements. This should include information on transportation to the extent this is necessary to obtain benefits.

Provider Directories/Provider Information (Proposed § 438.10(e)(3).

Comment: Some commenters believe that information on specialists should only be provided upon request due to the volume of information. These commenters supported this recommendation. They believe that if enrollees are provided with information on specialists, the enrollees may believe that they do not need a referral for speciality care. These commenters believe that this information should only be provided upon request and that it is best provided with the assistance by someone over the phone that has access to timely data. In contrast, we received a number of comments from individuals applauding us for requiring that information on specialists be included in the information, citing that a significant number of Medicaid beneficiaries have special needs and are more reliant on the specialists than the primary care physicians.

Response: Although we acknowledge that including information on specialists adds to the volume of information and further complicates the process of keeping information current, we do believe that a significant number of enrollees rely on this information and therefore continue to believe that, at a minimum, information on provider networks should include information on primary care physicians, specialists, and hospitals, as stated in the preamble to the September 29, 1998 proposed rule. To clarify this point, we have included this preamble reference to specialists in the regulations text at § 438.10(e)(3)(iv).

Comment: A commenter recommended that homeless enrollees receive information about which providers in the network in which they are enrolled have demonstrated competency in meeting their complex health and social needs. Similarly, commenters indicated that information should be available about (1) the ability of providers to treat adolescents and individuals with HIV; (2) the providers' language proficiency; and (3) the accessibility of providers for individuals with disabilities. One commenter suggested that this be required as part of the additional information on education and board certification status of health professionals.

Response: We believe that this type of information should be maintained by the State, MCO, PHP, or PCCM, or enrollment broker (as appropriate) and be available upon request in order to assist individuals when they have a question about a particular service, provider, or location. We have added a requirement in new § 438.10(f)(3) to specify that enrollees, and potential enrollees, are able to obtain any other information on requirements for accessing services or other factors necessary (such as physical accessibility) that may be needed to effectively access benefits.

Comment: Many commenters expressed the view that the requirement to include identification of those network providers who are not accepting new patients is difficult to keep timely and may be out of date by

the time it is printed. In contrast, we also received comments from individuals indicating that this information is critical if a beneficiary is expected to make an informed choice.

Response: We acknowledge that this information is time sensitive; however, it is our belief that beneficiaries need this information to make an informed selection. Therefore, we encourage States and their contractors to highlight to potential enrollees and enrollees that it is important to verify through a phone call, or other means, that the information is still current. We also expect that States and their contractors will provide updates to provider directories within a reasonable time frame, although the exact time is left to the State to determine.

Comment: Several commenters strongly recommended that HCFA require, and not simply suggest, that information on ancillary care provider options be provided. Additionally, commenters wanted information provided on Federal or State community health centers, dialysis centers, and mental health and substance abuse treatment centers (in addition to primary care physicians, specialists, and hospitals).

Response: As the enrolled population, and therefore the health needs of the enrollees, varies from State to State, we believe that the State is in the best position to determine what information needs to be included on ancillary care providers (including those listed by the commenters) in order to meet the needs of their respective beneficiaries. We do expect that this information will be available in all cases and that enrollees and potential enrollees will be notified about availability of additional information upon request.

Comment: A commenter recommended that the requirement for ''name and location'' of network providers be expanded to require the State to provide the name of the clinic or facility, as well as that of the provider, because many patients relate to the clinic and not the provider's name.

Response: While we acknowledge the commenter's point that an individual may be more familiar with a clinic name than a provider name, this is not always the case. We believe that the State or the MCO, PHP, or PCCM is in the best position to know the level of detail regarding site identification that should be included in the information a potential enrollee and enrollee receives.

Comment: A commenter stated that information regarding the education and board certification (and recertification) status of the health care professionals staffing the emergency departments in the enrollee's geographic region should also be provided. They further believe that this additional information should be provided, and not simply made available upon request, because of the need for quick decisions in emergency situations.

Response: Since emergency room physicians are considered health care professionals, *in a situation in which there is a direct contractual relationship* with emergency room physicians, they would be included in the provision at § 438.10(f)(2) that requires information be provided that includes the education and board certification and recertification of health professionals. While it is our belief that some beneficiaries may be interested in receiving these elements, and should be able to obtain them, they are not elements of information that every beneficiary typically uses in selecting a provider. In most cases, in an emergency situation in which time is of the essence, an enrollee would not be ''shopping'' for the best emergency room doctor but would go to the nearest emergency room. Therefore, while the information must be available ''upon request,'' we have not changed the regulation to require that this information be ''provided.'' Further, we note that if there are not direct contractual relationships with the emergency room physicians, as often is the case, there would be no way for an MCO or State to know this information, and therefore the enrollee or potential enrollee could not obtain the information from the MCO or State.

Comment: A commenter was concerned that HCFA was silent on how frequently the provider directory needs to be updated. The commenter recommended that we convey that the intent is not to mandate that the printed directory be updated more often than periodically, although the commenter expressed that we should expect that current information be available through the MCO and through other sources.

Response: We agree with the commenter's clarification regarding the frequency of printing provider directories, but do not believe that a regulation change is necessary. Specifically, we expect the provider directories to be updated periodically, as defined by the State, but also expect that current information always be available to the enrollee or potential enrollee through the State, MCO, PHP, or PCCM, or State contracted representative.

Comment: Several commenters strongly urged HCFA not to permit the use of ''subnetworks'' by MCOs. They believe it would be unfair to consumers to join an MCO and then discover that they could not access all providers because they had been assigned to a subnetwork. In addition, commenters recommended that HCFA require that plans clearly indicate if a network listing does not include all clinics and providers located at the facility.

Response: While we are not in a position to dictate permissible contracting entities for MCOs, we do require under § 438.10(e)(2)(iii) that if there are restrictions within a network, the beneficiary be informed of these restrictions as part of the information that they receive.

Information on Benefits

Comment: A commenter recommended that information also should be provided on which populations are excluded from eligibility to enroll, are subject to mandatory enrollment, or may enroll voluntarily. Commenters specifically cited the Native American population.

Response: We revised the regulations to include a requirement in § 438.10(d)(2)(i)(B)(vi) that requires State to provide information on which enrollees are excluded from eligibility to enroll, are subject to mandatory enrollment, or may enroll voluntarily.

Comment: Several commenters recommended that information be made available on drug formularies.

Response: As a requirement of § 438.10(e)(2)(i), information must be provided to enrollees on the benefits offered, and the amount, duration, and scope of benefits available under the contract, with ''sufficient detail to ensure that enrollees understand the benefits to which they are entitled, including *pharmaceuticals*, and mental health and substance abuse benefits.'' (Emphasis added.) In addition, there is now a requirement in § 438.10(f)(3) specifying that enrollees and potential enrollees can request other information on requirements for accessing services to which they are entitled under the contract. Therefore, although we support the commenter's goals, we believe that this is sufficiently addressed in the regulation.

Comment: A commenter recommended that this section should clearly define all Federally mandated ''benefits'' and ''services'' to which Medicaid enrolles are entitled, including nurse-midwifery services, consistent with section 1905(a)(17) of the Act. The commenter and others recommended the use of both ''benefits'' and ''services'' to convey the full range available under the State Plan.

Response: The terms ''benefits'' and ''services'' are synonymous. Section 1932(a)(5) of the Act uses the terms ''benefits'' in the information section, and therefore ''benefits'' is the word we have used throughout this section of the regulations. The terminology may be different in other sections if the statute used the word ''services'' with a different meaning in mind; however, the words are interchangeable.

Comment: A commenter recommended that information be provided on those benefits that are carved out of the program entirely, as well as those that overlap (for example, mental health benefits and prescription coverage).

Response: Information must be provided on all covered and noncovered benefits for each MCO and PHP. While States may determine that this additional information is necessary, it is our belief that it is the duty of the State, MCOs, PHPs, and providers to coordinate programs and not that of the enrollees.

Comment: Several commenters urged that proposed § 438.10(e) be amended to specifically require that the MCO's basic information list include the availability and scope of EPSDT benefits and family planning benefits. Another commenter stated that the information to enrollees should clearly state that the amount, duration, and scope of benefits provided to children under EPSDT are not limited.

Response: Section 438.10(e)(2)(i) requires that information be provided on the benefits offered and the amount, duration, and scope of benefits available under the contract. Section 438.10(e)(xii) requires that information be provided on the benefits that are not available through the contract but are covered as part of the State plan. Finally, § 438.10(e)(2)(vi) requires that information be provided on the extent to which an enrollee may obtain benefits from out-of-network providers. The preamble specifically cites family planning benefits (when appropriate) as an example. HCFA believes that EPSDT benefits are also benefits that fall within the purview of this requirement. Therefore, sufficient information on EPSDT and family planning benefits will be provided.

Comment: Many commenters believe that while providing information on benefits, as well as those carved out, seemed reasonable, the requirement to include information on the amount, duration, and scope was problematic and too voluminous to provide.

Response: We expect that States and MCOs, PHPs, or PCCMs would use general terms and groupings for benefits that have no limitations; however, additional information would be expected if there was a limitation in a particular service. We believe that individuals need sufficient detail to ensure that they receive the benefits that they are entitled to receive and therefore have not modified the regulation as suggested by the commenters.

Grievance Information (Proposed § 438.10(e)(11)

Comment: Proposed 438.10(e)(10) (recodified at § 438.10(e)(2)(xi)) required that enrollees and potential enrollees be provided information about any appeal rights made available to providers. Commenters suggested that we remove that requirement because it is not directly relevant to enrollees.

Response: This regulation reflects the requirement under section 1932(a)(5)(B)(iii) of the Act, ''Grievance and appeal procedures,'' which refers to information on procedures available to an enrollee *and* a health care provider seeking to challenge or appeal a failure to cover a service.

Primary Care Case Manager Requirements (Proposed § 438.10(h))

Comment: Some commenters contended that primary care case managers generally are provided a minimum case management fee that would not cover the cost of providing the information required under proposed § 438.10(h) (recodified as § 438.10(g)). A commenter suggested that the enrollment broker would be in a better position to provide this information. Another commenter believes that the State should be able to decide who provides the information required under proposed § 438.10(h).

Response: Under § 438.10(g), the State is afforded the flexibility of determining whether the State, contracted representative, or primary care case manager is to provide the information. However, if an enrollee requests information about the grievance procedure from the primary care case manager, he or she should be able to obtain it without having to contact the State. As this information must be available only ''upon request,'' we do not believe that it will be overly burdensome for the primary care case manager to provide the information.

Comment: Some commenters were concerned that a primary care case manager's duty to inform consumers about their grievance rights ''upon request'' may be perceived as supplanting the obligation of MCOs and States to provide written notice of an adverse decision, regardless of whether it is requested. They supported the requirement that case managers be aware of the procedures for filing a grievance and be required to provide information upon request but wanted a statement included that this did not replace the requirement to provide notification for adverse decisions.

Response: The requirements in § 438.10(g) are information requirements, analogous to the information requirements for MCOs under § 438.10(e)(x), and have no effect on the notice and appeal requirements in subpart F of part 438. We therefore do not believe any revisions to the regulations are warranted in response to this comment.

Comment: Certain commenters were displeased that there was no requirement that MCOs provide information about their quality assurance program to enrollees and potential enrollees in the Medicaid program. They believe the regulation should include, as information provided ''upon request,'' information of the type provided under § 422.111(c)(2), (4) and (5) of the June 29, 2000 Medicare+Choice regulations. Specifically, commenters believe that Medicaid beneficiaries should also have access to the following information that is provided to Medicare+Choice enrollees under those regulations: information on utilization control procures; information on the financial condition of the MCO; and a summary of physician compensation arrangements. They also recommended that States require MCOs to provide treatment protocol information to beneficiaries upon request and provide information on HEDIS indicators; results of plan quality studies; external reviews; compliance audits; and summarized complaint and grievance data.

Response: We agree with the commenters that the cited information would be useful to beneficiaries and have revised § 438.10(f) to require that MCOs provide the same information, upon request, that Medicare+Choice organizations are required to provide under § 422.111(c)(2), (4), and (5). With respect to the additional information requested regarding HEDIS indicators and the results of quality studies and external reviews, the results of external reviews under section 1932(c)(2) of the Act will be made available to enrollees and potential enrollees, as required under section 1932(c)(2)(A)(iv) of the Act. Given the lack of experience in analyzing HEDIS indicators or quality results, we are not requiring the disclosure of this information to enrollees at this time but would consider doing so at a future date after

we have more experience concerning the reliability and usefulness of these data.

Comment: Some commenters supported the requirement in proposed § 438.10(i)(2)(iv) (recodified in this final rule at § 438.10(h)(3)(iv)) that information on disenrollments be provided in the case of mandatory enrollment programs under section 1932(a) of the Act; however, many believe these reports would not be meaningful unless they specified the various types of disenrollment, such as voluntary disenrollments, emergency disenrollments, and involuntary disenrollments that occur, for example, due to the loss of Medicaid eligibility as these latter categories of disenrollments are outside of the MCO's control. In the absence of this level of specificity, commenters stated that the data were not useful and could be misleading.

Response: We recognize that disenrollment rates can mean different things, depending on what is included in the rate. For this reason, § 438.10(h)(3)(iv) refers to disenrollment rates ''as defined by the State.'' At a minimum, by requiring the State to define ''disenrollment rates,'' there will be uniform comparison of disenrollments among MCOs, PHPs, or PCCMs. We encourage States to consider the concerns noted by commenters when defining disenrollment rates.

Comment: Commenters observed that providing comparative information in chart form as required under proposed § 438.10(i)(1)(ii) (recodified at § 438.10(h)(1)(ii)) is relatively new and if done inappropriately could be misleading. These commenters stressed that to be effective, the presentation of comparative information needs to take into account the characteristics of each MCE as compared to others, as well as the relative size of the MCE, which may make sampling too small for validity.

Response: The actual design and format of the comparison chart required under § 438.10(h)(1)(ii) in the case of mandatory enrollment programs under section 1932(a) of the Act is left to the State to design. We suggest that States note the concerns listed.

Comment: A commenter sought clarification on how a comparative chart-like form is to be used for the proposed information if the MCE is a primary care case manager under a PCCM program.

Response: The comparative chart-like format specified in § 438.10(h)(1)(ii) is expressly required under section 1932(a)(5)(C) of the Act in the case of a mandatory enrollment program under section 1932(a)(1) of the Act. Section 1932(a)(5)(C) of the Act expressly refers to comparing ''managed care entities [MCEs] that are (or will be) available and information (presented in a comparative, chart-like form) relating to'' specified areas. The statute thus requires the use of these comparative charts in the case of MCOs, PHPs, or PCCMs, whether they be MCOs or primary care case managers. We believe that this is possible, though we would not expect information on primary care case managers to necessarily look similar to that used for comparing MCOs. For example, the chart could list only those primary care case managers that were different in regard to benefits covered and cost sharing imposed. Additionally, § 438.10(h)(3)(ii) requires that quality indicators be provided to the extent available.

6. Provider Discrimination (Proposed § 438.12)

Proposed § 438.12 would implement the prohibition on provider discrimination in section 1932(b)(7) of the Act. The intent of these requirements is to ensure that an MCO does not discriminate against providers, with respect to participation, reimbursement, or indemnification, solely on the basis of their licensure or certification. The requirements do not prohibit an MCO from including providers only to the extent necessary to meet their needs. Further, the requirements do not preclude an MCO from establishing different payment rates for different specialties and do not preclude an MCO from establishing measures designed to maintain the quality of services and control costs, consistent with its responsibilities.

Comment: We received several comments requesting that we clarify our September 29, 1998 preamble language in which we indicate that we did not interpret section 1932(b)(7) of the Act to be an ''any willing provider'' provision. Several commenters specifically recommended that we reference this statement in our final rule, while others recommended that we reiterate this statement in the preamble to the final rule. One commenter suggested that we reconsider this provision so as to require all willing providers to be included in an MCO's network.

Response: As we stated in the preamble to the September 29, 1998 proposed rule, we believe it is clear that section 1932(b)(7) of the Act does not require that MCOs contract with all licensed providers willing to undertake the provision of services to the MCO's enrollees. To the contrary, section 1932(b)(7) of the Act expressly provides that it ''shall not be construed'' to prohibit an organization from ''including providers only to the extent necessary to meet the needs of . . . enrollees.'' It also makes clear that restrictions based on maintaining quality or controlling costs are permissible. We believe that the requirements contained in this section of the regulation were intended only to ensure that providers are selected in a fair and reasonable manner and not discriminated against solely because of their license or certification. Thus, we indicated in the September 29, 1998 proposed rule, and we reiterate here, that this section does not require MCOs to contract with ''any willing provider.'' We do not believe it is necessary or appropriate to amend the regulations to expressly reflect this fact, since by its own terms, § 438.12 does not require contracting with all willing providers.

Comment: One commenter requested that we clarify how a State will determine compliance with this provider discrimination provision.

Response: We expect each State agency to develop its own mechanism to ensure that MCOs contract with providers in a fair and reasonable manner. Our regulation provides States sufficient flexibility to determine which mechanism works best for them. We plan to work with States to provide additional guidance on this issue in the future.

Comment: One commenter recommended that the final rule include written notice and appeals procedures for providers participating in an MCO. The commenter suggested that the process for a written notice and appeals procedure should be based, in part, on the interim final Medicare+Choice regulation.

Response: While the Medicare+Choice regulations do require, in the last sentence in § 422.205(a), that Medicare+Choice organizations provide written notice to providers or groups of providers stating the reasons why they were not accepted as part of the organization's provider network, there is no provision for a right to ''appeal'' such a decision. Under §§ 422.202(a) and 422.204(c), providers have appeal rights only once they have been accepted as a member of the Medicare+Choice organization's provider network. We similarly are not providing for any right to an appeal in this final rule, though States are free to do so. We agree with the commenter, however, that it would be helpful in enforcing the anti-discrimination requirement in section 1932(b)(7) of the Act if MCOs were required to provide written notice to providers seeking to contract with them of the reasons why

the providers were not included in the MCO's network. We therefore have revised § 448.12(a) to include the same written notice requirement that applies to Medicare+Choice organizations under § 422.205(a).

Comment: Several commenters suggested that additional protections be added to the regulation to further ensure nondiscrimination of providers. The commenters recommended that the regulation expressly prohibit nondiscrimination of providers who serve limited English-proficient populations, high-risk populations, and persons with HIV and AIDS. One commenter stressed the importance of culturally competent providers and recommended that we add a provision to require physicians to be added to an MCO's network because of the ''value'' they would add in terms of cultural competence.

Response: The statutory provision implemented in § 438.12(a)(1) and (b), section 1932(b)(7) of the Act, addresses only discrimination that is based solely on licensure and not the other types of discrimination addressed by the commenters. However, § 438.12(a)(2) incorporates requirements elsewhere in part 438 that we believe, along with other provisions in part 438, address the commenters' concerns. Specifically, § 438.12(a)(2) requires that providers be selected in accordance with the requirements in § 438.214 of subpart D. Section 438.214(c) in turn requires States to ensure that MCOs use provider selection and retention criteria that ''do not discriminate against particular providers, including those who serve high risk populations or specialize in conditions that require costly treatment.'' We believe that this prohibits the types of discrimination referenced by the commenters. In addition, we refer the commenters to § 438.206(e)(4), which requires MCOs to provide services in a culturally competent manner, including at least complying with the language requirements of § 438.10(b).

Comment: One commenter believes that there was a contradiction between proposed § 438.12 and proposed § 438.306 (recodified at § 438.206 in this final rule) and that clarification was needed in order to comply with the requirements of section 1932(b)(7) of the Act, as the commenter interpreted them. Specifically, the commenter referred to the preamble discussion of proposed § 438.306 in which we stated that if more than one type of provider is qualified to furnish a particular item or service, the State agency should ensure that the MCO's access standards define which providers are to be used and ensure that those standards are consistent with State laws.

Response: Section 438.12 speaks to discrimination by MCOs against providers of services solely on the basis of licensure. In contrast, § 438.206 requires States to establish standards to ensure the availability of services by MCOs. Although the preamble to proposed § 438.306 referred to ''types''of providers to be used, it specifies that the MCO's standards for inclusion of providers must be consistent with State law. We do not believe that § 438.206 could reasonably be read as inconsistent with § 438.12 (that is, to permit an MCO to discriminate against providers solely based on licensure or certification). Section 1932(b)(7) of the Act makes clear that MCOs may limit the number of providers with which they contract based on need or to control costs. If more than one type of provider can provide a State plan service, and an MCO already contracts with one such type of provider, we believe that it could under section 1932(b)(7) of the Act and § 438.12 decline to contract with the other type of provider based on cost-effectiveness considerations, unless there is a State plan service that only that type of provider can furnish. For example, if the State plan includes ''nurse-midwife'' services under section 1905(a)(17) of the Act or certified pediatric nurse practitioner/certified family nurse practitioner services under section 1905(a)(21) of the Act, these services can, by definition, only be provided by the type of provider in question.

Comment: One commenter expressed concern regarding a Medicare Operational Policy Letter, indicating that it could be used as a basis for denying chiropractic services to a Medicaid beneficiary.

Response: First, we note that Medicare Operational Policy Letters do not establish Medicaid policy and are not a valid basis for denying services to Medicaid beneficiaries that would otherwise be covered in accordance with a Medicaid State Plan. The Medicare Operational Policy Letter in question also would not have any applicability even by analogy, because of differences between the way chiropractic services are treated under Medicare and Medicaid. Under Medicare, ''chiropractor services'' are not listed as a specific covered service or benefit. Rather, under section 1832(a)(2)(B) of the Act, beneficiaries with Medicare Part B are entitled to coverage of ''medical and other health services,'' which in turn is defined in section 1861(s) of the Act as including ''physicians services.'' While there thus is a right to coverage of ''physician's services,'' there is no specific coverage category for the services of a chiropractor. Instead, under the definition of physician in section 1861(r) of the Act, a chiropractor can be considered a physician for purposes of being eligible to provide Medicare covered physician services but only to the extent the chiropractor is performing a manual manipulation of the spine to correct a subluxation. This manual manipulation thus can be reimbursed by Medicare as a physicians' service whether it is performed by a chiropractor or any other physician, such as an orthopedist, who performs this manual manipulation.

In Medicaid, in contrast, section 1905(a)(6) of the Act permits States the option of covering medical or remedial care ''furnished by licensed practitioners within the scope of their practice as defined by State law.'' To the extent a State has decided under section 1905(a)(6) of the Act to cover chiropractor services under its State plan, this covered service by definition could only be provided by a chiropractor.

Comment: We received several comments questioning the statutory basis for § 438.12(b)(2), which permits the MCO to pay different amounts for different specialties. Several commenters suggested that a provider performing the same service should be paid the same amount, regardless of the provider's specialty. They recommended that we remove paragraph (b)(2) or revise it to prohibit MCOs from paying lesser amounts for the same service when provided by different types of practitioners. Other commenters stated that paragraph (b)(2) had the practical effect of requiring MCOs to pay all specialists within the same specialty the same amount. These commenters suggested that HCFA clarify this provision, with one commenter recommending that we amend paragraph (b)(2) to not permit the MCO to use different reimbursement amounts for different specialties or for the same specialty.

Response: We disagree that the statute does not allow an MCO from establishing different reimbursement amounts for different specialties. Section 1932(b)(7) of the Act states that an MCO ''may establish measures designed to maintain quality and control costs consistent with the responsibilities of the organization.'' We believe that paying different amounts to individuals with different specialties can clearly be dictated as a ''measure[ ] * * * to control costs.'' This is because we believe that, in order to attract

highly qualified providers of all types, and to attract an adequate number of certain categories of specialists, MCOs may need to pay a higher amount than they would need to pay to attract other types of providers. It would not be cost-effective if the MCO was then required to pay this higher amount to other providers who would be willing based on market rates to join the network for a lower amount. Also, as a quality measure, MCOs should be free to pay providers with more training and experience a higher rate of reimbursement for the services they perform. Moreover, we do not want to preclude MCOs from using incentive payments to reward providers for demonstrating quality improvement or from attracting experienced providers to its network.

For the reasons stated above, we agree with commenters that paragraph § 438.12(b)(2) should be clarified to also permit different reimbursement amounts for the same specialty. Accordingly, we have amended the final regulation at § 438.12(b)(2) to state clearly that an MCO may use different reimbursement amounts for different specialties or for the same specialty.

B. State Responsibilities (Subpart B)

Proposed subpart B set forth the State option to implement mandatory managed care through a State plan amendment, as well as State responsibilities in connection with managed care, such as ensuring choice and continuity of care, enforcing conflict of interest standards and limits on payment, monitoring, and education.

1. State Plan Requirements: General Rule (Proposed §§ 438.50 and 438.56(b), (c), and (d))

Proposed §§ 438.50 and 438.56, implemented section 1932(a)(1) and (2) of the Act, which permits mandatory enrollment of Medicaid beneficiaries in MCOs or PCCMs on the basis of a State plan amendment, without a waiver under section 1915(b) or 1115 of the Act. Under these regulations, a State agency can require most Medicaid beneficiaries to enroll in MCOs or PCCMs without being out of compliance with provisions in section 1902 of the Act on statewideness, comparability, or freedom of choice. Paragraph (b) and (c) set forth the requirements for these programs and the assurances that States must provide. Proposed § 438.56(b) identified limitations on populations that could be mandatorily enrolled. Paragraphs (c) and (d) set forth requirements for enrollment priority and default assignment under these programs.

Comment: One commenter requested that we clarify that § 438.50 does not apply to 1915(b) and 1115 waiver programs since States can mandate enrollment in MCOs and PCCMs under theses waiver authorities without amending their State plan.

Response: We agree with the commenter and we have amended the final rule with comment period to expressly provide that programs operating under section 1915(b) or 1115 the waivers are exempt from the requirements of this section.

Comment: A few commenters expressed the concern that the Federal requirements permit certain SPAs to be effective as early as the first day of the quarter in which the SPA was submitted to us and recommended that we eliminate the retroactive approval of these SPAs. Two commenters erroneously believed that the State risk loss of federal money if the SPA is disapproved, apparently confusing this State plan process with the process of approving contracts under section 1903(m) of the Act. These commenters also expressed a concern that beneficiaries may be permanently adversely affected in the event they are harmed during the retroactive period. One commenter remarked that the State could begin enrolling beneficiaries into a mandatory managed care system that does not guarantee access to reproductive health services prior to the submission of the SPA. Another commenter emphasized that the short timeframes in implementing managed care have caused problems for the consumers and providers in the past, and guidelines from us are needed in areas of payment, enrollment, network adequacy and continuity of care, etc.

Response: We do not believe that the rules governing effective dates for SPAs which mandate enrollment in managed care should differ from the rules that apply to any other amendments to a State's plan. By allowing States to implement a SPA effective the first day of the quarter in which they submit the SPA to us for approval, § 438.50 is consistent with the other SPA effective date provisions in §§ 430.20 and 447.26. The retroactive effective date is only applicable in the case of an approvable SPA. During the retroactive period, the increased beneficiary protections such as grievance procedures, quality assurance, and disenrollment are applicable. Also, before the State may actually enroll beneficiaries into MCOs under this authority, all contracts between the State and the MCO must be approvable and in place and all statutory and regulatory requirements must be satisfied.

Comment: Two commenters indicated that the pre-print form is not sufficiently descriptive. They recommended that the form require the States to provide more detail on family planning, prenatal care, labor and delivery and other reproductive health services. In addition, they would like the States to specify the type of entities with which the State will contract in order to assure access to reproductive health services, supplies and procedures.

Response: We are in the early stages of developing this section of the State plan preprint for amendments under § 438.50, and will take these comments into consideration when designing that form. However, some States have already implemented approved programs under § 438.50 utilizing existing guidance issued in a December 17, 1997 letter to all State Medicaid Directors. We believe that the commenter's specific concerns are addressed in § 438.50(b), which requires States to specify the types of entities with which they will contract under a mandatory managed care program, in combination with § 438.206(c), which requires that contracts with the MCO specify the services that the entity is required to provide, and that States make arrangements to cover all Medicaid services available under the State plan, including any that may not be in the MCO contract.

Comment: One commenter stated that while States can assure that contracts between MCOs and themselves meet all requirements of the Act, a commitment that all MCOs and PCCMs will be in compliance at all times is unrealistic. This commenter recommended that the preferable language would be that the State/local district will take appropriate action against an MCO or PCCM whenever it is determined that one of these entities is not in compliance with the contract.

Response: We agree that a State cannot assure in advance that an MCO or PCCM will always be in compliance with all requirements, and that all we can ask is that the State take appropriate action if it is determined that one of these entities is out of compliance. Subpart I below discusses intermediate sanctions and civil money penalties that can be imposed when MCOs or PCCMs are out of compliance, and subpart J discusses the fact that FFP can be denied in contracts with MCOs that are substantially out of compliance. Proposed § 438.50(b)(4), however, refers to the State being in compliance with requirements in this part relating to MCOs and PCCMs.

Comment: We received one comment stating that the current regulations allow

our Regional Offices (ROs) to approve SPAs based on policy statements and precedents previously approved by the Administrator. Only disapproval of an amendment must come from the Administrator's office. Currently there are no policy statements or precedents from the Administrator's office to provide guidance to ensure uniform decision making by the ROs. This commenter recommended that approval of the managed care plan amendments should be the responsibility of our Administrator with assistance from the Regional Office until comprehensive guidelines have been developed and disseminated to the Regional Office.

Response: Section 430.15(b) gives our delegated authority to approve the State plan and plan amendments. The consults with our Central Office during the review process to ensure that the SPA meets the requirements of all relevant Federal statutes and regulations as stated in § 430.14. All reviewers in our Central and Regional Offices reference the same tools when reviewing a State plan amendment, including State Medicaid Director letters implementing the managed care provisions in the BBA of 1997 provisions. The delegations of authority are clear on the review of State plan amendments, and the collaboration between the our RO and central office is a long established process. Consequently, we are not making any changes in the approval authority for these SPAs.

State Plan Assurances (Proposed § 438.50(b) and (c))

Comment: A number of commenters felt that the regulation should require the States to publicize any plan amendment for mandatory managed care, and to solicit public involvement in all levels of development before the amendment is approved and implemented. Suggested methods for informing and involving the public included:

- Public hearings and comment periods;
- Involving the State Medical Care Advisory Committee in reviewing amendments and contracts.
- Using our website to notify the public of the submission and approval of State plan amendments.
- Publishing a **Federal Register** notice when States first submit an amendment.
- Requiring that the MCO and PCCM contracts, as well as bids, be designated public record and be available to the public.

Response: We agree with the commenters, and we have amended the final rule with comment period at § 438.50(b)(4) to require state plans to specify: ''The process the State uses to involve the public in both design and initial implementation of the program, and the methods it uses to ensure ongoing public involvement once the State plan has been implemented.'' This language is consistent with the public notice requirements of the State Children's Health Insurance Program.

Comment: One commenter recommended that we establish specific procedures to closely monitor, track and evaluate these State plans.

Response: We acknowledge this concern, and assure the commenter that we will continue to monitor, track, and evaluate State plans via review of provider contracts, site visits, and reporting requirements such as for external quality reviews. Amending the state plan to implement a program of mandatory managed care may eliminate the need for a State to apply for waiver renewals every two years, but does not eliminate the State's obligation to guarantee access to services and provide quality care to its beneficiaries, nor does it eliminate necessary monitoring and evaluation of these programs by us.

Comment: One commenter recommended that State plans and contracts with MCOs provide that the choice of primary care providers for children must include pediatricians, and ensure access to pediatric services. The commenter also recommended a pediatric definition of medical necessity. Other recommendations included that the contracts should ensure that information and training is provided to recipients, physicians and other providers, local agencies and human health services agencies regarding various aspects of the managed care programs. This commenter requested that we require States to describe their plans for conducting performance evaluations.

Response: For reasons discussed in more detail in section II. D. below, in a response to comments on proposed § 438.306 (now codified at § 438.206), with some exceptions (such as a women's health specialist), we generally do not believe it is necessary or appropriate to require that MCOs contract with specific categories of providers. However, also as discussed in that section, we are requiring in § 438.206(d) that in establishing an MCO's provider network, it must consider the anticipated enrollment, with ''particular attention to * * * children,'' and ''[t]he numbers and types (in terms of training and experience) of providers required to furnish the contracted services.'' We believe that these requirements address the commenter's concern about participation of pediatricians. With respect to the recommendation for a ''pediatric definition of medical necessity,'' also as discussed below in section II. D, we are requiring in § 438.210(a)(4)(ii)(B) that an MCO's definition of ''medical necessity'' address the extent to which it is responsible for covering services related to the ability to achieve age-appropriate growth and development, which is obviously ''pediatric-related.'' We have not required a separate definition. We believe that the commenter's suggestion concerning information requirements has been addressed in § 438.10(d) and (e). Finally, with respect to the issue of ''performance evaluations,'' as discussed in section II. D. below, § 438.240(c)(i) requires that MCOs and PHPs measure performance, while § 438.240(c) requires performance improvement projects.

Limitations on enrollment (Proposed § 438.56(b))

Comment: One commenter correctly noted that if a State wished to use the State plan option, yet wished to mandate managed care enrollment for elements of the Medicaid population exempted under that option, the State must still request a waiver to include the exempt populations, thereby negating the benefits of the State plan option. Another commenter complained of the continued administrative time, expense and confusion in the current waiver renewal process. This commenter also expressed the view that if the BBA is designed to allow greater flexibility for State administration, then greater allowance should be given to the State plan option rather than the waiver.

Response: The proposed rule implements section 1932(a), of the Act as enacted by the Congress. While it provides States with an alternative to the 1915(b) of the Act waiver process with respect to individuals not exempted, we acknowledge that the State plan amendment is not applicable to all situations, and that the State will need to submit a 1915(b) of the Act waiver to enroll exempted population into mandatory managed care programs. We have no discretion to change, this however, because the Congress was clear in exempting these populations.

Comment: One commenter noted that nothing in the BBA prohibits States from exempting populations other than those specified in the Act for mandatory enrollment in managed care, and recommended that language be added to the regulations to indicate that the State may exempt other populations. Another

commented that the regulation only lists categories of persons who may not be enrolled in managed care under the State plan managed care option. The commenter suggested that this rule should also allow States using the waiver option to exempt categories from mandatory managed care.

Response: We do not agree that it is necessary to add language to the regulation indicating that States may exempt other populations. Section 1932(a)(2), of the Act identifies those populations which *must be* exempted from mandatory enrollment under this provision. States have had and continue to have the discretion to exempt other populations from mandatory enrollment in managed care.

Comment: Several commenters expressed concern that beneficiaries might not be identified or notified of their exemption from mandatory enrollment, and run the risk of being defaulted into MCOs or PCCMs. They recommended that the State provide a mechanism to ensure that exempt populations are not enrolled into MCOs or PCCMs, and that State be required to permit exempt individuals to self-identify.

Response: Section 438.10(d)(2)(B) of the final rule with comment period has been modified to require that potential enrollees be informed of populations which are exempt from mandatory enrollment in any such program. We agree that self-identification would be an effective tool for individuals who fall into an exempt category, but are not identified as such by the State. Once identified, the State would be obligated to exempt such individual from mandatory enrollment, and to disenroll he or she immediately, if they had been enrolled by default.

Comment: We received comments concerning the applicability of the limitations in section 1932(a)(4) of the Act on the right to disenroll without cause to exempted populations. One commenter urged that the ''12 months lock-in'' provided for under section 1932(a)(4) of the Act should be restricted to individuals whose enrollment in managed care was mandated. Two commenters suggested that the 12 months lock-in should not be allowed for exempted groups unless a State can demonstrate in a waiver that the population's access to services will not be diminished due to enrollment in an MCO or PCCM.

Response: If an exempted individual voluntarily enrolls in an MCO or PCCM, the same lock-in and disenrollment provisions in section 1932(a)(4) of the Act apply, including the ability to disenroll without cause during the first 90 days of enrollment. This is because section 1903(m)(2)(A)(vi) of the Act incorporates section 1932(a)(4) of the Act in the case of MCOs, while section 1905(3)(E) of the Act incorporates section 1932(a)(4) of the Act in the case of PCCMs. With respect to the last recommendation concerning demonstration of access to services, MCOs must meet the requirements for access and availability of services as specified in §§ 438.206 and 438.207 of the final rule with comment period, while a PCCM contract must meet the requirements for access and services under § 438.6(k).

Comment: Some commenters agreed with the exempted groups as outlined in the proposed rule and recommended that we maintain this provision. Specifically, two commenters agreed that foster care children should be exempted as foster care children move frequently and they may need to change providers for geographic reasons. These commenters also noted that if the child has a disability and moves often because of foster care, it may be important to maintain a single provider to prevent frequent disruption of complex care. Another comment indicated that children under 19 years of age who are eligible for SSI and eligible for dental coverage under EPSDT should not be subject to mandatory enrollment in managed care.

Others felt certain populations should not be excluded from managed care programs, with one commenter recommending legislative action to revise the rules to delete all impediments to enabling managed care programs for the broadest possible populations. The commenters cited positive experiences with exempted populations in mandatory managed care programs and felt that the special needs can best be addressed and coordinated through a network of providers. The commenters' experience has shown that Medicaid clients believe the service is better and the more complicated the care, the more there is a need for managed care. Two commenters expressed the concern that by limiting managed care for certain populations, the message conveyed is that managed care does not work for these populations. They continued to say that many States have been very successful in operating managed care for these exempted populations and it has been shown to be a strong factor in assuring access to primary and preventive care and other needed medical services. One commenter stated that they have taken steps to ensure that MCOs identify and serve children with special health care needs appropriately, including the implementation of broad, functional definitions of Disability and Special Health Care Needs. This commenter partnered closely with the advocate community to develop appropriate standards for this population. They felt that we were incorrect to assume that managed care will not work for these populations.

Response: Section 1932(a)(2) of the Act identifies those groups exempted from mandatory enrollment under this provision. We do not have the authority to add groups or delete groups from this list. The statute does not prevent voluntary enrollment if a voluntary contract exists and an individual believes that his or her needs will be best met with an MCO or PCCM. If a State desires to enroll any of these exempted populations into a managed care program, it may do so by offering voluntary enrollment as an alternative to unrestricted fee-for-service, or it may mandate enrollment through section 1915(b) of the Act or 1115 of the Act waiver authority.

Comment: We received many comments requesting that additional populations be exempt from mandatory managed care because of the complexity of the beneficiaries' medical needs. Commenters recommended that the additional exempted groups should include—

Children with HIV, but who have not developed AIDS;
Patients awaiting transplants and organ transplant recipients;
Patients suffering from cancer;
Patients suffering from arthritis, osteoporosis, chronic and debilitating musculoskeletal conditions;
Children and adults with mental retardation;
Patients with severe and persistent mental illness (SPMI), brain disorders;
Adults with disabilities;
Homeless persons; and
People for whom English is not their primary language or people residing in areas where provider awareness of cultural diversity is limited.

Several commenters suggested that the language in § 438.56(b)(3)(v) (redesignated as § 438.50(d)(3)(v)) narrowly defines children with special needs in Title V programs who are exempted from enrollment. These commenters recommended that this section should be amended to cover all children eligible for Title V special needs as defined by the State's Title V agency. Commenters proposed definitions for foster care or ''otherwise in an out-of-home placement.'' A few commenters recommended the adoption of the Maternal and Child Health

Bureau's definition of children with special health care needs.

A couple of commenters recommended voluntary enrollment for dual eligibles and for adults with disabilities. One commenter recommended that individuals who have significant, chronic disabilities should have the option to voluntarily enroll and not be subject to any State being eligible to obtain such a waiver from HCFA.

Response: As indicated above, in section 1932(a)(2), of the Act the Congress specified the groups that are exempt from mandatory managed care enrollment through the State plan provision. We do not have the statutory authority to exclude any other populations. Because of variations in States regarding the identification of individuals receiving services through a family-oriented, community based, coordinated care system receiving grant funds under Section 501(a)(1)(D) of Title V, of the Act the December 17, 1997 SMD letter offered guidance to States about developing more detailed operational definitions of this group. The State also has the option to define this group in terms of their special health care needs and to develop a process whereby individuals who are not identified through the initial exemption process could request exemption based on special needs as defined in the State plan.

Although we considered using the Maternal and Child Health Bureau's definition of children with special health care needs, we believe that the identification of this specific group by either program participation or accepted State definition more closely reflects the statutory language while being more administratively feasible.

Enrollment by Default (Proposed § 438.56(d)

Proposed section 438.56(d) set forth the requirements relating to default enrollment of beneficiaries in SPA programs who do not make a choice from among the available MCOs or PCCMs. (**Note:** As indicated above, this section is being moved to § 438.50 in the final rule with comment period because it applies only to SPA programs.) This provision required that the default enrollment process preserve existing relationships between beneficiaries and health care providers, and relationships with providers that have traditionally served Medicaid beneficiaries. If this is not possible, States are required to distribute the beneficiaries equitably among the available MCOs or PCCMs qualified to serve them.

Comment: A number of commenters pointed out that the proposed rule did not address what constituted an acceptable level of default enrollments. The commenters urge us to encourage States to keep the rate of default enrollments as low as possible, and to use the comment/response section of the final rule with comment period to discuss the successful practices of States like New Jersey and Rhode Island to keep default enrollments low. The commenters urged us to require States to collect and report uniform data on default enrollments (some commenters suggested that the data be broken down by geographic area). Most commenters identified 25 percent as the threshold at which further action should be taken, although one commenter suggested that default enrollments be halted in cases where the default rate goes above 10 percent. The commenters had various suggestions as to what should happen in cases where the rate of default enrollments exceeded the threshold—some said default enrollments should be halted, some said we should review the State's processes, and some said the State should develop and implement corrective actions in their outreach and enrollment processes.

Response: Although the BBA did not specify an acceptable level of default enrollments, we agree that this can be an important measure of the extent to which beneficiaries make informed decisions about enrollment. We agree that States should endeavor to keep default rates low, and the enrollment and information provisions of the regulation are designed to help States achieve a high rate of enrollee choice. Default enrollment rates vary widely because States have greatly different levels of experience with managed care, and because of measurement variation. Although we have decided not to mandate a single acceptable level of default enrollments in the final rule with comment period we will continue to monitor default enrollments in Medicaid managed care programs.

Comment: A number of commenters pointed out that the proposed rule did not specify the time allowed for beneficiaries to choose an MCO or PCCM before default enrollment takes place. The commenters suggested a number of minimum timeframes—20, 30, or 60 days. One commenter also suggested that States be required to offer a longer time period for persons with serious and persistent mental illness.

Response: Section 1932(a)(4)(D)(i) of the Act, as established by the BBA, refers to ''the enrollment period specified by the State.'' Therefore, we believe the Congress intended for each State to be able to set its own enrollment period, depending upon its population and its own experience with managed care. To date, States have demonstrated that a wide variety of time periods can be effective, depending upon their own populations and outreach and educational programs. For example, one State with a low default enrollment rate only allows enrollees 10 days to choose a plan. We have decided not to specify a minimum time period in the final rule with comment period.

Comment: We received one comment urging that default enrollments be prohibited. A number of other commenters indicated that some limitations should be placed upon a State's ability to make default enrollments. A number of limitations were suggested. One commenter said default enrollments should be prohibited in cases of persons with disabilities. Another indicated that the enrollment period should be suspended if the beneficiaries had requested information and not received it, or had requested a face-to-face meeting that could not be scheduled during the enrollment period. Also, this commenter said if the recipient or his guardian could not be reached through no fault of their own, there should be no default enrollment. One commenter said States should be required to assign beneficiaries to a PCCM instead of default enrolling them into an MCO.

Response: The Congress spoke clearly on which groups should be exempt from mandatory enrollment in SPA programs, and these groups are similarly not subject to default enrollments pursuant to section 1932(a)(4)(D) of the Act. For those individuals who are not exempt, the statute requires a default enrollment process for MCOs and PCCMs generally, not just primary care case managers. Specifically, section 1932(a)(4)(D) of the Act provides that under a mandatory program under section 1932(a)(1) of the Act, ''the State *shall establish* a default enrollment process * * * under which any * * * individual who does not enroll *with a managed care entity* during the enrollment period. * * *'' In granting States the discretion to specify the time period for making an enrollment, we believe that the statute gives States the flexibility to provide for extensions of this time period, or other accommodations when warranted by the needs of the population, so long as they are applied in a uniform manner. We recommend that States grant extensions and other accommodations when they consider it to be appropriate.

Comment: One commenter pointed out that many persons with disabilities, who may be subject to mandatory

enrollment, have a representative payee. The commenter recommended that we require States to notify representative payees when default enrollments are made.

Response: We agree with the commenter that there may be situations when it would be appropriate for the State to notify someone other than (or, at State option, in addition to) the enrollee. However, we believe the final rule with comment period should provide for notification of a broader scope of enrollee representatives than representative payees. In response, we have added language to the final rule with comment period adding references to an enrollee or his or her ''authorized representative.'' This would cover situations including, but not limited to, a representative payee situation. (We have added this language to § 438.56.)

Comment: One commenter said the final rule with comment period should address how enrollees are assigned to PCPs once they have been default enrolled in an MCO, and recommended that we require that MCOs consider geographic, cultural, and linguistic accessibility when assigning enrollees to a PCP.

Response: In requiring States to preserve existing provider-recipient relationships in the default enrollment process, the Congress clearly intended there to be as little disruption as possible in the provision of medical care. We encourage States to monitor this process and to require that MCOs, to the extent possible, make PCP assignments that promote recipient access to care. Additionally, we believe that the access requirements for MCOs contained in § 438.206 will assist in this regard. We do not believe, however, that it is necessary to insert an additional regulatory requirement.

Comment: We received a large number of comments on the default enrollment methodology. One commenter expressed general support for the enrollment by default provisions. A handful of commenters indicated that they thought we had placed too many requirements in the default enrollment section. The bulk of the commenters, however, encouraged us to place additional requirements on States in developing their default enrollment procedures. The commenters who disagreed with our proposed regulations believed either that States should not have to take relationships with existing providers into account, or that the default enrollment procedures should not favor traditional providers. Two commenters felt that favoring traditional providers may discourage participation in managed care programs by commercial MCOs. The commenters who want us to place additional requirements on States disagree with the concept of equitable distribution if it means States are not permitted or required to take additional factors into consideration. Commenters suggested that the rule should require States to take the following factors into account when default enrolling beneficiaries: Geographic accessibility, especially for rural residents; cultural and linguistic competency; experience with special needs populations; physical accessibility; and capacity to provide special care and services appropriate to the needs of the individual. Commenters said persons who are homeless, persons with HIV, and individuals with special health care needs or developmental disabilities should only be assigned to MCOs or PCCMs with demonstrated competency serving them. In addition, commenters said that we should not allow States to favor MCOs or PHPs in their default enrollment methodologies just because they are the lowest cost Entity, and that no default enrollments should be made to plans that do not offer the full scope of basic health care services, including family planning services. Commenters said States should be allowed to consider such factors as success rates in completing EPSDT screens, price, quality, and customer satisfaction in their default enrollment methodology.

Response: The statute clearly indicates that States must take existing relationships into account, ''or relationships with providers that have traditionally served beneficiaries under this title.'' Section 1932(a)(4)(D)(ii)(II) of the Act goes on to specify that if maintaining such relationships is not possible, States must arrange for ''the equitable distribution of such individuals among *qualified* managed care entities available to enroll such individuals, consistent with the *enrollment capacities* of the entities. (Emphasis added)'' We believe that in using the term ''qualified,'' the Congress intended to permit States to consider such factors as experience with special needs populations. Additionally, for rural residents or beneficiaries with needs for special cultural or linguistic competencies, States may consider MCOs or PCCMs that are equipped to serve them as more qualified. Also, the statute does not define the term ''enrollment capacity.'' We believe States have flexibility to determine that cultural and linguistic competency and other similar factors are related to MCOs'or PCCMs' capacity to serve certain individuals, depending upon their needs. We believe the language as proposed gives States sufficient flexibility to consider these factors, therefore, we have not added new requirements to the final rule with comment period.

Comment: Commenters were divided on the subject of whether members of the same family should be default enrolled to the same plan. Four commenters indicated that family members should be default enrolled in the same MCO or PCCM. One commenter in this group said family members ''in general'' should be enrolled in the same MCO or PCCM; presumably this indicates there may be circumstances in which family members could be enrolled in different MCOs or PCCMs. Four commenters said there may be circumstances in which family members could be better served by different MCOs or PCCMs. Other commenters raised the same question with regard to whether family members could choose to enroll in different MCOs or PCCMs, as opposed to being defaulted into them.

Response: The statute is silent on whether the default enrollment rules should require family members to be enrolled together. Because State enrollment and eligibility systems may not permit family members to be divided up, we do not recommend placing any requirements on this subject in the final rule with comment period. If States have the capacity to allow family members to choose different MCOs, they should be permitted to do so. Likewise, we assume States will want to default enroll families to the same MCO, and we believe they should be permitted to do so as well. This same policy applies to the question of whether States wish to permit individual family members to choose to enroll in different MCOs or PCCMs.

Comment: A number of commenters discussed our definition of existing relationships between enrollees and providers in the context of making default enrollments. Opinion was divided on the extent to which States should be required to consider existing relationships between beneficiaries and providers. The proposed rule defined an existing relationship as ''one in which the provider was the main source of Medicaid services for the recipient during the previous year'' and goes on to say that States may establish this through fee-for-service or managed care records, or by contacting the recipient. Several commenters specified that this provision would be difficult to operationalize or even ''unworkable.'' One indicated that if the recipient's previous experience with Medicaid was

in a fee-for-service system where it was difficult to find participating providers, the existing relationship may not have been an ideal one. However, a number of commenters said the language in the proposed rule did not go far enough. The majority of these commenters indicated that we should require States to examine previous records, and that the look-back period should be 3 years instead of 1 year. One commenter also said States should be required to examine payment records pertaining to services from ancillary providers such as DME suppliers and home health agencies as well. Some commenters also said MCOs should be subject to similar requirements in making enrollee assignments to PCPs.

Response: Because section 1932(a)(4)(D)(ii)(I) of the Act refers to considering existing relationships, we do not have statutory authority to exempt States from this requirement. We do, however, have the authority to define how States meet the requirement. We believe that the regulation gives States the flexibility to determine existing relationships in whatever way makes sense in the context of their program. Therefore, we have decided not to include additional requirements in the final rule with comment period.

Comment: We received a large number of comments urging us to present a more comprehensive definition of traditional providers than the one included in the preamble and proposed rule. The text defined a traditional provider as a provider who has ''experience in serving the general Medicaid population.'' Many commenters pointed to what they felt was confusing language in the preamble: ''Under § 438.56(d)(4) we would define 'traditional providers' to be any provider who has been the main source of care for a beneficiary within the last year, and has expertise and experience in dealing with the Medicaid population.'' Commenters felt this definition either unnecessarily confused existing relationships with traditional providers, or indicated that any provider who had been the main source of care for any recipient could be considered a traditional provider. Two commenters said States should be permitted to develop their own definitions of traditional providers. However, most commenters favored a HCFA definition that would be much more specific than the definition included in the proposed rule. Examples of what commenters said that we should include in the definition are: A certain percentage of Medicaid and uninsured utilization (either a set percentage or a percentage at least equal to the statewide mean); a significant number of years spent serving Medicaid patients; DSH hospitals; public hospitals; FQHCs; CHCs; and Health Care for the Homeless projects.

Response: Although default enrollments may be made to MCOs and not necessarily to individual providers, the statutory language refers specifically to providers. Section 1932(a)(4)(D)(ii)(I) of the Act requires that the default enrollment process take into consideration maintaining ''relationships with providers that have traditionally served beneficiaries under this Title.'' Clarification can be found in the BBA Conference Report, which states that the default enrollment process ''must provide for enrollment with an MCO that maintains existing provider-individual relationships or *has contracted with providers that have traditionally served Medicaid [beneficiaries]''* (emphasis added). Therefore, we believe the Congress intended for States to favor MCOs and PCCMs that contract with traditional providers in their default enrollment process. However, because the statute does not define traditional provider, we have the flexibility to either write a definition or allow States to develop their own. Because of the volume and variety of comments, we decided to allow States to develop their own definitions that could include, but not be limited to, DSH hospitals, public hospitals, FQHCs, CHCs, and Healthcare for the Homeless projects.

2. Choice of MCOs, PHPs, or PCCMs (Proposed § 438.52)

Proposed § 438.52 implemented the requirement in section 1932(a)(3) that States must permit an individual to choose from at least two MCOs or PCCMs, including the exceptions to this requirement in a case in which a State elects the option under section 1932(a)(3)(B) to offer a single MCO in a ''rural area,'' and the exception in section 1932(a)(3)(C) permitting a State to offer a single HIO in certain counties.

General Rule

Section 438.52(b) of the proposed rule required that States allow beneficiaries to choose from at least two MCOs or PCCMs.

Comment: We received comments expressing general support for the requirement for choice. One commenter, however, said that merely offering choice may not provide sufficient beneficiary protection, and we should consider alternative ways to provide consumers with accountability and responsiveness.

Response: The requirement for choice of MCO or PCCM appears in the statute, and is consistent with our longstanding policy of generally requiring at least two options in a mandatory managed care program. However, choice is only one piece of an overall strategy to ensure that beneficiaries receive quality services. This regulation implements new requirements for quality, access and availability, and beneficiary protection. We believe these requirements address the concern voiced by the commenter.

Comment: We received a number of comments disagreeing with our decision to apply the requirement for choice to PHPs. The commenters indicated that in the case of behavioral health carve-outs and certain long term care programs, it is not appropriate to require choice. Commenters indicated that the requirement for choice in carve-outs increases administrative costs because the State would be required to solicit business from two MCOs which would utilize the same limited set of providers. One commenter believed that in the case of PHPs, States should be allowed to request waiver authority to limit choice to one PHP, so long as that PHP offers beneficiaries a choice of providers. The commenter stated that we should clarify this in the final rule. The commenter also believed that PHPs should be chosen through a competitive process except when the State has decided to utilize a local governmental organization as a sole source provider. One commenter recommended that § 438.8 be amended to state that the provisions of subpart B apply to PHPs.

Response: Under this final rule with comment period, outside the context of a demonstration project or waiver program, we believe it is appropriate to give enrollees a choice of PHPs, along with the right to disenroll that is provided under section 1932(a)(4) to MCO and PCCM enrollees. As in the case of other PHP requirements, we have based this rule on the authority in section 1902(a)(4) of the Act to provide for methods of administration determined to be necessary for proper and efficient operation of the Medicaid program. Regulations based on provisions in section 1902, however, may be waived by the Secretary under section 1915(b) of the Act or as part of a demonstration project under section 1115 of the Act. Nothing in this regulation changes this waiver authority. Thus, we agree with the commenter that States should be allowed to request a waiver to permit a State to limit enrollees to a single PHP if the enrollees have a choice of providers within the PHP. With respect

to the comment on competitive procurement, § 434.6(a)(1) requires that in the case of all Medicaid contracts, States comply with competitive procurement requirements in 45 CFR, part 74. Under these requirements, States are required to engage in competitive procurement ''to the maximum extent practical.'' Thus, we agree with the commenter that PHPs should be chosen through a competitive process. We do not agree, however, that the State necessarily should be exempted from this requirement when it contracts with a government entity. While part 74 at one time exempted such cases from competitive procurement requirements, there is no longer such an across the board exemption. HCFA has, however, exercised discretion it has under part 74 on a case-by-case basis to permit government entities to contract as PHPs without a competitive procurement.

Finally, in response to the last comment, in the final rule with comment period, we have amended § 438.8 to specify that all subpart B provisions except § 438.50 apply to PHPs, because we agree with the commenter that the reference should be made more explicit.

Comment: One commenter said we should clarify our preamble language pertaining to PCCMs. This commenter said it appeared that States could satisfy the requirement for choice with a single PCCM. This commenter said that was contrary to the intent of the BBA, and pointed out that the only exception to the requirement to choice is for rural areas and certain HIOs.

Response: The commenter has confused a PCCM, which we clarify in this final rule with comment period refers to a ''primary care case manager'' as defined in section 1905(t)(2), with a primary care case management ''system,'' under which beneficiaries have the option of enrolling with one of two or more PCCMs. We recognize that our use of two terms in proposed § 438.2 that would fit with the acronym ''PCCM'' may have caused this confusion. The term ''primary care case management'' refers to ''a system under which a primary care case manager contracts with the State,'' while the term ''Primary care case manager'' is defined as the contracting individual or entity. As discussed in section II. A. above, we have clarified in §§ 400.203 and 438.2 of this final rule with comment period that PCCM refers to a primary care case manager. We agree with the commenter that unless the rural area exception in section 1932(a)(3)(B) applies, a State cannot satisfy the choice requirement through the use of a single PCCM. It can, however, do so through a primary care case management *system,* under which a beneficiary has a choice of two or more PCCMs. We have clarified § 438.52(b) to emphasize this distinction.

Comment: We received a comment recommending that the final rule specify that all beneficiaries must have a choice between two MCOs or PCCM providers that are qualified and experienced in HIV/AIDS care.

Response: We agree that for persons with special needs, including those with HIV/AIDS, being able to choose from MCOs or PCCM providers qualified to meet their needs is essential. Section 438.206 of this final rule with comment period requires States to develop standards for access to care, including attention to special needs populations. The section requires all MCOs to assure that they have the adequate capacity and appropriate services to meet the needs of the expected enrollment. This includes being able to serve any special needs populations that could potentially be enrolled in the MCO. We also require MCOs to consider the experience needed by network providers to serve the expected needs of their enrollees. Lastly, we expect States to aggressively monitor such indicators as grievances, appeals, fair hearing requests, and disenrollment requests as indicators that persons with special needs are not being adequately served.

Comment: One commenter recommended that where there is choice between two MCOs, at least one MCO must offer the full scope of services, including family planning services.

Response: Unlike the case of the Medicare program, the Congress chose not to require that MCOs agree to contract to provide particular services. The text for a comprehensive contract in section 1903(m)(2)(A) makes clear that the MCO and the State have the discretion to decide which Medicaid services will be covered under the MCO's contract. Also, in the case of family planning services, under section 1902(a)(23), an MCO is not permitted to restrict an enrollee to using the MCO's network providers for family planning services. This creates an incentive for MCOs to exclude family planning services from their contracts, since they have no control over when and where such services are obtained. Whether for this reason, or for reasons of conscience, some MCOs are likely to not agree to cover family planning services under their contracts.

However, § 438.10(d) and (e) of this final rule with comment period, enrollees and potential enrollees must be informed of ''benefits that are available under the State plan but are not covered under the contract, including how and where the enrollee may obtain those benefits, any cost sharing, and how transportation is provided,'' and in the case of enrollees ''the extent to which, and how, enrollees may obtain benefits, including family planning services, from out-of-network providers.'' We believe that these provisions ensure that enrollees have information on the availability of, and access to, required family planning services, regardless of whether these services are included in their MCO's contract.

Comment: We received a few comments recommending that each MCO offer each beneficiary a choice between at least two providers who are geographically, culturally, and linguistically accessible.

Response: This final rule with comment period contains requirements addressing geographic, cultural, and linguistic accessibility. Section 438.206, contains a requirement that MCOs maintain a network of providers sufficient in number, mix, and geographic distribution to meet the needs of the anticipated number of enrollees. Section 438.206(d)(1)(v) specifically requires that MCOs consider the geographic location of beneficiaries in developing their provider networks. Section 438.206(e)(2) requires that MCOs deliver services in a culturally competent manner, and § 438.10 requires that States and MCOs, PHPs and PCCMs make information available in languages in use in the enrollment area. MCOs, PHPs, and PCCMs are also required to provide translation services under § 438.10.

Definition of Rural Area

For the purpose of applying the exception for ''rural areas'' in 1932(a)(3)(B) to the choice requirement in section 1932(3)(A), the notice of proposed rulemaking proposed three definitions of a ''rural area.'' The choices included (1) any area outside an ''urban area'' as defined in § 412.62(f)(1)(ii), the definition found at § 491.5(c), or an alternative State or HCFA definition. After considering all comments, in this final rule with comment period we define a rural area as any area other than an ''urban area'' as the latter is defined in § 412.62(f)(1)(ii) of the HCFA rules.

Comment: There was no clear consensus among commenters. A few commenters said our proposed provision was overly broad, and recommended that HCFA make clear in the final rule with comment period that the rural exception would be very

narrowly construed. Others said there should be no State or HCFA definition apart from the two Medicare definitions. One commenter said we should keep the choice of three definitions, but if we are required to choose only one, we should use the definition found at Part 412 of this chapter. Other commenters said they agree with our prohibition against designating an entire State as a rural area, but one commenter said in some cases it may be appropriate to designate an entire State as a rural area. One commenter said we should choose a single definition of rural, but indicated no preference as to which definition we chose.

We also received a number of recommendations of alternative definitions or criteria. One commenter said any area with at least two qualified bidders should not be considered rural. One commenter said we should allow any medically under served area to be considered rural, and one commenter recommended that we use the Office of Management and Budget definition of non-metropolitan counties as a proxy for rural areas. One commenter recommended that we clarify that any area that is part of a Metropolitan Statistical Area could not be considered rural under a State or HCFA definition.

Response: We have considered all of the comments and decided to accept the commenter's suggestion that a single definition be adopted, as well as the suggestion by the commenter that if a single definition is adopted, we adopt the first definition incorporating the definition of ''urban area'' in part 412.

Exception for Rural Area Residents

Proposed § 438.52(c), outlined the rural exception to the requirement for choice. Under the proposed rule, in a ''rural area'' as defined in § 438.52(a), a State may limit beneficiaries to one MCO provided the beneficiary—

- Can choose from at least two physicians or two case managers; and
- Can obtain services from any other provider under any of the following circumstances:

(1) The service or type of provider the enrollee needs is not available within the MCO network.

(2) The provider is not part of the network, but has an existing relationship with the enrollee.

(3) The only plan or provider available to the enrollee does not, because of moral or religious objections, provide the services sought by the enrollee.

(4) The State determines that other circumstances warrant out-of-network treatment.

In the final rule with comment period, in response to comments discussed below, § 438.52(b)(2)(ii)(D) also provides that enrollees may also go outside the network for services if he or she needs related services (for example, a cesarean section and a tubal ligation) to be performed at the same time; not all of the related services are available within the network; and the enrollee's primary care provider or another provider determines that receiving the services separately would subject the enrollee to unnecessary risk. Also in response to comments, we have revised the provision permitting a beneficiary to go out of plan to a provider with ''an existing relationship with an enrollee'' to be limited to cases in which the provider is the ''main source of a service.''

Comment: We received a few comments on the overall issue of whether a rural exception should exist. One commenter agreed with the rural exception, while other commenters disagreed. One of these commenters said that in cases where there is only one MCO, States should be required to offer higher capitation rates in order to entice more MCOs to join the market. Other commenters said that in rural areas, States should be required to offer a PCCM option if they cannot get two MCOs to bid. One of these commenters also said States should ensure that primary care providers in rural areas should receive high enough capitation rates to cover their costs.

Response: The rural exception is provided by statute as a State option, and we thus have no authority to deny States this option by either requiring a second managed care entity (a PCCM) or mandating that payment be increased enough to attract a second MCO.

Comment: A few commenters said they do not believe HCFA should allow plans that do not offer family planning services to serve as the single MCO in a rural area. One commenter pointed out that if the only plan available does not offer family planning services, and a pregnant enrollee desires a cesarean section and a tubal ligation, the enrollee would be required to have her cesarean section through the MCO and would then have to go out of network for the tubal ligation, thus having a separate surgical procedure that would subject her to undue risk. Other commenters said the final rule with comment period should specify that when rural enrollees go out of plan for a service that is not offered by the MCO, they should also be able to get ''related services'' out of network. The commenters said this would assist pregnant women who desire a tubal ligation simultaneously with a cesarean section delivery.

Response: As discussed above, the statute allows MCOs to decide which services they choose to agree to cover under their contracts. However, in the case of a single MCO in a rural area, these decisions could affect the health of a Medicaid beneficiary in the manner suggested by the commenter. Thus, as noted above, in response to these comments, we have provided in § 438.52(b)(2)(ii)(D) that enrollees may also go outside the network for services if he or she needs related services (for example, a cesarean section and a tubal ligation) to be performed at the same time; not all of the related services are available within the network; and the enrollee's primary care provider or another provider determines that receiving the services separately would subject the enrollee to unnecessary risk.

Comment: A number of commenters recommended that we add language to § 438.52(b) requiring that rural enrollees have a choice between two physicians or case managers. One commenter said we should require that the two physicians or case managers are ''qualified to provide the beneficiary with appropriate and necessary health care services consistent with the beneficiary's initial assessment and treatment plan.'' One commenter said that in the case of enrollees with HIV, they should have a choice between two PCPs who are qualified and experienced in providing HIV/AIDS care. One commenter said the PCPs should be within 30 minutes or 30 miles from the beneficiary, except in frontier areas. Another commenter said there should also be a requirement for choice between two specialists or the ability to continue existing provider relationships out of network, and the final commenter said if the choice is between two PCCM case managers, they should be affiliated with separate practices if possible. Another commenter said rural beneficiaries in general do not have enough protection. This commenter suggested that we add a new subsection to the final rule with comment period cross-referencing all other exemptions and requirements, such as geographic accessibility, language and cultural competency, etc.

Response: The comments listed above all pertain in some way to accessibility to qualified and experienced providers. As stated above, this regulation contains extensive requirements designed to ensure beneficiary access to services, and these requirements pertain to rural as well as non-rural managed care providers. The relevant requirements can be found in § 438.6 (Contracting

requirements), § 438.10 (Information requirements), § 438.110 (Assurance of adequate capacity and services), and § 438.206 (Availability of services). Also, under § 438.52(b)(2) (rural beneficiaries have the ability to continue existing provider relationships under this regulation. In light of the above protections, discussed in detail elsewhere in this preamble, we do not agree that it is necessary to add additional language to § 438.52 in response to these comments.

Comment: One commenter suggested that we delete § 438.52(b)(2), which lists the reasons rural beneficiaries may go out of network. This commenter believes these provisions go beyond our statutory authority and are in some cases redundant because if a certain service is not available within the network, the MCO would be contractually obligated to pay for it anyway.

Response: We disagree with the commenter. Section 1932(a)(3)(B)(ii) of the Act, provides that rural beneficiaries can be limited to one MCO, if the MCO ''permits the individual to obtain such assistance from any other provider in appropriate circumstances (as established by the State under regulations from the Secretary).'' The Congress clearly intended for rural beneficiaries to access out-of-network services in appropriate circumstances, and clearly granted HCFA the discretion to define those circumstances in regulations. Section 438.52(b)(2) of the final rule with comment period extends these rights in a manner that recognizes both State flexibility and the importance of protecting enrollees.

Comment: We received one comment suggesting that the final rule include an additional reason beneficiaries can access out of network services. This commenter said the State should be required to let beneficiaries go out of network if treatment or services have been reduced or eliminated within a geographic area covered by the MCO.

Response: As discussed in section II. D. below, § 438.206(d)(5) allows beneficiaries to seek out-of-network treatment if the type of service or provider needed is not available within the network. We believe this language responds to the situation outlined by the commenter.

Comment: Another commenter suggested that we add a new subsection to the final rule outlining an additional reason beneficiaries can go out of network. This commenter suggested allowing beneficiaries to go out of network because ''The only plan or provider available to the enrollee is not able, because of prior court-ordered (involuntary) receipt of services from that provider, to develop a therapeutic relationship with the enrollee for the provision of mental health services.''

Response: We agree that in cases where the only available provider had previously treated the enrollee against his or her will, it would be difficult to establish a therapeutic relationship. We have decided not to add the suggested language to the final rule with comment period, however, because we believe the scenario outlined by the commenter would be covered by the existing language, particularly the section indicating that rural enrollees can go out of network in ''other circumstances.''

Comment: One commenter stated we should add clarifying language to this section indicating that when rural enrollees go out of network for services under the circumstances outlined in the regulation, they do not incur any additional cost.

Response: Section 438.106, Liability for payment, already covers these circumstances. Section 438.106(c) specifies that MCOs cannot hold Medicaid enrollees liable for ''payments for services furnished under a contract, referral, or other arrangement, to the extent that those payments are in excess of the amount that the enrollee would owe if the MCO provided the services directly.'' We believe enrollees in rural exception areas going out of network in the circumstances outlined in this chapter are protected by this provision. Therefore, we do not believe it is necessary to include the suggested language in § 438.52(b)(2). However, if a beneficiary chooses to go out of network for reasons other than those outlined in the rural provisions, the beneficiary would be liable for payment for the service.

Comment: We received a few comments recommending that the provisions allowing beneficiaries to go out of network be rewritten to specifically address the needs of rural enrollees with disabilities who have multiple medical needs. The commenters are concerned that enrollees be able to preserve existing relationships with DME suppliers. In addition, one commenter said enrollees should be able to go out of network if the only provider available does not have experience with the individual's disability, a provider cannot meet the needs of an enrollee (for example, an enrollee needs a home health aide in the morning but the only agency in the network only has aides available mid-day), or the enrollee has had ''previous problems'' with the provider. In addition, this commenter said the rural exception should make clear that in border areas, the out of network provider can be in a different State if that provider is geographically closer.

Response: Regarding the comment about border areas, the Medicaid program already accommodates crossing State lines in circumstances in which this is consistent with traditional patterns of care. We do not expect that this regulation will disrupt or change this situation. Regarding the other situations mentioned by commenters, as we have stated previously, the ability to go out of network is meant to be interpreted broadly. We expect that in cases in which enrollees with disabilities can make a case that their needs are not well-served by the MCO, they would be allowed to go out of network by the State pursuant to § 438.52(b)(2)(A) or (E). However, we also expect that because of the breadth of these provisions, MCOs serving rural beneficiaries will make strong efforts to have a comprehensive network that meets the needs of all of their enrollees. Rural MCOs, like all other MCOs, are responsible for making sure they have a network adequate to meet the needs of their anticipated enrollment, and this includes individuals with disabilities.

Comment: We received a few comments recommending that the provisions allowing enrollees to go out of network be expanded. Some commenters said all enrollees in all mandatory and voluntary managed care systems should have the same rights to go out of network. One commenter said urban beneficiaries should be able to use FQHC services if they are enrolled in MCOs that do not offer FQHC services.

Response: We believe that where there is a choice between MCOs, it is not necessary to give beneficiaries the same rights to go out of network that exist in rural areas with a single MCO. Regarding the FQHC comment, FQHC services are already a mandatory service under the Medicaid program. FQHC services must be available through a State's managed care program, or be provided as an out-of-network option. We expect beneficiaries who have a choice of MCOs and who wish to use FQHCs to choose their MCO accordingly. In addition, beneficiaries who either choose or are enrolled by default into an MCO that does not include an FQHC have 90 days to disenroll without cause.

Comment: We received a number of comments stating that the provision allowing beneficiaries to go out of network if the service or type of provider desired is not available within the MCO network is too broad. One commenter simply said the provision is

inappropriate. Other commenters said that this should be permitted only if the MCO does not have other in-network alternatives.

Response: In providing for a rural exception to choice, the Congress clearly intended to protect enrollees by giving them the right to go out of network in appropriate circumstances. We expect States to monitor their managed care programs, particularly in rural areas, to ensure that enrollees have access to appropriate services. We are not revising § 438.52(b)(2) in response to these comments.

Comment: We received a number of comments recommending that we clarify what is meant by not available within the network. The commenters recommended that we define ''available'' to encompass such factors as geographic accessibility, cultural and linguistic competency, appointment waiting times, and appropriateness of provider (for example, pediatric verses adult specialist). One of the commenters also recommended that we make it clear that when we refer to providers in this provision, we are including safety-net providers and clinics.

Response: We do not agree that it is necessary to amend the regulation. Under this final rule with comment period, rural MCOs must meet many new requirements addressing geographic, cultural, and linguistic accessibility. Section 438.207(b)(2) requires that MCOs maintain network of providers sufficient in number, mix, and geographic distribution to meet the needs of the anticipated number of enrollees. Section 438.206(d)(1)(v) requires that MCOs consider the geographic location of enrollees in developing their provider networks. Section 438.206(e)(2) requires that MCOs deliver services in a culturally competent manner, and § 438.10 requires that States and MCOs, PHPs, and PCCMs make information available in languages in use in the enrollment area. In the instance of a service for which there is no available provider who meets the above provisions, that service would not be considered available, and under § 438.206(d)(5), the enrollee would be able to obtain the service out-of-network. Regarding the comment about appropriateness of provider, we do expect States and MCOs to consider this when evaluating requests to obtain needed services out-of-network. In evaluating such requests, States may consider such factors as age, medical condition, general medical practice in the area, and overall availability of specific providers. Regarding the clinic and safety-net services, we have decided not to amend the regulation in response to this comment. This provision is meant to address beneficiary choice, and is not meant to single out certain types of providers for guaranteed participation.

Comment: A large number of commenters disagreed with giving rural beneficiaries the right to go out-of-network when they have an existing relationship with a provider who is not in the MCO network. Some commenters recommended that HCFA place a time limit on how long the relationship can be continued, and a few said the final rule should define what is meant by an existing relationship. Other commenters recommended that various limitations be placed on this provision, such as only allowing it when the beneficiary also meets one of the other criteria for going out-of-network; only permitting it when the individual has a chronic or terminal illness; only permitting it when the provider is in the MCO's service area; and permitting it only when a change in the provider relationship will result in an adverse health outcome. In addition, one commenter said it should be left to the MCO's discretion whether the relationship should be continued, and one commenter said the provider should be required to pass the MCO's credentialing process. One commenter said we should clarify that an existing relationship includes the example of a pregnant woman who initiated prenatal care with a provider before enrolling in the MCO.

Response: The requirement for choice in managed care programs is an important right granted to enrollees by the Congress. Where there is no choice, such as in rural areas with one MCO, The Congress intended for beneficiaries to have the protection of going out-of-network in appropriate circumstances, and directed the Secretary to publish regulations to specify the circumstances. However, we agree with the commenters who urged us to clarify what is meant by an existing relationship, and how long the relationship should be continued. Therefore, we amended the regulation to specify that this provision applies when the provider is the main source of a service to an enrollee and that the enrollee may continue to see the provider as long as the provider continues to be the main source of the service. We believe that these provisions cover a pregnant enrollee who, before enrolling in the MCO, had initiated prenatal care with a provider outside the MCO's network, and wished to continue seeing that provider.

Comment: We received a few comments recommending that we add to the scope of the provision allowing rural beneficiaries to go out of plan to a provider with whom they have an existing relationship. Some commenters recommended that the final rule clarify that this exception applies to specialists as well as primary care providers. One commenter said the final rule should specify the scope of services the out-of-network provider may provide. For example, this commenter said an obstetrician caring for a high-risk pregnant woman should be able to order tests without any limitation.

Response: In providing for this exception, and in further clarifying it, we clearly intend for specialists as well as PCPs to be included. We do not believe any further clarification is necessary. Furthermore, we intend for the scope of services provided by the out-of-network provider to be directly related to the beneficiary's overall condition and medical history, and we expect out-of-network providers and the MCO to share information regarding the patient's care for all treatment, because the MCO is ultimately responsible for payment. Again, we do not believe it is necessary to add language allowing providers the right to provide unlimited diagnostic and treatment services.

Comment: We received two comments recommending that the provision allowing rural beneficiaries to go out of network also apply to urban beneficiaries who want to go out of network to use Indian Health Service/Tribal providers/Urban Indian (I/T/U) providers.

Response: We disagree that it is necessary to add the suggested language to the regulation because Indian enrollees, whether in urban or rural areas, already have the right to access I/T/U providers outside of their networks in programs established under section 1915(b) or section 1115 authority, and in voluntary programs. Neither the BBA nor this regulation removes that authority. Additionally, Indians are exempt from mandatory enrollment into an MCO or PCCM under the new section 1932(a) authority, except where the MCO or PCCM is an I/T/U provider.

In responding to this comment, we have noted that Urban Indian health programs were inadvertently omitted from the list of entities into which an Indian eligible could be mandatorily enrolled under section 1932(a). In this Final rule with comment period, we have modified § 438.50(d)(2) to correct this omission.

Comment: One commenter recommended that we increase the State requirements for quality monitoring in areas falling under the rural exception.

Response: This regulation implements strong new quality requirements for

Medicaid managed care arrangements. We expect States to aggressively monitor quality in all managed care programs, including those covered by the rural exception. We do not agree with the commenter that the quality requirements for rural programs should be different from the general quality requirements.

3. Enrollment and Disenrollment: Requirements and Limitations (Proposed § 438.56)

Applicability

Section 1932(a)(4) sets forth a number of requirements relating to enrollment and disenrollment in Medicaid managed care programs. Proposed § 438.56(a)(2) specified that most of the enrollment/disenrollment provisions apply to all MCO, PHP, and PCCM contracts, regardless of whether enrollment is mandated under a waiver or section 1932, or is voluntary. The only provisions in this section that apply only to programs under which enrollment is mandated under section 1932(a)(1)(A) are the limitations on enrollment and default enrollment provisions. (In the final rule with comment period, these Section 1932 provisions have been moved to § 438.50.)

Comment: We received a number of comments objecting to the proposed rule's provisions concerning the applicability of enrollment requirements. One commenter contended that the 90-day right to disenroll without cause, the disenrollment for cause provisions, and the appeals provisions should apply only to mandatory managed care programs under section 1932(a)(1)(A) of the Act. A number of other commenters did not believe a 12-month lock-in should be applied in cases of voluntary enrollment. Two comments appear to be based upon misunderstanding because the proposed rule as written already reflected their suggestions. (One comment urged us to apply subsections (e) through (h) of the proposed rule to PHPs, and one comment says subsections (b) through (d) should apply only to section 1932 programs.) The commenters who indicated we applied various provisions too broadly would like HCFA to restrict the applicability of the provisions to mandatory enrollment under section 1932 programs.

Response: The BBA amended section 1903(m)(2)(A) of the Act to require, in a new paragraph (xi), that MCOs and MCO contracts ''comply with the applicable requirements of section 1932.'' The BBA also amended section 1903(m)(2)(A)(vi) to require that contracts with MCOs permit ''individuals to terminate * * * enrollment *in accordance with section 1932(a)(4)*,'' and must provide for ''notification in accordance with [that] section.'' (Emphasis added.) These requirements apply to all MCO contracts, regardless of whether enrollment in the contracts is voluntary, mandated under a waiver, or mandated under section 1932(a) of the Act. The enrollment requirements the proposed rule applies to MCOs all either apply by their own terms to MCOs, or are incorporated as set forth above under section 1903(m)(2)(A)(vi) of the Act.

In the case of primary care case managers, section 1905(t)(3)(F) similarly requires that primary care case manager contracts comply with ''applicable provisions of section 1932,'' while section 1905(t)(3)(F) requires that enrollees be provided the ''right to terminate enrollment in accordance with section 1932(a)(4).'' Again, this provision is not limited to cases in which the primary care case manager is participating in a mandatory program under section 1932(a).

The only provisions of section 1932 of the Act that not are applicable to all MCO, PHP, and PCCM contracts are those which include the language ''In carrying out paragraph (1)(A),'' which refers to the statutory authority to establish mandatory managed care programs through the State Plan Amendment process. These are the provisions we have designated as applicable to section 1932(a)(1)(A) programs only. In order to prevent any future confusion regarding which provisions apply only to section 1932(a)(1)(A) programs, we are in this final rule with comment period moving all such provisions to § 438.50.

With respect to the commenters who believed that the 12-month lock in should not apply when enrollment is voluntary, again, this result is dictated by the statute. Under section 1903(m)(2)(A)(vi) of the Act, an enrollee in an MCO has the right to disenroll only to the extent this is provided for in section 1932(a)(4) of the Act, which permits disenrollment without cause only in the first 90 days and annually thereafter. Under section 1915(a) of the Act, where enrollment is voluntary such an arrangement will not be considered to violate the general freedom of choice provision in section 1902(a)(23).

Disenrollment by the Recipient: Timing

Section 438.56(e) of the proposed rule (recodified at § 438.56(c) in the final rule with comment period) set forth the general rules regarding disenrollment rights. These provisions apply to all situations in which States choose to restrict disenrollment. Beneficiaries are permitted to disenroll for cause at any time, without cause during their first 90 days of enrollment, and annually thereafter. In certain circumstances (rural areas with only one MCO, or areas in which the statute permits contracting with only a single county-sponsored HIO), these rules apply to changes between individual physicians or primary care case managers.

Comment: We received one comment suggesting that the proposed rule did not go far enough in setting up a consistent process for disenrollment. The commenter recommended that HCFA include a requirement in the final rule that the disenrollment (and enrollment) process should be consistent across all MCOs, and PCCMs in a State.

Response: We are sensitive to the concern that to the greatest extent possible, a State's program should be consistent in order to avoid confusion and misunderstanding on the part of enrollees. We encourage States to establish uniform procedures in the area of enrollment and disenrollment, and we note that this section sets forth rules regarding the process that must be followed in all Medicaid managed care programs that restrict disenrollment in any way. We believe the proposed regulation provided a great degree of consistency in this process. We also believe the information requirements in § 438.10 and the notice requirements in § 438.56 will alleviate any potential confusion among enrollees. Therefore, we have decided not to change the final rule with comment period in response to this comment.

Comment: Several commenters noted that the proposed rule did not include a provision providing for MCO or PCCM disenrollments of beneficiaries for cause. Commenters recommended that HCFA adopt the language in the Medicare+Choice regulation allowing MCOs and PCCMs to request disenrollment of beneficiaries for uncooperative or disruptive behavior, or for fraudulent behavior.

Response: The previous regulation (at § 434.27) required PHP and HMO contracts to specify the process by which they could request that the State disenroll beneficiaries. It appears that the omission of this provision in § 438.56 was simply an oversight. In response to this comment, we are including a provision in this rule allowing MCOs, PHPs, and PCCMs to request disenrollment of enrollees. Section 438.56(b) of the final rule with comment period requires that MCO, PHP, and PCCM contracts specify the

reasons for which an MCO, PHP, or PCCM may request disenrollment of an enrollee. This section also prohibits MCOs, PHPs, and PCCMs from requesting disenrollment on the basis of the enrollee's adverse changes in health status, diminished mental capacity, utilization of medical services, or uncooperative or disruptive behavior resulting from an enrollee's special needs. The only exception to this rule is where the beneficiary's continued enrollment in the MCO, PHP, or PCCM seriously impairs the entity's ability to furnish services to either this enrollee or other enrollees in the entity.

Contracts must also specify how the MCO, PHP, or PCCM will assure the State agency that it will not request disenrollment for reasons other than those permitted under the contract. As suggested by the commenter, these changes reflect the provisions contained in the Medicare+Choice regulations.

Comment: We received comments regarding the special circumstances of persons who are homeless, particularly related to their transience and special needs in obtaining information critical in choosing an MCO or PCCM.

Response: We agree that persons who are homeless present a unique situation. Due to the lack of a mailing address and general transience, it is likely that they may not receive information about choice of MCOs or PCCMs or the fact they have been enrolled in an MCO or PCCM until they attempt to receive care. As a protection for this population, we are revising the regulation to include, as a cause for disenrollment, (under paragraph (d)(2) of the section) the fact that a person was homeless (as defined by the State) or a migrant worker at the time of an enrollment by default. This is in addition to all other disenrollment rights offered to all enrollees.

Comment: We received many comments asserting that cause is not adequately defined. Commenters urged HCFA to publish a broad definition of cause. Comments suggesting what would constitute cause included—inadequacy of an MCO's medical personnel in treating HIV; inability to access primary and preventive care; inability to access family planning services; the MCO's failure to offer family planning services; geographic, cultural, and linguistic barriers; an enrollee's PCP has left the MCO; lack of access to pediatric and pediatric sub-specialty services; the need for the enrollee to access local Indian health care services that are not available in the MCO; inability to obtain information in an accessible format; and inability to receive services appropriate to the medical condition. In addition, one commenter suggested that States be required to ''look behind'' HIV-related disenrollment requests to determine whether there are systemic problems in serving individuals with HIV.

Response: We agree that cause should be more specifically defined, and have revised § 438.56(d)(2) to provide examples that will be deemed to constitute cause. These reasons for disenrollment are similar to the grounds for going out of plan where the rural area exception applies. Specifically, under § 438.56(d)(2), an enrollee may disenroll for cause if (1) the enrollee was homeless (as defined by the State) or a migrant worker at the time of enrollment and was enrolled in the MCO, PHP or PCCM by default, (2) the MCO or PCCM does not, because of moral or religious objections, cover services the enrollee seeks, (3) the enrollee needs related services (for example a cesarean section and a tubal ligation) to be performed at the same time; not all related services are available within the network; and the enrollee's primary care provider or another provider determines that receiving the services separately would subject the enrollee to unnecessary risk, and (4) other reasons, including but not limited to, poor quality of care, lack of access to services covered under the contract, or lack of access to providers experienced in dealing with the enrollee's health care needs.

Further regarding the related services provision, we recognize that enrollees in this situation who are otherwise satisfied in their MCO or PHP may not want to disenroll in order to receive the related services together. We note that § 438.206 specifies that if the network cannot provide the necessary services covered under the contract (including related services) needed by the enrollee, these services must be adequately and timely covered out-of-network for as long as the MCO or PHP is unable to provide them. Under this provision, the enrollee would be able to avoid the need to disenroll from his or her current MCO or PHP but could still receive the related services concurrently.

Comment: One commenter pointed out that while a later section of the proposed rule speaks to the effective date of for-cause disenrollments, it does not address the effective date for without-cause disenrollments. The commenter recommended that there be a required effective date, and that it be no later than the timeframe provided for in the for-cause section, that is the beginning of the second calendar month following the month in which the request for disenrollment was made.

Response: We realize that the heading of § 438.56(f) in the proposed rule, ''Procedures for Disenrollment for Cause,'' suggests that we intended to limit these requirements to disenrollment for cause. However, HCFA did not intend that States be required or encouraged to set up a different process based upon whether or not the disenrollment request is for cause. Therefore, we have retitled the two paragraphs which now contain the same provisions (§ 438.56(d) and (e)) as ''Procedures for Disenrollment'' and ''Time-frame for disenrollment determination''

Comment: We received a number of comments disagreeing with giving enrollees the right to disenroll without cause for 90 days after enrolling in (or being default enrolled into) an MCO, PHP or PCCM. Several commenters believed that the 90-day period was too lengthy, but one commenter stated that ''[t]he removal of the right to disenroll at any time troubles us.'' The commenters opposing the 90-day period did not offer suggestions of a shorter time period. One commenter recommended that there should only be one 90-day period, and not a new opportunity to disenroll without cause every time a recipient enters a new MCO, PHP, or PCCM.

Response: The requirement to allow beneficiaries to disenroll without cause for 90 days appears in section 1932(a)(4), so we do not have authority to remove or alter this right, or the length of the 90 day time period. As for the question of whether there is a new 90-day period with each new MCO, PHP, or PCCM enrollment, the statute refers to enrollment with the MCO or PCCM and not initial enrollment in the managed care program. Therefore, there is no room for interpretation of that provision as just allowing for a single 90-day disenrollment period without regard to whether the beneficiary enrolls in a new MCO or PCCM.

Comment: A number of commenters disagreed with our interpretation that the right to disenroll for 90 days without cause only applies the first time a recipient is enrolled in a particular MCO, PHP, or PCCM. The commenters recommended that the final rule provide for a right to disenroll for 90 days each time a recipient enters an MCO, PHP, or PCCM, even if he or she has been enrolled in that MCO. PHP, or PCCM previously. Commenters indicated that this is justified on the basis that there could have been substantial changes in an MCO, PHP, or PCCM since the recipient's previous enrollment.

Response: The statute does not make clear whether the 90 day period

following notice of enrollment with an MCO or PCCM applies only once, when the individual is initially enrolled with the MCO or PCCM, or each time the individual enrolls with an MCO or PCCM, even if he or she has been enrolled in the MCO or PCCM before. We believe that the purpose of the extended 90 day disenrollment period is to allow the beneficiary to become familiar with an MCO or PCCM before deciding whether to remain enrolled. Once a beneficiary has been an enrollee of an MCO or PCCM this rationale no longer applies. While it is true that an MCO, PHP, or PCCM might change in the interim, this is equally true of an MCO, PHP, or PCCM that the enrollee might remain enrolled with. A beneficiary would still have an annual opportunity to disenroll in both cases. We believe that the interpretation the commenter has suggested would create a potential for abuse by providing an incentive for frequent changes in enrollment that could result in multiple 90 day periods for the same MCO, PHP, or PCCM.

Comment: The proposed rule specifies that the 90-day clock for enrollees to disenroll without cause begins upon the actual date of enrollment, and further provides that if notice of enrollment is delayed, the State may extend the 90-day period. All comments we received on this issue urged HCFA to adopt what they consider to be stronger language. The commenters suggested that HCFA provide that the 90-day disenrollment period begins when notice of enrollment is actually received. Furthermore, they contended that States should be required, rather than permitted, to extend the 90-day period in the event that notice to the enrollee is delayed. A couple of commenters also believed that States and MCOs, PHPs, and PCCMs should be required to guarantee that the notice is actually received; and in the case of homeless individuals, that the notice is received prior to the initial assessment by the MCO, PHP, or PCCM.

Response: By providing for the 90-day period to begin when the enrollment takes effect, HCFA was attempting an interpretation of the statute that would offer maximum protection to enrollees. That is because in many States, notice of enrollment may be sent to the recipient up to 60 days before the effective date of the enrollment. However, because there is such a high level of concern that beneficiaries will be harmed in cases when notice of enrollment is mailed after the effective date, we are adding regulation text providing that the 90 day period begins upon the enrollment, or the date the notice is sent, whichever is later. Regarding the request that States and MCOs, PHPs, and PCCMs be required to guarantee that notices are actually received, we do not believe it is appropriate to require such a guarantee when there are certain factors beyond the control of the State or MCO, PHP, or PCCM. However, it is in a State's best interest to make the maximum effort possible to ensure that notices are received, and we encourage States to take measures to ensure this to the best of their ability.

Comment: We received one question about whether States should be able to differentiate between different types of MCOs, PHPs, and PCCMs in the 12-month lock-in provision. The commenter recommended that States be allowed to have different lock-in periods depending upon whether the enrollee was locked into a PCCM or an MCO.

Response: Section 1932(a)(4), which applies to both MCOs and PCCMs, requires that enrollees be allowed to disenroll for cause at any time, and without cause during the initial 90 days, and ''at least every 12 months thereafter.'' As long as no enrollee is locked-in for a period of more than 12 months, there is no prohibition against States implementing different lock-ins for MCOs, PHPs, and PCCMs.

Comment: A number of commenters said they believe the provision for an annual disenrollment opportunity may create confusion. The commenters suggested that States be required to hold an annual open enrollment period.

Response: The statute requires States to permit enrollees to disenroll from an MCO or PCCM for a 90-day period at the beginning of enrollment, and ''at least every 12 months thereafter.'' As long as the State meets the requirement to inform beneficiaries of their right to terminate or change enrollment at least 60 days in advance, the State may structure the annual opportunity in whatever way it sees fit. This may involve holding an annual open enrollment period as the commenters suggested, or individually offering each recipient an opportunity to change enrollment upon his or her enrollment anniversary.

Comment: Section 438.56(e)(2) of the proposed rule (moved to § 438.52(c) in the final rule) provided that in rural areas with only one MCO, States may meet the disenrollment requirements by allowing enrollees to change physicians or case managers within the MCO. A commenter contended that PCCM enrollees in rural areas should be allowed to disenroll and transfer to fee-for-service Medicaid if only a single PCCM is available, since section 1905(t)(3)(E) of the Act requires that a beneficiary have a choice.

Response: Section 1905(t)(3)(E) of the Act requires that primary care case manager contracts permit disenrollment in accordance with section 1932(a)(4) of the Act. As defined in § 438.2, a primary care case manager may be an individual physician or a group of physicians. Therefore, a State arguably would be complying with the requirement in section 1932(a)(4) of the Act if it allows enrollees to change primary care case managers since (to the extent these individual managers are each considered managed care entities.) More importantly, however, we believe that section 1932(a)(3)(B) provides an exception not only to the rule set forth in section 1932(a)(3)(A) of the Act that an enrollee have a choice of more than one MCO, but as an implicit exception to the requirement in section 1932(a)(4)(A) of the Act that a beneficiary be able to disenroll from an MCO. Thus, even if the State has only a single MCO contract in a rural area pursuant to section 1932(a)(3)(B) of the Act, we believe that the requirements in section 1932(a)(4) of the Act would be satisfied by permitting disenrollment from an individual primary care physician. The authority in section 1932(a)(3)(B) of Act to permit the choice of entity requirement in section 1932(a)(3)(A) of the Act to be fulfilled by providing a choice of individual physicians would be meaningless if section 1932(a)(4) of the Act were nonetheless construed to permit an individual to disenroll from an MCO, as opposed to changing individual physicians. Thus, where the conditions in section 1932(a)(3)(B) have been satisfied, the requirement in section 1932(a)(4), as made applicable by section 1905(t)(3)(E), is satisfied by permitting beneficiaries to disenroll from their primary care physician.

Procedures for Disenrollment

Section 438.56(f) of the notice of proposed rulemaking set forth the required procedures for processing disenrollment requests. (We note here that the proposed rule referred to ''Procedures for disenrollment for cause,'' but as noted above, in response to comments, we have renamed the two paragraphs containing material from proposed § 438.56(f) ''Procedures for disenrollment'' and ''Timeframe for Disenrollment Decisions.'') In § 438.56(f), we proposed that enrollees be required to submit written requests for disenrollment to the State agency or to the MCO, PHP, or PCCM. MCOs, PHPs, and PCCMs are required to

submit copies of disenrollment requests to the State agency. Proposed § 438.56(f) provided that while MCOs, PHPs, and PCCMs may approve disenrollment requests, only the State agency may deny such requests.

In cases where the State agency receives the request, under proposed § 438.56(f) it could either approve the request or deny it. Requests for disenrollment had to be processed in time for the disenrollment to take effect no later than the first day of the second month following the month in which the enrollee made the request. Proposed § 438.56(f) further provided that if the State or MCO, PHP, or PCCM does not act within the specified timeframe, the request was considered approved.

Response: This comment is quoting language from proposed § 438.56(e)(1), which is retained in the final rule with comment period in § 438.56(c). This language states that if the State chooses to limit or restrict enrollment, it must permit enrollment without cause in the first 90 days an individual is enrolled in an MCO, PHP, or PCCM, and annually thereafter. This rule would be irrelevant if a State chose not to limit disenrollment at all. To clarify our position in response to the commenter, if a State wishes to permit disenrollment at any time, or more frequently than the minimum disenrollment rights required under § 438.56(c), the same rules on notice and effective date apply as apply when a State ''chooses to restrict disenrollment.''

Comment: Several comments felt that the final rule should specify that disenrollment requests may be submitted by either the enrollee or his or her representative. In addition, others felt that we should delete the reference to 20 CFR part 404, subpart R in the definition of authorized representative. The commenters believed that these rules, which generally govern representative payees for Social Security programs, have little, if any, relevance to the Medicaid program and that these requirements would limit assistance to beneficiaries in the Medicaid managed care enrollment process. They indicated that current rules recognize that beneficiaries may require assistance in a variety of circumstances and provide that applicants and recipients may obtain that assistance from a variety of sources. For example, commenters pointed out that in formal proceedings such as fair hearings, Medicaid beneficiaries enjoy the right to ''represent themselves, use legal counsel, a relative, friend or other spokesman.'' (42 CFR 431.206). If the applicant is incompetent or incapacitated, anyone acting responsibly for the applicant can make application on the applicant's behalf (42 CFR 435.907). People with disabilities who are incompetent or incapacitated can currently be represented by anyone acting responsibly on their behalf. Commenters indicated that State law is available, and is used to step in when a person cannot make medical decisions on his or her behalf.

Response: We concur with the commenters and have modified § 438.56(d) to add ''his or her representative'' to enrollee. In addition, we have deleted the reference to 20 CFR Part 404. We have also deleted the reference to ''authorized'', using only the term representative to allow for a broad range of representatives, consistent with existing policies and practices. The definition, which has been moved to § 430.5, now reads ''Representative has the meaning given the term by each State consistent with its laws, regulations, and policies.''

We agree with the commenters that the appropriateness of a representative depends on the significance of the activity for which they are acting as representative, so that States should have the flexibility to determine who may represent the beneficiary in various activities. The State may establish various criteria depending upon the situation (for example, disenrollment requests, choice of health plans, receiving notices, filing grievance and appeals (including requests for expedited review, being included as a party to the appeal and the State fair hearing, receiving marketing materials, being provided opportunity to review records, etc.) In determining who may represent beneficiaries, we anticipate that States will provide special consideration for individuals with cognitive impairments, who are unable to appoint their own representatives, but who may be especially vulnerable and require assistance in accessing the protections offered in these regulations.

Comment: A number of commenters disagreed with the requirement that disenrollment requests be submitted in writing, contending that this may present a barrier to some enrollees, and that the process should be as barrier-free as possible.

Response: We agree and are interested in reducing or eliminating barriers wherever possible. Therefore, § 438.56(d) has been amended to specify that disenrollment requests may be written or oral. Further, we note that States cannot impose a requirement that beneficiaries appear in person to request disenrollment.

Comment: We received a number of comments relating to the time allowed for processing disenrollment requests. The only references to a timeframe appeared in the proposed rule at § 438.56(f)(2)(ii) and § 438.56(f)(4)(i). (These sections are redesignated as § 438.56(d)(3)(ii) and § 438.56(e)(1) in the final rule.) Disenrollment requests, if approved, must take effect no later than ''the first day of the second month after the enrollee makes the request.'' (This is re-wording of previous statutory language, formerly found at section 1903(m)(2)(A)(vi) of the Act, which required disenrollment requests to be effective at the ''beginning of the first calendar month following a full calendar month after the request is made for such termination.'' This specific language was removed by BBA and was not replaced with any alternative timeframe.) Commenters urged HCFA to spell out a more specific list of requirements relating to processing of requests. Although not all comments suggested a specific timeframe, most urged an ''expedited'' process for urgent or emergency situations. Commenters who did specify a timeframe for urgent or emergency situations indicated that requests should be required to be processed within 3 or 5 days. One commenter said disenrollment requests on behalf of children with special health care needs should be processed within 72 hours. It is important to note that the comments addressed ''processing'' of disenrollment requests, and not the effective dates. It is safe to assume, however, that the commenters would support an expedited effective date as well as expedited processing.

Response: Because of the removal of the effective date requirement in section 1903(m)(2)(A)(vi) of the Act, the statute is silent on how long the disenrollment process should take.

In response to the above comments, we believe that other beneficiary protections within this final rule with comment period, for example § 438.206(d)(5), provide adequate protection and access to necessary medical services covered under the contract out-of-network for as long as the MCO pro PHP is unable to provide them.

Comment: One commenter recommended that HCFA require States to establish an Ombudsman program to intervene in the disenrollment process.

Response: We are sensitive to the need for enrollees to have adequate protection in the enrollment and disenrollment process. This is particularly a concern for those who may have limited experience with managed care systems. We believe we have built numerous protections into

§ 438.56, including a provision for an appeals process when disenrollment requests are denied. In addition, it is important to note that many States use enrollment brokers, who act as independent third parties and assist enrollees in making their choice of managed care organizations. We believe that it is not necessary to require States to establish Ombudsman programs, although we would encourage them to do so.

Comment: One commenter believed the provision describing how MCOs, PHPs, and PCCMs should process disenrollment requests was too prescriptive. The commenter felt we should allow States to individually develop the process for MCO, PHP, and PCCM handling of disenrollment requests. However, other commenters felt this provision was too flexible, and recommended that MCOs, PHPs, and PCCMs not be permitted to process disenrollment requests. These commenters recommended that only the State or an independent third party, such as an enrollment broker, be permitted to handle disenrollment requests.

Response: Disenrollment is an important right granted to beneficiaries by the Congress, especially in an environment in which States can now require a lock-in period of up to 12 months. The consistent process required under this regulation is intended to guarantee that beneficiaries will be able to exercise this right as intended by the Congress. However, the statute is silent on certain aspect of disenrollment, including who should process such requests. Allowing MCOs, PHPs, and PCCMs to process requests is longstanding policy, and is based upon the principle of State flexibility, because States are closest to the situation and should be aware of whether such a policy would be beneficial to enrollees.

Further, we understand the concern that MCOs, PHPs, and PCCMs may have an incentive to discourage beneficiaries from disenrolling, or to disenroll more costly beneficiaries, but we believe adequate safeguards have been built into the process to protect enrollees. For example, MCOs, PHPs, and PCCMs may approve disenrollment requests, but they may not disapprove them. If an MCO, PHP, or PCCM does not take action to approve a request, it must refer the request to the State agency for a decision. States are also required to give enrollees who disagree with disenrollment decisions access to the State fair hearing system. It is important to note, also, that involving the MCO, PHP, or PCCM in the process may benefit enrollees. In many instances, the MCO, PHP, or PCCM may be able to resolve the problem that led the enrollee to request disenrollment, thus meeting the beneficiary's needs while preventing the necessity to disenroll. In addition, we expect that MCOs would track reasons for these requests as part of their quality improvement programs.

In this rule we believe we have taken the interests of beneficiaries and States into account and balanced the need for beneficiary protection with the need for flexibility in program administration. We therefore disagree with the commenters, and have decided not to change this provision in the final rule with comment period.

Comment: A number of commenters asked for clarification of the requirement that MCOs, PHP, and PCCMs to notify the State if they do not take action on a request for disenrollment. Commenters recommended that the final rule be revised to provide that MCOs, PHPs, and PCCMs are required to notify the State when they disapprove requests, as well as when they do not take action. In addition, one commenter proposed that HCFA require the State to aggressively monitor MCO, PHP, and PCCM denials of disenrollment requests. These commenters apparently did not understand that MCOs, PHPs and PCCMs would not be permitted to disapprove disenrollment requests.

Response: We disagreed with the commenters who argued the provision (re-designated as § 438.56(d)(5) in the final rule with comment period) should be deleted. We have decided to retain the provision for two reasons. First, the internal grievance process can eliminate the need to disenroll by resolving the issue that led to the disenrollment request. We consider this to be beneficial from a continuity of care standpoint, as well as a quality standpoint. Secondly, we believe that States should have flexibility to decide whether the internal grievance process is helpful in the context of disenrollment requests. States are in the best position to make this determination based upon their programs and beneficiaries. We do agree, however, that there are cases where requiring the use of the internal grievance process may not be appropriate, therefore, we have specified that in cases expedited disenrollment, this provision does not apply.

Comment: Proposed § 438.56(f)(3) provided that States may require beneficiaries to use the internal MCO grievance process before making a determination on a request for disenrollment if a delay would not pose jeopardy to the enrollee's health. Some commenters disagreed with this provision, while another recommended that enrollees be required to use the internal grievance process. Other commenters said enrollees should be allowed to go straight to the State's fair hearing process for disenrollment requests. Still other commenters commented proposed that HCFA clarify that the exception for jeopardy to health should apply in cases in which the harm to an enrollee's health may not become apparent until later. Also, the commenter recommended that we include language indicating that in the case of pregnant women, jeopardy to the health of the fetus also be considered. Another commenter recommended that in the case of children, the delays that would jeopardize development be addressed.

Response: We disagreed with the commenters who argued the provision (redesignated as § 438.56(d)(5) in the final rule) should be deleted. We have decided to retain the provision for two reasons. First, the internal grievance process can eliminate the need to disenroll by resolving the issue that led to the disenrollment request. We consider this to be beneficial from a continuity of care standpoint, as well as a quality standpoint. Secondly, we believe that States should have the flexibility to decide whether the internal grievance process is helpful in the context of disenrollment requests. States are in the best position to make this determination based upon their knowledge of their programs and beneficiaries.

Comment: The proposed rule requires disenrollment requests, if approved, to take effect no later than the first day of the second month following the month in which the enrollee makes the request. A number of commenters were dissatisfied with this provision and said it should be made more specific. One commenter recommended that the timeframes specified in the Subpart F (Grievance System) be applied to the disenrollment process. A number of commenters recommended that the timeframe be made more specific, with a number of recommendations that requests be processed within five days.

Response: As stated elsewhere, the required timeframe for processing disenrollments is meant to be a maximum, not a minimum. However, the regulation is also designed to be workable in all States, and States have very different systems capabilities to accommodate changes in managed care enrollment. As noted above, the timeframes we have adopted were in place for many years under section 1903(m) before the BBA. Because

capitation payments are made on a monthly basis, most States may want to make disenrollments effective on the first day of a month. However, there is no prohibition against a State adopting a process that calls for timeframes that mirror those contained in Subpart F, as the commenter recommended.

Comment: Proposed § 438.56(f)(4)(ii) provided that if the State agency fails to make a determination on a disenrollment request within the specified timeframe, the request is deemed approved. Commenters recommended that HCFA make clear that the ''deemed approved'' language applies whether the State or the MCO, PHP, or PCCM is processing the disenrollment request.

Response: We agree that in cases where MCOs, PHPs, and PCCMs are permitted by the State to process disenrollment requests, the same timeframes should apply. Section 438.56(e)(3) of the final rule with comment period makes this clear.

Notice and Appeals

Section 438.56(g) of the proposed rule (§ 438.56(f) in the final rule with comment period) specified that States restricting disenrollment in Medicaid managed care programs must require MCOs and PCCMs to notify beneficiaries of their disenrollment rights at least 60 days before the start of each enrollment period and at least once a year. The paragraph further required that the State establish an appeal process for any enrollee dissatisfied with a State agency determination that there is not good cause for disenrollment.

Comment: Some commenters disagreed with our approach of providing for MCOs and PCCMs to provide disenrollment rights notices, while others agreed with this general approach, but said we should impose additional requirements on States. In addition, some commenters believed that the provision is too prescriptive.

The commenters who disagreed with permitting MCOs and PCCMs to provide disenrollment rights notices said the final rule should provide that only the State or an enrollment broker should notify enrollees of their disenrollment rights. In addition, these commenters proposed that States be required to develop a model from which would be translated into all languages in use in the State, and field tested before being used in the Medicaid program.

Commenters who supported additional requirements said the regulation should require such notice to be provided upon initial enrollment, and that we should add language requiring that the notice be understandable to beneficiaries, consistent with the provisions of regulations that apply to the Medicare + Choice program.

The commenters who said the provision was too prescriptive recommended that we mirror the statutory language requiring one annual notice 60 days before the beginning of the enrollment period, and that the final rule should reflect that the enrollee handbook constitutes sufficient notice regarding disenrollment rights. One commenter suggested that we require ''adequate notice'' at a time specified by the State.

Response: Section 1932(a)(4) requires an annual notice at least 60 days before the beginning of an individual's annual opportunity to disenroll, but does not specify whether the MCO, PHP, PCCM or the State should send the notice. In response to the concerns raised by the commenters, and in recognition of the fact that some States may want to send the notices themselves (or employ an enrollment broker to perform this function), the final rule with comment period (at § 438.56(f)) requires the State to provide that enrollees are given written notice and ensure access to State fair hearing for those dissatisfied with a denial based on lack of good cause. Regarding the model form comment, this seems to be a reasonable approach and it is one we believe many States will employ, but we do not believe it is necessary or prudent to make this a regulatory requirement. Regarding the comment about mirroring the Medicare+Choice regulation, we believe that the statutory requirements provide sufficient protections to beneficiaries in this case. We also believe the information requirements found at § 438.10 provide a great degree to specificity in terms of how States will inform enrollees of their rights and responsibilities.

Comment: One commenter said we should require that the notice of disenrollment rights be sent to a representative payee, if one exists.

Response: The concerns of this commenter have been addressed by our decision to revise the final rule with comment period to provide that notice be provided to an enrollee or his or her representative. We note that a representative payee would not necessarily be authorized by the enrollee, or under State law, to represent the enrollee for purposes other than handling the benefits check. The final rule with comment period provides for notice to the representative.

Comment: Two commenters said that in addition to laying out notification requirements, the final rule should speak to the form used to request disenrollment. One commenter suggested that HCFA develop a model form, while the other suggested that HCFA require States to develop a single form for use throughout their program.

Response: We agree that in many cases, use of a standard form for disenrollments (both annual and for-cause) can aid in program administration. Many States will probably choose this approach, which they are free to do under this final rule with comment period as long as they also permit oral disenrollment requests as required under § 438.56(d). Because we believe that States may have legitimate reasons for choosing other approaches, however, and in light of our decision in response to comments to permit oral disenrollment requests, we have decided not to make this a regulatory requirement.

Comment: We received a number of comments on the requirement for States to establish an appeals process for enrollees who disagree with denials of disenrollment requests. The commenters said that when enrollees disagree with a State denial of a disenrollment request, they should be able to proceed directly to the fair hearings process without going through a separate appeals process.

Response: The cited provision was not intended to require States to establish a process separate from the fair hearing system. As noted above, § 438.56(f)(2) of the final rule with comment period requires that State fair hearings be made available.

Automatic Re-enrollment

Proposed § 438.56(h) reflected the provision in section 1903(m)(2)(H) of the Act specifying that if the State plan so provides, MCO and PCCM contracts must provide for automatic re-enrollment of individuals who are disenrolled only because they lose Medicaid eligibility for a period of two months or less.

Comment: One commenter pointed out that the proposed language did not specify how the enrollment/disenrollment provisions (such as timeframes for changing MCOs and PCCMs) in this rule apply in cases of automatic re-enrollment.

Response: Section 438.56(h) reflects a statutory provision that was enacted in 1990, and is simply being incorporated into regulation. The commenter is correct that the proposed rule did not address how to apply the enrollment/disenrollment provisions to enrollees who have a temporary loss of Medicaid eligibility. We have decided to add

clarifying language to the final rule with comment period in § 438.56(c)(2)(iii) indicating that if a temporary loss of eligibility causes a recipient to miss the annual right to disenroll without cause, that right will be given upon re-enrollment. The enrollee would not, however, be entitled to a new 90 day period.

Comment: Two commenters pointed out that the preamble and regulations text of the proposed rule were in conflict regarding the re-enrollment timeframe. (The preamble indicated a window of up to four months.) The commenters indicated their preference for the four-month window. One commenter said they favor State flexibility and indicated they currently use a window of 90 days in their program. Two other commenters suggested a three-month window.

Response: Section 1903(m)(2)(H) provides a re-enrollment window of two months, therefore, the reference to four months in the preamble to the proposed rule was an error. States may use a shorter timeframe, but not a longer one.

4. Conflict of Interest Safeguards (§ 438.58)

Proposed § 438.58 required as a condition for contracting with MCOs that States establish conflict of interest safeguards at least as effective as those specified in section 27 of the Office of Federal Procurement Policy Act.

Comment: One commenter supported the provision as written requiring that there be conflict of interest safeguards on the part of State and local officers and employees and agents of the State who have responsibilities relating to MCO contracts or default enrollments.

Response: The final rule with comment period makes no change in the proposed language, other than to reflect the applicability of this provision, like other provisions in subpart B, to PHPs (see section 2. above).

Comment: Two commenters suggested that the safeguards be applied to all MCOs, PHPs and PCCMs, not just MCOs.

Response: Section 438.58 implements section 1932(d)(3), which specifies only contracts under section 1903(m) (i.e, contracts with MCOs). For this reason, we referenced only MCOs in proposed § 438.58. However, while the conflict of interest standards in § 438.58 are triggered by MCOs, in the sense that the State cannot enter into MCO contracts unless they are in place, they apply to anyone with responsibilities ''relating to'' MCOs or to the ''default enrollment process specified in § 438.56,'' which would also include responsibilities for PCCMs. In addition, as discussed in section 2. above, we have made all provisions in subpart B except for § 438.50, applicable to PHPs.

Comment: One commenter agreed that these safeguards regarding conflicts of interest for State and local officials were necessary and welcome; however, it envisioned additional protections for any entity engaged in ''determining or providing managed health care to Medicaid-eligible beneficiaries [should] have policy-making bodies that consist of at least 60 percent'' of beneficiaries who will be served by the program.

Response: We do not believe that the regulation should be amended. Ensuring 60% Medicaid beneficiary representation on any board involved in determining how managed care will be provided to Medicaid eligibles is not feasible, given resource constraints at the State level. Furthermore, we have no statutory basis for requiring such representation.

5. Limit on Payment to Other Providers (§ 438.60)

Proposed section 438.60 prohibited payment for services which were covered under a contract between an MCO and the State, except for emergency and post-stabilization services in accordance with section 438.114(c) and (d).

Comment: All commenters maintained that the language in § 438.60 is too restrictive: the only exempted service are emergency services and post-stabilization services. Additional ''exceptions'' proposed were—family planning, school-based services, immunizations by local health agencies, certified nurse midwife services, tribal health provider services, and EPSDT services.

Response: We believe that the commenters have misunderstood this provision and that the exemption for emergency and post stabilization services in the proposed rule may have helped create this confusion. The intent of section 438.60 is to prohibit duplicate payments (once through capitation, once through FFS) for services for which the State had contracted with an MCO to provide. We believe that the exemption for emergency and post stabilization services was incorrect, since the MCO is obligated to cover and pay for these services for its enrollees. Thus, any payment by the State would be a duplicate payment. We are deleting this exemption from the final rule with comment period.

A State has in effect already paid for services that are included in an MCO's contract, and does not have an obligation to pay for them a second time, if a beneficiary obtains the services outside of the MCO's network.

In instances where out-of-network services may be authorized, e.g., the rural exception to the choice requirement, family planning, school-based services, immunizations, CMN or tribal services either the MCO or the state has the financial obligation to pay for the services. The State may pay for the services that were under the contract only if there is an adjustment or reconciliation made to the amounts paid the MCO in its capitation payments. In this situation, the services were not considered ultimately to be covered under the MCO contract. In situations where any of these services are carved out of the contracts (and the capitation rates paid the MCO) this is not an issue. State option to allow beneficiaries to go out-of-network for these services is not hindered by this section.

In addition, this provision precludes States from making additional payments directly to providers for services provided under a contract with an MCO or PHP, except when these payments are required by statute or regulation, such as with DSH or FQHC payments. We have clarified this provision accordingly in the final rule.

Comment: One commenter wanted HCFA to clarify what ''service availability'' actually means.

Response: For purposes of this provision, ''available'' would refer to services covered under the contract. A State is held accountable (§ 438.306) for ensuring that all covered services are available and accessible to enrollees—both services under the contract and those State plan services not included in the contract with the MCO.

6. Continued Service to Recipients (§ 438.62)

Proposed § 438.62 required States to arrange for continued services to beneficiaries who were enrolled in an MCO whose contract was terminated or beneficiaries who were disenrolled for any reason other than a loss of Medicaid eligibility.

Comment: We received a series of general comments that, overall, § 438.62 did not address the continuation of an enrollee's ongoing treatment when transitioning to managed care. Specifically, the commenters expressed concern that the proposed regulation did not highlight the need for identification and continuation of an enrollee's treatment when transitioning from FFS into managed care or from one managed care organization to another. Several commenters stated that the interruption of treatment for only a short period of time could have serious

and possibly irreversible consequences on an individual's health. Other commenters suggested that ongoing treatment without interruption was especially critical for persons suffering from mental illness, substance abuse, and chronic conditions such as HIV/AIDS.

Response: Section 438.308 addresses continuity and coordination of care requirements on MCOs, and comments on this provision generally are discussed in more detail in section II. D. below, discussing comments on proposed subpart E. We believe, however, that some comments on perceived inadequacies in § 438.308, specifically those expressing concerns about continued access to services as beneficiaries are transitioned from FFS into managed care, could be addressed in part by amending proposed § 438.62. Proposed § 438.62 represented a recodification of a longstanding requirement in part 434, at § 434.59, which required that provision be made for continued services when enrollment in an MCO or a PHP is terminated. This requirement was imposed under our authority in section 1902(a)(4) to specify methods necessary for proper and efficient administration. In response to the above comments, we believe it is appropriate to extend the requirement in § 438.62 (previously in § 434.59) to situations other than the transition out of an MCO or PHP.

We believe that most States already have mechanisms in place to transition enrollees into managed care from fee-for-service and from one MCO to another. However, we acknowledge the commenters' concerns that our proposed regulation does not address an enrollee's potential disruption of services, even for a short period of time, from the period of initial enrollment until the time of assessment by the new primary care physician or specialist in the receiving MCO or PHP.

In response to the large number of comments received on this issue, we are in this final rule with comment period, again under our authority in section 1902(a)(4), expanding the scope of § 438.62. The commenters referred to ''managed care'' generally, in asking that our regulations address ''transitioning from FFS into managed care.'' We therefore are extending § 438.62 to enrollees in PCCMs, as well as MCOs and PHPs. The language of the proposed version of § 438.62 becomes paragraph (a) in the final rule with comment period, except with reference to MCOs, PHPs, and PCCMs rather than only MCOs, to afford enrollees of PHPs and PCCMs the same protections. The added paragraph (b) requires States to have mechanisms to ensure continued access to services when an enrollee with ongoing health care needs is transitioned from fee-for-service to an MCO, PHP, or PCCM, from one MCO, PHP, or PCCM to another, or from an MCO, PHP, or PCCM to fee-for-service.

We wish to emphasize that we are not mandating any specific mechanism that States must implement, nor are we mandating a specific list of services or equipment that must be covered during the transition period. However, we are requiring that the mechanism apply to at least the following categories of enrollees: (1) Children and adults receiving SSI; (2) children in Title IV–E foster care; (3) recipients aged 65 or older; (4) pregnant women; (5) any other recipient whose care is paid for under State-established, risk-adjusted, high-cost payment categories; and (5) any other category of recipients identified by HCFA. We also specify that the State must notify the enrollee that a transition mechanism exists, and provide instructions on how to access the mechanism. Further, the State must ensure that the enrollee's ongoing health care needs are met during the transition period by establishing procedures to ensure that, at a minimum, the enrollee has access to services consistent with the State plan, and is referred to appropriate health care providers; new providers are able to obtain copies of appropriate records consistent with applicable Federal and State law; and any other necessary procedures are in effect.

Comment: One commenter believes that it is unclear what level of effort by the State is sufficient to comply with the requirement. In an FFS environment, referral services are less comprehensive and ''delays'' might be defined differently.

Response: We believe that both terms, ''without delay'' and ''delay'' represent straightforward guidance and that no further changes are needed.

7. Monitoring Procedures (§ 438.66)

Proposed section 438.66 states that a State must have in place procedures for monitoring MCO practices and procedures with regard to enrollment/termination, implementation of grievance procedures, violations subject to intermediate sanctions (such as failing to provide services for which it has contracted), and violations for the conditions for FFP (such as conditions of FFP for enrollment broker services). As noted above, we have made this and most other provisions applicable to PHPs in response to comments. We therefore in this final rule with comment period have added ''to the extent applicable, for PHPs,'' since not all of these provisions apply to PHPs.

Comment: One commenter noted that with regard to enrollment and termination practices, HCFA did not specify ''beneficiaries'' or ''providers,'' but assumes we meant beneficiaries only.

Response: This section of the regulation does not implement a BBA requirement, and was incorporated from existing regulations without substantive changes. We did not intend to modify or expand its meaning. That said, we agree that paragraph (a) needs clarification, and in response to this comment, the final rule with comment period specifies that it applies to ''recipient enrollment and disenrollment,'' and adds a paragraph (e) ''All other provisions of the contract, as appropriate.''

Comment: Another commenter states that the regulation should specify timeframes, and suggests annual monitoring for grievance procedures, and quarterly monitoring for enrollment/termination. This commenter furthermore notes that we have required the latter in some 1915(b) waivers and 1115 demonstrations.

Response: Given our desire to maximize States' flexibility in administering their State plans, we do not specify for each item how often the monitoring must be done, merely that it is a requirement to do so. Our experience with States' monitoring of MCOs in section 1115 demonstrations and in 1915(b) program waivers suggests to us that States implementing these procedures will do so on an annual or quarterly basis—if not more often than that.

Comment: One commenter suggested that HCFA require States to have procedures to monitor specialty referral services.

Response: With respect to the suggestion of monitoring procedures for specialty referral services, we note that 438.10 already requires MCOs to make available information to beneficiaries on how to access services, including those (such as referrals) that may require authorization. If these procedures are not being followed, we believe that the complaints and grievances data (which the State is required under this subsection to monitor) will demonstrate whether the MCO is following its own (State-approved, see § 438.700) procedures. Furthermore, we have clarified with new paragraph (e) what has always been our expectation; namely, that States monitor compliance with all aspects of the contract. Such a requirement implicitly includes the monitoring of special referral services.

Comment: One commenter believed that HCFA should require States to have procedures in place to monitor the degree of enrollment of pediatricians/other providers, the provision and access to services not covered under the contract, and EPSDT services.

Response: We believe that it would be unnecessarily onerous to add requirements regarding monitoring the participation of pediatricians and other providers and EPSDT services. The MCOs have already agreed to provide all medically necessary services in their contract (including EPSDT, if included in a particular contract) and therefore have strong incentives to have adequate provider and specialist network capacity, especially because if it they do not, the State can impose intermediate sanctions or terminate the contract before it would otherwise expire (see § 438.718). Furthermore, it is a contract requirement that MCOs provide for arrangements with, or referrals to, ''sufficient numbers of physicians and other practitioners to ensure that services under the contract'' are furnished (see § 438.6). Furthermore, again, we have clarified in paragraph (e) that States monitor contract compliance. Such a requirement implicitly includes the monitoring of number of pediatricians and other providers. Moreover, States are required at § 441.56 to meet certain EPSDT targets, whether or not they are contracted services. With regard to ''wraparound services,'' we note that § 438.206(c) makes clear that it is the responsibility of the State to ensure that services not covered by the contract are provided to Medicaid beneficiaries. If such services are not being provided, a State's monitoring of trends in its Fair Hearings process should reveal any problem with respect to access to ''wraparound'' services.

Comment: One commenter believed that HCFA should require the State to have procedures for monitoring training (of both beneficiaries and providers).

Response: We believe the fact that under § 438.218, the information requirements in § 438.10 are part of the State's quality assurance program provides assurance that the State will have to monitor the training and education of beneficiaries with respect to their enrollment and participation in MCOs or PCCMs. Furthermore we have clarified with (e) what has always been our expectation; namely that States monitor contract compliance. Such a requirement implicitly includes the monitoring of beneficiary education. We believe that with respect to provider training, it is the responsibility of the State to ensure that MCOs, PHPs, or their subcontractors have the requisite training and information for program participation.

Comment: One commenter requests that States be required to monitor samples of all notices sent to the enrollee by the MCO, PHP, or PCCM, and by all subcontractors.

Response: HCFA believes that the requirement at 438.700, which makes a plan's or subcontractor's distribution of materials that are not State-approved subject to sanctions addresses the concern raised by this commenter. Such a requirement implicitly includes the State's monitoring of materials sent to beneficiaries by the MCOs, PHPs or PCCMs. This also would be the subject of monitoring under § 438.66(e).

Comment: We received a number of general comments on the need for greater understanding of persons with special health care needs by MCOs and their providers. Specifically, in the area of coverage and authorization, a commenter contended that the managed care industry has very little knowledge of the needs of persons with disabilities. commenters further argued that the importance of certain services is often overlooked by the managed care industry. Another commenter argued that we should require MCOs to make every effort to provide training and education for their practitioners on the diagnosis of certain conditions such as HIV and AIDS. We also received comments on the need for MCO providers to have appropriate knowledge and skills to treat adults and children with special health care needs, including recipients with mental illness, substance abuse problems, developmental disabilities, functional disabilities, and complex problems involving multiple medical and social needs. One commenter specifically recognized the need for MCO recognition of the unique needs of the homeless population.

Response: Based on comments described here and other general comments requesting additional consumer protections for persons with specific conditions or disabilities, we are persuaded that additional requirements are necessary to ensure appropriate education of all managed care entities and providers on the unique care needs of special needs populations. Accordingly, the final rule with comment period contains a new § 438.68 Education of MCOs, PHPs, and PCCMs. This section requires that the State agency have in effect procedures for educating the MCO, PHP, and PCCM and any subcontracting providers about the clinical and non-clinical service needs of enrollees with special health care needs.

C. Subpart C (Enrollee Protections)

Proposed subpart C set forth a variety of enrollee protections including the following: (1) requiring information on benefits be specified (proposed § 438.100); (2) rights concerning provider communications with enrollees (proposed § 438.102); (3) limits on marketing activities (proposed § 438.104); (4) limits on enrollee liability for payment (proposed § 438.106) and cost-sharing (proposed § 438.108); (4) an obligation for MCOs and PHPs to provide assurances of adequate capacity (proposed § 438.110); (5) rights in connection with emergency and post-stabilization services (proposed § 438.114); and (6) MCO solvency standards (proposed § 438.116).

1. Benefits (§ 438.100)

As proposed, § 438.100 required that Medicaid contracts between States and MCOs specify the benefits the MCO is responsible for providing or making available to Medicaid enrollees. The proposed section also required States to make arrangements for furnishing those State plan services that MCOs were not responsible to provide under the contract, and to give written information to enrollees on how and where they may obtain these additional services. Many commenters were confused by this section because it duplicated provisions in other sections. To eliminate duplication, the requirements in proposed § 438.100 have been incorporated into other sections, notably § 438.10, Information requirements; § 438.206 Availability of services; and § 438.210 Coverage and authorization of services. The requirement in proposed § 438.100(a) that contracts specify the services the entity is required to provide to Medicaid enrollees is now set forth in § 438.210(a)(1). The requirement in proposed § 438.100(b) concerning the State's obligations to services not covered under the contract is now set forth in § 438.206(c), while the requirement to provide information to enrollees and potential enrollees is in § 438.10(d)(2)(ii)(E), § 438.10(e)(2)(vii), and § 438.10(g).

We have moved the requirements relating to enrollee rights from proposed § 438.320 to § 438.100. Throughout the preamble, we have responded to comments according to their numerical sequence in the proposed rule. This section only addresses responses to comments regarding proposed § 438.100 (Benefits). Comments and responses relating to the enrollee rights are now in § 438.100 but were in the proposed § 438.320 are discussed in section II. D.

below in the discussion of comments on the subpart in which these enrollee rights appeared in the proposed rule. In this final rule with comment period the content of proposed subpart E has been redesignated as subpart D with sections redesignated from the 300 series to the 200 series.

Comment: One commenter believed that we went beyond the authority in the statute by requiring the contract to specify the services the MCO, PHP, or PCCM is required to provide.

Response: We believe that the commenter apparently read the proposed rule to preclude States from incorporating the description of the benefits covered under the contract by referencing a separate document describing the benefits (for example, a provider agreement). However, the proposed rule was not intended to prohibit accepted methods of incorporating substantive contract provisions by cross-referencing separate documents. The reference documents must be sufficiently detailed to make clear to all parties the types and scope of the services for which the MCO is responsible.

Comment: Several commenters urged that we require States to include specific contract language holding MCOs responsible for the early prevention, screening, diagnosis and treatment (EPSDT) of eligible enrollees through the full scope of EPSDT benefits required under States' Medicaid plans. Commenters also expressed the view that States must make arrangements for providing at no cost to enrollees EPSDT services and benefits that are not covered or are not provided by the entities in accordance with the contract.

Response: These issues are addressed in section II. D. below in responses to similar questions raised with respect to § 438.210 Coverage and authorization of services and § 438.206(c) Availability of services.

Comment: Commenters strongly recommended that we clarify that contract language must address MCO, PHP, or PCCM and State agencies' roles for case management when covered services overlap with services that are not the responsibility of the MCO, PHP or PCCM to provide or to make available. Some of the commenters noted that mental health services for chronic conditions are frequently not included under MCO, PHP, or PCCM contracts. Without clear delineation of responsibility between the mental health services provided by the entity and those covered outside the MCO, PHP, or PCCM, enrollees may not receive the services they are entitled to receive under the State plan.

Response: We agree that coordination of care is an important component of managed care and that coordination may be challenging because an MCO may not cover all of the services included in the State plan. To ensure that care is appropriately coordinated, § 438.208(h)(7) of this final rule with comment period requires that each MCO and PHP implement a program to coordinate the services it furnishes to the enrollee with the services the enrollee receives from any other MCOs or PHPs. In section 438.10(d)(2)(i)(C), we also require that the information furnished to potential enrollees include general information about MCO responsibilities for coordination of care.

Comment: One commenter recommended that a mechanism be established to assist enrollees with obtaining the services they are entitled to under the State plan, but that are not covered by the MCO, PHP, or PCCM. Proposed § 438.100 required States to give enrollees written instructions on how to obtain those services, but it did not specify how enrollees would know to contact the State for instructions.

Response: Proposed § 438.100(b) set forth the State's obligation to make services under the States plan available and give enrollees instructions on how to obtain them, but did not specifically address the general provision of information to beneficiaries on this obligation as required under section 1932(a)(5)(D) of the Act, Information on Benefits not Covered. As noted above, in § 438.10(d)(2)(ii)(E), § 438.10(e)(2)(vii), and § 438.10(g) of this final rule with comment period, we address the information requirements relating to availability of services, and specify that this information include information about benefits that are available under the State plan but not covered under the contract, including how and where the enrollee may obtain these benefits, any cost sharing, and how transportation is provided.

Comment: Several commenters urged that MCO, PHP, or PCCM contracts specify the services that the entity is to provide to Medicaid enrollees. For those Medicaid services that are not included in the MCO, PHP, or PCCM contract, the commenters believed that the State should make arrangements for providing those services and give enrollees written instruction on how to obtain them. Another commenter found the meaning of the term ''arrangement'' in proposed § 438.100(b) unclear.

Response: Proposed § 438.100(a) required that MCO contracts (and § 438.8(d) PHP contracts) specify the services that have to be provided to Medicaid enrollees. In this final rule with comment period, this requirement is in § 438.210(a). In proposed § 438.100(a), we did not require that PCCM contracts specify this information, this was an error, since section 1932(b)(1) of the Act requires that PCCM contracts ''specify the benefits the provision (or arrangement) for which the PCCM is responsible.'' Section 1932(a)(5)(D) of the Act sets forth the obligation to inform enrollees in an entity of services ''not made available to the enrollee through the entity,'' and of ''where and how enrollees may access'' benefits, applies to ''managed care entities,'' or ''MCEs'' (a term that includes both MCOs and PCCMs). We therefore are including PCCMs in § 438.210(a)(1) (which contains the requirement that contracts specify covered services that was in proposed § 438.100(a)) and § 438.206(c) (which contains the State obligation formerly in proposed § 438.100(b)).

With respect to the requirement that information be provided on what State plan services are not covered by the contract, and how and where enrollees may obtain services, proposed § 438.10(g) already extended this requirement to PCCMs. This is retained in § 438.10(g) of this final rule with comment period.

Proposed § 438.100(b) provided that States must make ''arrangements'' for furnishing services not covered under the contract with the MCO. We agree with the last commenter that the term is unclear. Therefore, in § 438.206(c), we provide that if an MCO contract does not cover all of the services under the State plan, the State must make available those services from other sources and provide to enrollees information on where and how to obtain them, including how transportation is provided. We interpret the phrase ''make available from other sources'' to mean that the State must directly pay for the service through a fee-for-service contract or contract with another organization to provide the service.

Comment: One commenter recommended that the representative payee or other responsible person be included in dissemination of information advising enrollees on how and where to access these additional benefits.

Response: We did not adopt the exact language recommended. The information requirements in § 438.10 provide for informing authorized representatives.

2. Enrollee-Provider Communications (§ 438.102)

Medicaid beneficiaries are entitled to receive from their health care providers

the full range of medical advice and counseling that is appropriate for their condition. Section 1932(b)(3) of the Act added by the BBA clarifies and expands on this basic right by precluding an MCO from establishing restrictions that interfere with enrollee-provider communications. In § 438.102 of the proposed rule, we provided a definition of the term ''practitioner'' and outlined the general rule prohibiting interference with provider-enrollee communications. We also specified that this general rule would not require the MCO to cover, furnish or pay for a particular counseling or referral service if the MCO objects to the provision of that service on moral or religious grounds, and provides information to the State, prospective enrollees, and to current enrollees within 90 days after adopting the policy with respect to any particular service.

Comment: Several commenters found the definition of ''practitioner'' at § 438.102(a) too restrictive and felt that it needed to be expanded to include professionals as: dental hygienists; marriage, substance abuse, and family counselors; interns; licensed psychiatric technicians; and pharmacists. One commenter pointed out that the proposed definition referred to a limited number of providers and excluded several of those referenced in the statute. Commenters recommended either adding those professions referenced in the statute or specifying that those listed in the regulations served as examples only. Another commenter suggested adding ''including, but not limited to'' language.

Response: Section 1932(b)(3)(C) of the Act provides an exact list of professions that are covered under this provision. In the proposed rule, we erroneously omitted several classes of professionals that were included in the statute. Therefore, we have revised § 438.102(a) to mirror the list contained in the statute. We have also replaced the term ''practitioner'' with ''health care professional'' in order to be consistent with the statute.

Comment: One commenter expressed concern that proposed § 438.102(b) did not require that State contracts with MCO or MCO contracts with providers be made available for public viewing.

Response: In this final rule with comment period, we do not require that contracts be made available to the public because doing so may deter MCOs from bidding on Medicaid contracts and may result in States not getting the best price. However, in § 438.10(f)(5), we have required that States and MCOs make available, upon request, information relating to the type of compensation arrangements that physicians have with MCOs and States.

Comment: Several commenters preferred the language included in the Medicare+Choice regulation implementing statutory authority for protecting provider-enrollee communications that is similar to that in the BBA for Medicaid. The commenters believed that the Medicare+Choice provisions in § 422.206 are more encompassing than those in proposed § 438.102 because they also bar Medicare+Choice organizations from—(1) restricting providers from advocating on the patient's behalf; (2) prohibiting providers from sharing information regarding alternative treatment; and (3) prohibiting providers from discussing the risks, benefits, and consequences of treatment or lack of treatment, and the opportunity for the enrollee to refuse treatment or express preferences for future treatment. The commenters also state that violations are subject to Federal sanctions. Two commenters stressed that providers must be free of all restrictions on communicating with enrollees and be able to provide complete information on all treatment options.

Response: We agree with the commenters who favor the approach taken in the Medicare+Choice regulations and have revised § 438.102(b) to parallel the requirements in § 422.206. We note that since the intermediate sanctions in subpart I apply only to MCOs, the new paragraph referring to sanctions applies only to MCOs.

Comment: Some commenters suggested that we reinforce the fact that a health care professional cannot be prevented from furnishing needed information to patients during the course of routine primary and preventive care visits or other treatment. These commenters expressed concern about language in the preamble to the proposed rule which states that, '' an MCO may not limit a provider's ability to counsel or advise an enrollee on treatment options that may be appropriate for the enrollee's condition or disease, unless the terms of § 438.102(c) apply and are satisfied.'' Specifically, the commenters requested that we remove reference to § 438.102(c).

Response: We agree with the commenters that the preamble language was misleading in implying that § 438.102(c) would permit an MCO to actually prevent a provider from providing counseling. We have revised § 438.102 in this final rule with comment period so that it is clear that § 438.102(c) only relieves an MCO from being required to provide, arrange, or pay for counseling or referrals as the result of the prohibition in § 438.102(b)(1), but does not give the MCO the right to prevent a physician from giving counseling if the physician is willing to forego any payment that may be associated.

Comment: One commenter recommended allowing an enrollee to terminate or change enrollment at any time after they receive notification that an MCO will exercise its right under § 438.102(c) not to provide, reimburse, or provide coverage of a counseling or referral service that is provided as the result of the requirement in § 438.102(b).

Response: We agree with the commenter. Section 438.56(d)(2)(ii) of this final rule with comment period provides that if an MCO does not provide a service because of moral or religious objections (whether pursuant to § 438.102(c), or otherwise) the enrollee may disenroll for cause. It is important to note that regardless of whether the MCO covers a certain service that is included in the State plan, the enrollee will have access to that service. If an MCO contract does not cover all of the services under the State plan (regardless of the reason) the State must make available those services from other sources. In addition, the Medicaid statute guarantees freedom of choice for family planning services so an enrollee may always seek services out-of-network. Therefore, we permit enrollees to disenroll if services are not covered because of moral or religious objections. We emphasize that disenrollment is not necessary in order to access the services.

Comment: Most commenters supported the conscience clause provision at proposed § 438.102(b)(2) which provides that, subject to certain information requirements, an MCO is not required to provide, reimburse for, or provide coverage of a counseling or referral services furnished as the result of the rule in § 438.102(b)(1) if the MCO objects on moral or religious grounds. However, several commenters objected to the policy that MCOs may elect not to provide coverage for some services that are included in the State plan. They stated that if the MCO objects to a Medicaid-covered service on moral or religious grounds, it is their responsibility to arrange for coverage through subcontracts or by providing access to the service out-of-network. Others stated that to allow MCOs to pick and choose what services they will be responsible for runs counter to how

managed care contracts are designed and bid out. This provision would in these commenters' view complicate bid pricing and evaluation, increase administrative costs to the State (to make separate arrangements for these services and provide notice to beneficiaries), and could be confusing to beneficiaries.

One commenter believed that the proposed rule creates an undue burden for enrollees who are seeking family planning services and disrupts their continuity of care, and that these disruptions could result in lower quality of family planning care for women. Commenters recommend either removing the conscience protection provisions or changing the regulation to allow States to require MCOs that have moral objections to providing certain services to obtain them through subcontracts or out-of-network arrangements.

Response: We do not have the authority to delete the conscience protection provision because it is required by section 1932(b)(3)(B) of the Act. However, this conscience provision alone would not by itself permit an MCO to avoid providing a State plan service that it has contracted to provide. As noted in the preamble to this final rule with comment period, the conscience protection in section 1932(b)(3)(B) of the Act only protects an MCO from being required to pay for something as the result of the rule in section 1932(b)(3)(A) of the Act. Section 1932(b)(3)(B) of the Act begins with the words ''*Subparagraph (A) shall not be construed as requiring* a Medicaid managed care organization to provide, reimburse for, or provide coverage of, a counseling or referral service'', if the MCO objects and gives the required notice. This is an exception to the obligations under paragraph (A), not a ''blanket'' authority to decline to cover services the MCO would otherwise be obligated to provide. As noted in section II. B above, however, unlike a Medicare+Choice organization, that must contract to provide Medicare services, a Medicaid contracting MCO is free to negotiate with the State over which services it will provide. Clearly, section 1932(a)(5)(D) of the Act (requiring that certain arrangements be made with respect to State plan services not furnished through an MCO or PCCM) contemplates an MCO's right to decide which State plan services to agree to include in its contract. An MCO that objects to covering a State plan service would not agree in the contract to provide that service. In such a case, the State is clearly obligated to ensure the availability of the service out of plan. If the MCO did agree to provide a State plan service under its contract, it could not attempt to ''change its mind'' by relying on the ''conscience protection'' in section 1932(a)(3)(B) of the Act, since its obligation to provide the State plan service would be pursuant to its contract, not section 1932(a)(3)(A) of the Act. It is important to note that under existing regulations, MCOs may not restrict an enrollee's freedom of choice with respect to family planning services. In other words, enrollees may always seek family planning services out-of-network.

Comment: Commenters expressed concern about how enrollees will receive notice of an MCO change in policy. One commenter recommended linking this requirement with the information requirements in § 438.10(c), which requires plans to use easily understood language and format and take into consideration the special needs of those, for example, are visually impaired or have limited reading proficiency. Others recommended that we explain how an MCO should provide notice to ensure enrollees are adequately informed.

Response: We agree with the commenters that the information furnished to enrollees and potential enrollees under this section should be governed by the same rules as the information furnished under § 438.10. Therefore, we have revised § 438.102(c) to require that the information furnished under this section be ''consistent with the provisions of § 438.10.''

We believe that it is critical that enrollees and potential enrollees have sufficient information to understand how and where to obtain a service that is not covered by the MCO. This responsibility is shared by the MCO and the State. As discussed in section II. A. above under § 438.10(e)(1)(ii), an MCO or PHP must inform potential enrollees of any ''significant'' change in the information in § 438.10(e)(2) at least 30 days prior to the change. Section 438.10(e)(2) includes a description of what services the MCO or PHP covers. This advance notice requirement would ordinarily apply to a change in what the MCO or PHP would cover. While section 1932(a)(3)(B) of the Act requires only that notice be provided within 90 days after a decision was made not to cover something under its provisions, and meeting this condition would permit an MCO to qualify for the exception in section 1932(a)(3)(B) of the Act. We believe that the general rule in § 438.10(e)(1)(ii) should continue to apply, and are revising § 438.102(b)(1)(B) to clarify this fact.

Comment: Commenters were concerned that public entities may want to exercise the conscience protection exception at § 438.102(c), which the commenters believe could violate the Constitution (presumably because the first amendment ''establishment clause'' would prevent a public entity from citing a ''religious'' objection to covering a service). These commenters recommended that we state that public entities that sponsor or operate MCOs cannot assert moral or religious objections, and thus decline to provide, reimburse for, or provide coverage of any counseling or referral service.

Response: We have not incorporated the commenters suggestion because section 1932(b), (3)(B) of the Act and § 438.102(c) are not limited to an objection on ''religious'' grounds, but also on ''moral'' grounds, and there is nothing to preclude a governmental entity from expressing a moral objection. However, there is no basis in the BBA for making a distinction between public and private MCOs in this area.

Comment: One commenter was concerned that subcontractors may not be required to adhere to the provisions of § 438.102 regarding enrollee-provider communications. The commenter suggested that subcontractors should expressly be covered as they were in proposed § 438.310(b)(1), which explicitly sets forth requirements for ''the MCO and its subcontractors.''

Response: In § 438.6(l) of this final rule with comment period, we state that all subcontracts must fulfill the requirements of this part that are appropriate to the service or activity delegated under the subcontract. In addition, § 438.230 provides that for all 1903(m) contracts, ''the State must ensure that each MCO oversees and is accountable for any functions and responsibilities that it delegates to any subcontractor * * *''. We believe that the combination of these two provisions satisfies the commenter's concerns and that additional subcontractor language is not needed in § 438.102.

Comment: One commenter indicated that § 438.102 does not address enforcement mechanisms nor remedies for providers that believe they were penalized or terminated by the plan for providing information to an enrollee. The commenter suggest that we provide these enforcement mechanisms.

Response: If providers believe that an MCO has violated the requirements of section 1932(b)(3)(A) of the Act and § 438.102(b), they should bring this to the attention of the State Medicaid agency, which could then investigate the situation and determine whether to

impose sanctions under § 438.102(e) and § 438.700(d). We believe that this sanction authority provides a sufficient enforcement mechanism.

3. Marketing (§ 438.104)

In accordance with section 1932(d)(2) of the Act, proposed § 438.104 set forth requirements for, and restrictions on, marketing activities by MCO, PHP and PCCMs. (The regulations text referred to ''MCEs,'' includes MCOs and PCCMs and proposed § 438.8(d) made the requirements applicable to PHPs.). Proposed § 438.104 included definitions of ''choice counseling'', ''cold-call marketing'', ''enrollment activities'', ''enrollment broker'', ''marketing materials'', and ''recipient and potential recipient.'' The definitions related to enrollment broker functions (''choice counseling,'' ''enrollment activities,'' and ''enrollment broker'') were included in error and have in this final rule with comment period been moved to § 438.810, Expenditures for Enrollment Broker Services. We also proposed requirements and prohibitions for MCO, PHP, or PCCM contracts. Specifically, § 438.104(b)(1) proposed that the contract must specify the methods by which the entity assures the State agency that the marketing plans and materials are accurate and do not mislead, confuse, or defraud the recipients or State agency. Section 438.104(b)(2) proposed restrictions on MCO, PHP, or PCCM contracts, which are discussed in detail below. Section § 438.104(c) proposed to require the State to consult with a MCAC or an advisory committee with similar membership in reviewing marketing materials. Comments we received on these issues and our responses follow.

a. General Comments

Comment: Proposed § 438.8(d) provided that the error of subpart C, including § 438.104 applies to PHPs to the same extent that the sections apply to MCOs. Section 438.104 only includes references to managed care entities (MCEs) which appears to mean the section is not applicable to PHPs.

Response: The marketing rules set forth in § 438.104 apply to MCOs, PCCMs and, as specified in § 438.8(d), to PHPs as well. Given the confusion reflected in this comment, throughout this final rule with comment period, we have revised the regulation text to indicate in each requirement whether it applies to PHPs, while also retaining § 438.8.

Comment: One commenter believed that we should establish specific and significant monetary fines for coercive or unethical marketing practices.

Response: Many States have already determined what marketing violations are punishable and have set significant fines or sanctions. In addition, § 438.700 requires States that contract with MCOs to establish intermediate sanctions and includes as reasons for imposing these sanctions: (1) discrimination among enrollees based on health status or need for services; (2) misrepresenting or falsifying information furnished to either the State, enrollees, potential enrollees, health care providers or us; and (3) distributing marketing materials that have not been approved by the State, or that contain false or materially misleading information. States have the flexibility to impose sanctions or restrictions as they find appropriate. In addition, § 438.730 allows us to impose a sanction either based upon a State agency's recommendation, or directly.

Comment: Several commenters urged HCFA to prohibit other types of marketing, and require more strict oversight of MCOs'', PHPs'', and PCCMs' activities.

Response: Some degree of flexibility is needed if MCOs, PHPs, and PCCMs are to continue offering Medicaid products in a competitive environment. Section 438.104(b)(2)1)(i) requires States to review and approve all marketing materials prior to distribution, and § 438.104(b)(2) requires assurances that marketing materials do not confuse, mislead or defraud. Section 438.104(b)(1)(v) prohibits specific marketing practices, such as door to door, telephone, or other ''cold call'' marketing. It is not clear what ''other types of marketing'' would warrant a prohibition. Therefore, we do not believe that additional regulatory requirements are necessary.

Comment: Commenters suggested that we revise the preamble to indicate that the marketing limitations apply to homeless shelters as well as other institutional settings. The commenters believe that it is not appropriate to approach homeless people, and that strong Federal protection is needed.

Response: The general prohibition on ''cold call'' marketing would prohibit ''approaching'' homeless people in a shelter (or elsewhere) or other institutionalized individuals. We agree with the commenters, and are stating here that all limitations on marketing apply equally in these settings.

Comment: One commenter indicated that it makes little sense to mandate choice of an MCO when under the proposed regulation, MCOs may not use marketing to effectively differentiate their Medicaid products and compete for greater enrollment.

Response: We do not believe that these marketing rules unfairly restrict an MCO, PHP, or PCCM's ability to compete in the marketplace. We do not prohibit all types of marketing activity. States may permit MCO, PHP, and PCCMs to—(1) participate in health fairs and community presentations; (2) use various forms of ''broadcast'' advertising; (3) send mailings to potential enrollees; (4) respond to individual requests for information; and (5) engage in other activities as long as they are approved and subject to sufficient oversight. Even where MCOs, PHPs, and PCCMs have similar structures and networks, it is possible for them to offer additional benefits, for example, child care to differentiate one MCO, PHP, or PCCM from another. In addition, MCOs, PHPs and PCCMs can provide results of enrollee satisfaction surveys, report cards, or other types of information on quality of care to potential enrollees.

b. Cold-Call Marketing

Proposed § 438.104(a) defined cold-call marketing as any unsolicited personal contact by the MCO, PHP, or PCCM with a potential enrollee for the purpose of influencing the individual to enroll in that particular MCO, PHP, or PCCM. Cold-call marketing includes door-to-door, telephone or other related marketing activities performed by MCOs, PHPs, or PCCMs and their employees (that is, direct marketing) or by agents, affiliated providers, or contractors (that is, indirect marketing). In the preamble to the proposed rule, we noted that cold-call marketing includes activities as a physician or other members of the medical staff, or a salesperson, or other MCO, PHP, or PCCM employee or independent contractor approaching a beneficiary in order to influence a beneficiaries decision to enroll with a particular MCO, PHP, or PCCM. In proposed § 438.104(b)(2)(v), we expressly prohibited MCO, PHP, or PCCMs from directly or indirectly engaging in door-to-door, telephone, or other cold-call marketing activities.

Comment: One commenter felt that the definition of ''cold-call marketing'' could inadvertently prohibit appropriate marketing activities, for example, direct contact at health fairs and community-based organization offices.

Response: The prohibition on cold-call marketing only applies to ''unsolicited'' contact by the MCO, PHP, or PCCM. For example, if a beneficiary attends a health fair or similar event, the beneficiary would be seeking information about health care and, therefore, the contact between the MCO,

PHP, or PCCM and the beneficiary would not be considered ''unsolicited.'' We note, however, that MCO, PHP, or PCCM participation in health fairs and other community activities is considered marketing and, therefore, must have the State's approval.

Comment: Commenters suggested that we return to the statutory language defining cold-call marketing. The commenters' rationale was that because the regulations apply to voluntary as well as mandatory programs, the prohibited activities would preclude viable enrollment numbers.

Another commenter contended that the proposed definition of ''direct marketing'' went beyond the statutory prohibition of ''cold-call'' marketing. Another commenter believed that the restriction against providers attempting to influence patients' choice could severely limit opportunities for MCOs, PHPs, and PCCMs to attract members and might unintentionally create an unlevel playing field because this sort of marketing is currently conducted by PSOs, hospital systems, and providers with a particular interest in one health plan.

Response: Section 1932(d)(2)(E) of the Act prohibits direct or indirect door-to-door, telephonic, or other ''cold-call'' marketing of enrollment. These provisions were added to the Act by section 4707 of the BBA, Protections Against Fraud and Abuse. Our interpretation of the Congress' intent is that the statutory language was meant to minimize the potential for abusive marketing practices in both voluntary and mandatory programs. Specifically, we interpreted the term ''direct marketing'' to mean marketing by an MCO, PHP or PCCM or its employees; the term ''indirect marketing'' to mean marketing by an MCO, PHP, or PCCM, or its agents, affiliated providers, or contractors. The terms ''door-to-door'' and ''telephonic'' marketing are self-explanatory. We interpreted the term ''other cold-call marketing'' as other unsolicited contacts. If the Congress intended to prohibit only unsolicited door-to-door or telephone contacts, the ''other'' forms would not have been included in the prohibition. There are several other types of marketing that are permitted under this regulation. For example, States may permit the use of billboards, newspaper, television, and other media to advertise MCOs, PHPs, MCOs, or PHPs. Mailings are also permitted as long as they are distributed to the MCO's, PHP's, or PCCM's entire service area covered by the contact. States may also provide marketing materials on behalf of MCOs, PHPs, and PCCMs.

Comment: Several commenters, while indicating support for the ban on door-to-door, telephonic and other cold call marketing, expressed concern over the inclusion of physician activities including approaching a beneficiary to influence a decision to enroll with a certain plan. The commenters considered it inappropriate to place any limits on information provided to a beneficiary within the context of a doctor-patient relationship. Another commenter stated that the prohibition on contact by affiliated physicians and medical staff seems to conflict with the need to preserve continuity of care between patients and providers. The commenters observed that, although these providers may have incentives to recruit patients, these incentives must be balanced against the desire of many Medicaid patients to continue seeing providers with whom they have established a relationship.

Response: There is no prohibition against a physician responding to a patient's request for advice in the context of the doctor-patient relationship, or identifying all MCOs, PHPs, or PCCMs with which the physician has a contract. The intent of § 438.104(b)(1)(v) is to prohibit unsolicited marketing activities. Medical advice given as part of a doctor-patient relationship is not considered marketing. Our definition of cold-call marketing as ''unsolicited'' leaves patients free to seek out the advice of their providers. However, the cold call prohibition would prevent providers or their staff from approaching a patient about choosing an MCO, PHP, or PCCM. Providers are often members of several MCOs, PHPs, and PCCMs and permitting them to approach a member about any particular MCO, PHP, or PCCM could give the appearance of influence by factors not necessarily in the best interests of the patient.

Comment: One commenter called the cold-call provision ''overly restrictive'' and felt that it presented serious problems for MCOs, PHPs, and PCCMs that use clinic-based community providers. The commenter also felt that the regulation contradicted the proposed default assignment process because States are expected to assign individuals to existing providers and these providers would be restricted from giving information to assist in the process. The commenter recommended that participating physicians be permitted to provide approved informational materials about plans in which they participate to patients in their offices in an unbiased, non-threatening manner, and that the State monitor to ensure compliance.

Response: The default assignment process is considered a State's last resort for matching a non-responding individual with a provider. The fact that an individual is in a physician's office inquiring about what MCOs, PHPs, or PCCMs the provider participates in, indicates that default assignment is not likely to be necessary. However, if the individual does not make a selection, the office visit may facilitate the default assignment process because, under § 438.50(f), the State's default enrollment process must seek to preserve existing provider-beneficiary relationships. In addition, a State may choose to permit providers to display approved materials about all plans in which they participate. The regulation only prohibits unsolicited personal contact by any person or entity representing a particular MCO, PHP, or PCCM.

Comment: A commenter pointed out that safety net providers often perform outreach to uninsured individuals who may be eligible for Medicaid. The commenter believes that the marketing prohibition could discourage providers from promoting Medicaid enrollment. It was suggested that a discussion on the subject of maintaining an existing provider relationship could be interpreted as cold-call marketing. A safety-net provider indicated that they allow their physicians and medical staff to discuss options and provide literature supplied by MCOs, PHP, or PCCMs. They felt that a patient's physician often provides the best assistance and information for making an informed decision.

Response: We encourage outreach to those individuals who may be eligible for Medicaid. However, outreach which relates to establishing Medicaid eligibility should be distinct from marketing, which is considered to have a bias in favor of one MCO, PHP, or PCCM or provider option over another. Medical staff will be assumed to be acting in the best interest of the beneficiary's health when discussing or encouraging a Medicaid application. This activity would not be considered marketing unless it also includes a distinct attempt to encourage selection of a particular MCO, PHP, or PCCM. If, in the course of a discussion, a beneficiary inquires about how to continue seeing a particular provider, there is no prohibition on providing information on the MCOs, PHPs, or PCCMs in which that provider participates. On the other hand, contact with an enrollee or potential enrollee by any other person or entity on behalf of a particular MCO, PHP or PCCM (prior to establishing Medicaid eligibility or

selecting an MCO, PHP, or PCCM option) will be considered marketing and will be subject to State and Federal scrutiny.

Comment: A commenter called the restriction on physicians advising their patients ''an unnecessary gag rule'' and indicated that it would prevent a physician from steering a severe asthmatic to an MCO, PHP, or PCCM that excels in managing asthma care. The commenter also pointed out that the rule would not prevent physicians from ''trashing'' other MCOs, PHPs, or PCCMs.

Response: A distinction should be made between patient counseling based on a patient's request done by medical staff on the basis of medical factors, and steering, which may be based on inappropriate factors such as administrative or fiscal issues. Providers are free to advise their patients, as specified in § 438.102, and they may respond to questions about the availability of specific services from MCOs, PHPs, or PCCMs with which they are affiliated. States should keep in mind, however, that medical staff providing patient counseling may not necessarily be aware of other factors, such as health conditions of other family members required to join an MCO, PHP, or PHP or of areas in which other MCOS, PHPS, or PCCMs may excel.

We agree with the commenter that negative marketing activities (''trashing'') should also be addressed in this regulation, and we have done so through a new definition of ''marketing'' in § 438.104(a). Under this definition, any communication by an MCO, PHP, or PCCM (or any of its agents or independent contractors) with an enrollee or potential enrollee that can reasonably be interpreted as intended to influence that individual to decide to enroll or re-enroll in that particular Medicaid product, or either not to enroll in or to disenroll from another MCO's, PHP's, or PCCM's Medicaid product would be considered marketing and, therefore, would be covered by this regulation. We also have revised the definitions of ''marketing materials'' and ''cold call marketing to incorporate the new marketing definition.

Comment: One commenter contended that the language of the regulation was inconsistent with the language in the preamble because the regulation merely prohibits unsolicited personal contact by the MCO, PHP, or PCCM with a potential enrollee for the purpose of influencing the individual to enroll. The commenter noted that the preamble describes cold-call marketing as unsolicited contact by an employee, affiliated provider or contractor of the entity. The commenter stated that the language of the regulation was clear and concise and did not require the explanation in the preamble.

Response: In § 438.104(a), we state that any reference to MCO, PHP, or PCCM and entity includes ''any of the entity's employees, affiliated providers, agents, or contractors.'' Therefore, the regulatory language is consistent with the preamble.

Comment: Commenters agreed with the prohibition against providers attempting to influence patients to join a particular MCO, PHP, or PCCM. However, the commenters pointed out that it is difficult for States to detect this type of activity.

Response: As systems have become more sophisticated, new and more effective methods of oversight continue to evolve. The difficulty in detecting certain inappropriate activities does not relieve MCOs, PHPS, and PCCMs or States from the obligation to protect the interests of the beneficiary. Many standard methods of monitoring marketing, such as reviewing grievances and appeals from beneficiaries and providers, tracking enrollment and disenrollment trends, and conducting beneficiary surveys will help detect patterns of aggressive or unfair marketing practices.

Comment: A commenter expressed concern that this provision unduly restricts the ability of MCOs to educate enrollees or potential enrollees about managed care and does not focus on group settings for example, schools, day care centers, and churches, where MCOs could target larger groups of Medicaid enrollees. The commenter asked HCFA to broaden the provision by giving additional examples of State approved activities.

Response: This regulation does not prohibit educational activities on the part of MCOs. However, any contacts other than patient counseling by any MCO, PHP, or PCCM staff or representative would be considered marketing, subject to State oversight. The regulation does not prohibit States from permitting MCOs, PHPs, or PCCMs to market to groups, for example, schools, churches, and day care centers. States are responsible for approving and monitoring these types of presentations and ensuring that beneficiaries attend voluntarily with knowledge that they are attending a marketing presentation.

Comment: Another commenter indicated that the definition of ''cold-call marketing'' might be too broadly defined and should not apply to public places where MCOs are engaging in marketing practices approved by the State.

Response: States may permit and establish rules for marketing in public places. However, States may not permit uninvited personal solicitations in public places, for example, eligibility offices and supermarkets. Some States allow representatives of available MCOs, PHPs, and PCCMs to be in eligibility offices or other locations on certain days, or on a rotating basis to answer questions and provide information to beneficiaries. In these situations, there should be provisions to monitor contacts to ensure that unbiased information is available about all options and that beneficiaries are not coerced. However, marketing or other MCO, PHP, or PCCM representatives who approach beneficiaries as they enter or exit eligibility offices or other public places, call at residences uninvited, are considered cold-call contacts and are not permitted.

Comment: One commenter expressed concern that the regulation narrows marketing options by restricting the role of MCOs in community-based efforts.

Response: We believe the statute gives States broad authority to determine what marketing activities are permitted with the exception of unsolicited personal contacts by MCOs, PHPs, and PCCMs or their representatives. States are free to use MCOs in community-based efforts. However, those efforts are considered marketing, therefore the materials (for example, activities and presentations) are subject to State review and approval.

Definition of Marketing Materials

In the NPRM, we proposed to define marketing materials as materials that—(1) are produced in any medium, by or on behalf of an MCO, PHP, or PCCM; (2) are used by the MCO, PHP, or PCCM to communicate with individuals who are not its enrollees; and (3) can reasonably be interpreted as intended to influence the individuals to enroll or re-enroll in that particular MCO, PHP, or PCCM.

Comment: Some commenters said that the definition of marketing materials should not include communication intended to serve the needs of existing enrollees and suggested that the regulation be revised to clarify that marketing materials are those materials intended to influence non-enrollees to join a particular MCO, PHP, or PCCM. One commenter thought the definition of marketing materials was incomplete and should be changed to read ''can reasonably be interpreted as intended to influence the individual to enroll or re-enroll in that particular MCO, PHP, or

PCCM.'' Another commenter indicated that the combination of requirements at proposed § 438.104(a) (definition of marketing materials) and proposed § 438.104(b)(2)(1) (prohibition on the distribution of marketing material without State approval) required States to approve all marketing materials prior to distribution, whether or not they are targeted to Medicaid beneficiaries. It was pointed out that this would be administratively impossible and could raise constitutional issues.

Response: We disagree with the first commenters who favored limiting marketing materials to those directed at individuals who are not enrollees (which was the position taken in the NPRM), and agree with the second commenter who endorsed the language in the definition referring to influencing individuals to ''re-enroll.'' In such a case, the individual already is enrolled and the portion of the definition referring to ''individuals not enrolled'' conflicts with the language favored by the commenter. We therefore have removed the portion of the definition limiting its applicability so that it is clear that marketing materials include those intended to influence both enrollees and potential enrollees. States retain the authority to interpret the term and are responsible for evaluating whether certain materials satisfy the definition. States may interpret this term broadly and determine that all materials are subject to review, but we assume that many States will determine that routine correspondence (such as appointment reminders) do not fall within the definition of ''marketing materials'' and therefore are not subject to review.

We have incorporated the new definition of marketing into the definition of ''marketing materials.''

Comment: Commenters supported our broad definition of marketing materials and our efforts to ensure the accuracy and truthfulness of the materials. However, some commenters felt that an absence of a clear definition of marketing could mean that many activities, for example, hiring community residents to talk about the benefits of belonging to a particular plan or persuading neighbors to join a plan, might not be covered. The commenters indicated that a common usage understanding of the term ''materials'' would not appear to include a spokesperson or representative. They also stated that it was unclear whether paying neighbors to say nice things about a plan would constitute cold call marketing. They suggested that we include a broad definition of marketing and include examples of marketing, and of false and misleading marketing. One commenter suggested that the following language, ''inaccurate, false, or misleading statements include, but are not limited to, any assertion or statement (whether written or oral) that—(1) the beneficiary must enroll in the MCO, PHP, or PCCM in order to obtain benefits or in order not to lose benefits; or (2) the MCO, PHP, or PCCM is endorsed by the Federal government, State government or us.'' Another commenter recommended that we expand the regulation by requiring States to review marketing materials to ensure that MCOs do not imply that all persons are required to enroll in managed care in order to continue receiving Medicaid benefits.

Response: The comments recommending a ''definition of marketing'' have been addressed by our inclusion of a separate definition of marketing in this final rule with comment period. As noted above, we have defined ''marketing'' as ''any communication, from an MCO, PHP, or PCCM to an enrollee or potential enrollee that can reasonably be interpreted as intended to influence the recipient to enroll or re-enroll in that particular MCO's, PHP's, or PCCM's Medicaid product, or either not to enroll, or to disenroll from another MCO's, PHP's, or PCCM's Medicaid product.'' We also agree that language suggested by the commenter would be helpful, and provide in § 438.104(b)(2) that inaccurate, false, or misleading statements include, but not limited to any assertion or statement (whether written or oral) that the beneficiary must enroll in the MCO, PHP, or PCCM in order to obtain benefits, not to lose benefits, or that the MCO, PHP, or PCCM, is endorsed by either the Federal government, State government, similar entities or us.

States are required to review and approve all marketing materials under § 438.104(b)(1)(i). We expect this review to include screening for misleading information including any implication that individuals who are not required to enroll will lose their benefits if they do not enroll. In addition, the revised information provision at § 438.10(d)(2)(i)(B) requires that beneficiaries must be informed prior to selection of an MCO about which populations are excluded from enrollment, subject to mandatory enrollment, or free to enroll voluntarily.

Comment: One commenter believed that the definition of marketing materials was too narrow because it did not address materials developed by State agencies (for example, the Office of Mental Hygiene and the Office of Developmental Disabilities) that participate in informing and encouraging potential enrollees about managed care. The commenter recommended that other parties have the authority to refer materials being used for marketing purposes to the MCAC or similar reviewing body to review and determine if the materials are unbiased.

Response: Section 438.104 addresses marketing materials that are produced by or on behalf of an MCO, PHP, or PCCM. To the extent that a State agency such as those mentioned by the commenter is acting as a PHP (for example, as a provider of behavioral health services under a ''carve-out''), any materials it generates would be subject to the requirements in § 438.104. If, however, the agency has no stake in where an individual enrolls, and is essentially acting on behalf of the State Medicaid agency, it is not clear what ''bias'' the agency would have that would be detected by review. We therefore do not believe that review of such materials pursuant to § 438.104 is necessary or appropriate.

We note that § 438.10 requires that all information for enrollees and potential enrollees meet language and format requirements to facilitate understanding and take into consideration special needs. This applies to information furnished by any State or local agencies. States may choose to require the review of materials other than those subject to review as marketing materials under § 438.104.

Comment: A commenter suggested that we require that marketing material be distributed to the entire geographic area at least 90 days prior to enrollment, and only after the material is approved.

Response: The length of time needed for distribution of marketing materials may vary from State to State depending on factors, for example, Medicaid managed care penetration. Therefore, we do not mandate specific time frames for marketing activity. We encourage States to carefully consider the timing of the distribution of any marketing or other materials to maximize informed choice. The information provision at § 438.10(d)(1)(iii) requires that basic information be provided within a time frame that enables potential enrollees to use the information in choosing among available MCOs. With respect to mandatory managed care programs, we require States to establish standards and time requirements for fully informing and providing sufficient time to make an informed choice.

In response to the last part of the commenter's concerns, the regulation does require that all marketing materials

be reviewed and approved by the State prior to distribution. Failure by an MCO, PHP, or PCCM to submit materials for review may result in sanctions by the State in accordance with § 438.700(c).

Comment: Several commenters asked that we clarify requirements related to reproductive health services. The commenters believe that we should require marketing materials to contain clear and prominent information about any reproductive health services not covered by the plan. Commenters recommended that marketing materials specify any Medicaid-covered reproductive health benefits that are not provided by the plan and state that all Medicaid beneficiaries have the right to obtain family planning services and supplies from any Medicaid participating provider. They also recommended that materials clearly indicate which subcontracting entities, for example, hospitals, medical groups, or subnetworks restrict access to reproductive health services.

Response: We agree with the commenters that Medicaid beneficiaries should have clear and complete information on the availability of family planning services. We have not, however, included specific requirements relating to family planning services in this section. In § 438.10, we require that the information furnished to enrollees and potential enrollees specify any benefits that are available under the State plan but are not covered under the contract, including how and where the enrollee may obtain those benefits, any cost-sharing, and how transportation is provided. We have also revised the information requirements to require that the information furnished to enrollees identify the extent to which, and how, enrollees may obtain benefits, including family planning services, from out-of-network providers. We refer the commenters to the comments and responses for proposed § 438.10.

Comment: A commenter asserted that the requirement that the State approve marketing materials prior to distribution would be difficult to implement because of time constraints. The commenter speculated that documents would have to be provided at least 30 days in advance and the State would incur additional administrative burden and costs. The commenter recommended that legislative action be taken to delete this requirement. Another commenter stated that the regulations did not specify that all health plan information and marketing materials must be approved by the State agency. The commenter suggested that we mandate strict requirements for accuracy and disclosure and require State review of all health plan information.

Response: The commenter is correct that legislative action would be required to eliminate the requirement for State review and approval of marketing materials under section 1932(d)(2)(A) of the Act. We note that many States already required prior approval of marketing materials prior to enactment of this requirement in the BBA. One State commented that these provisions posed no problem because its contracts and marketing manual already contained provisions that comply with or exceed these requirements. We believe that State review and approval is extremely important and that any burden should be offset by the additional protections afforded Medicaid beneficiaries. Marketing materials for MCOs contracting with Medicare undergo similar review prior to distribution, so this provision aligns Medicaid more closely with the Medicare rules.

Comment: A commenter suggested that marketing materials be made available in formats other than Braille for the visually impaired. The commenter believes that States and MCOs, PHPs, or PCCMs need flexibility in determining the appropriate formats, such as large print, audiotape or other formats in addition to Braille.

Response: There is no requirement in the regulations that marketing materials be in Braille for the visually impaired. The discussion of § 438.10 in the preamble of the proposed rule stated that all materials take into account specific needs of enrollees and potential enrollees, including furnishing information in alternative formats for the ''visually impaired (through other media for example, large print, Braille, or audio tapes) * * *'' (63 FR 52029). Section 438.10(c)(2) requires that materials be available in alternative formats that take into consideration, for example, the special needs of those who are visually impaired or have limited reading proficiency. States have the flexibility to decide which formats are most appropriate.

c. Requirements and Prohibitions

Proposed § 438.104(b) provided that MCO, PHP, and PCCM contracts must specify the methods by which the entity assures the State agency that marketing plans and materials are accurate and do not mislead, confuse, or defraud beneficiaries or the State. The proposed rule also stated that MCO, PHP, and PCCM contracts must provide that the entity distribute materials to the entire service area—(1) does not distribute marketing materials without prior approval; (2) complies with the information requirements in § 438.10; (3) does not seek to influence enrollment with the sale of other insurance; and (4) does not engage in cold-call marketing.

Comment: Several commenters believed that the language in proposed § 438.104 was vague, merely repeated the statutory language, and provided little concrete guidance to States or MCOs, PHPs, and PCCMs. Commenters suggested that we establish a detailed review guide with specific criteria developed with input from Medicaid beneficiaries and their advocates and that we review all MCO contracts for their marketing plans.

Response: We currently have marketing guidelines that will be updated to reflect the requirements of this final rule with comment period. In developing these guidelines, we often rely on prior implementation experience, including input from affected parties. We regularly use these types of guidelines, as we review and approve MCO, PHP, and PCCM contracts.

Comment: One commenter argued that it was unnecessary to require that MCO, PHP, and PCCM contracts specify the methods by which they will assure that marketing materials do not mislead or confuse. The commenter stated that the requirement that marketing materials be submitted to the State prior to use would be sufficient to ensure the desired outcome.

Response: We believe that both prior approval and contract review provide important beneficiary protections and both are specifically required by the law. Section 1932(d)(2)(A)(i) of the Act specifically requires prior approval of marketing materials by the State and that the materials do not contain false or misleading information. The requirement that the contract contain such assurances has been in § 434.36 since 1988, based on a provision of the Act which the BBA did not remove. States and MCOs should be used to complying with this provision.

d. Service Area

Proposed § 438.104(b)(2)(ii) required that marketing materials be distributed to the entire service area.

Comment: One commenter applauded this requirement stating that without it health plans might attempt to engage in preferential selection of enrollees by excluding geographic areas where Medicaid beneficiaries have higher costs. The commenter believes that we should expand this requirement to ensure that MCOs, PHPs, and PCCMs do not attempt similar preferential

practices through other means, for example, refusing to provide marketing materials in certain languages, developing marketing materials that are difficult to understand, or by distributing materials in ways or in places that exclude people with disabilities. The commenter recommended that we state explicitly in regulations that discrimination on any of these bases is not permissible. Another commenter suggested that MCOs', PHPs', and PCCMs' marketing activities not be permitted to ''red-line'' certain areas of the community or certain groups of people because vulnerable populations, such as those with mental retardation are often targets for marketing ''scams.''

Response: We believe that the commenters' concerns are addressed in other sections of the regulation. Section 438.10 specifies general requirements that apply to all information furnished to enrollees including requirements relating to language and format. Section 438.6(d)(3) requires that MCO, PHP, and PCCM contracts provide that the MCO, PHP, or PCCM will not, on the basis of health status or need for health services discriminate against individuals eligible to enroll. In addition, MCO, PHP, and PCCM contracts must specify that the MCO, PHP, or PCCM will not discriminate against individuals eligible to enroll on the basis of race, color, or national origin, and will not use any policy or practice that has the effect of discriminating on the basis of race, color, or national origin. In § 438.206(d)(7), we require the State to ensure that an MCO ensure that its providers do not discriminate against Medicaid enrollees. We specifically provided in § 438.100(d) that the State must ensure that each MCO, PHP, and PCCM complies with applicable Federal and State laws, (for example, Title VI of the Civil Rights Act of 1964, The Age Discrimination Act of 1975, The Rehabilitation Act of 1973, and Titles II and III of the Americans with Disabilities Act). We believe that these sections sufficiently protect the beneficiary against the discriminatory practices identified by the commenter, and therefore we have not incorporated any additional changes into § 438.104.

Comment: Several commenters believed that the service area requirement in proposed § 438.104(b)(2)(ii) could impede an MCO's, PHP's, or PCCM's ability to reach targeted populations with unique needs or characteristics within service areas. Commenters provided examples such as mailings to certain zip codes informing members of activities at a hospital in their neighborhood and mailings to specified non-English speaking populations in the service area. One commenter asserted that the proposed policy makes distribution problematic because services must be provided in a culturally competent manner but a marketing plan cannot be varied to target specific populations. In addition, a commenter explained that States often allow new MCOs to begin rolling out a program in certain counties within the service area. The commenter asserted that the proposed rule would prohibit MCOs from mailing to just those portions of the service area in which they are allowed to enroll. Some commenters believed that the proposed requirement was unnecessary, unduly burdensome and costly. One commenter contended that because the proposed definition of marketing materials included billboards and media advertisements, the ''service area'' requirement was unrealistic. One commenter felt that the provision would also inappropriately prohibit activities such as health fairs if material disseminated during these activities has not been distributed to the entire service area. Another commenter suggested that MCOs, PHPs, and PCCMs be encouraged to distribute materials where they have current capacity to serve more members and should be permitted to conduct local advertising, such as that carried out in collaboration with a particular clinic or group practice where appropriate. Another commenter acknowledged the need to ensure that MCOs, PHPs and PCCMs do not engage in risk pool segmentation, but felt that the regulation needed to be more flexible to accommodate circumstances where MCOs, PHPs, and PCCMs may wish to communicate information about locally available services to those residing in subareas of the overall service area.

One commenter recommended that we require MCOs, PHPs and PCCMs to distribute materials to all eligible enrollees in a specified county or region to avoid confusion to those in a particular sector in which the marketing materials do not apply. Some commenters indicated that MCOs, PHPs, and PCCMs, should have the ability to tailor the form and style of marketing to communicate effectively with demographic subgroups of a service area. Others suggested that the service area-wide distribution requirement apply just to MCO, PHP, and PCCM mailings of marketing materials and that those currently enrolled in the MCO, PHP, or PCCM be excluded from the requirement. One commenter thought it reasonable to require that materials be sent only to those who are eligible or potentially eligible for Medicaid in a given service area.

Response: Section 1932(d)(2)(B) of the Act requires that marketing materials be distributed to the entire service area. The intent of this provision is to prohibit marketing practices that favor certain geographic areas over those thought to produce more costly enrollees. However, the regulation might not allow for diversity and cultural sensitivity. In response to the commenters' concerns, we have revised proposed § 438.104(b)(2)(ii) (redesignated as § 438.104(b)(1)(ii) in this final rule with comment period) to require that each MCO, PHP, and PCCM contract must provide that the entity ''distributes the materials to its entire service area as indicated in the contract.'' The phrase ''as indicated in the contract'' is intended to provide States and MCOs, PHPs, and PCCMs with some flexibility in designing and implementing marketing plans and in developing marketing materials. We expect that when States review MCO, PHP, PCCM, or marketing and informing practices, they will not only consider accuracy of information, but also factors such as language, reading level, understandability, cultural sensitivity, and diversity. In addition, the State review should ensure that MCOs, PHPs, and PCCMs do not target or avoid populations based on their perceived health status, cost, or for other discriminatory reasons. For example, a State may permit distribution of materials customized for an Hispanic population group as long as the materials are comparable to those distributed to the English speaking population. While the presentation and formats of the information may be varied based on the culture and distinct needs of the population, the information conveyed should be the same in accordance with § 438.10. In the above example, the materials for the Hispanic population group must be distributed to all those Medicaid eligibles or enrollees who require or request Hispanic-related materials. Materials would not need to be distributed to every individual in a given service area, but they would need to be distributed to all known Medicaid eligibles or enrollees in an area. States that use this flexibility to allow selective marketing may permit distribution by zip code, county or other criteria within a service area if the information to be distributed pertains to a local event such as a health fair, a provider, hospital or clinic. However, States must ensure that health fairs are not held in areas only known to have or perceived

as having a more desirable population. We have chosen not to limit the distribution requirement only to mailings because broadcast advertising and other marketing activities can also be done selectively. All marketing activities should be conducted in a manner that provides for equitable distribution of materials and without bias toward or against any group.

Comment: Some commenters asked whether marketing materials must be distributed to the entire service area all at once. Because materials may generate significant interest and phone calls to the MCO, PHP, or PCCM, and distributing materials to the entire service area at one time could be overwhelming. The commenters asked that staggered mailings be allowed so that responses to potential member inquiries can be timely. They also wanted flexibility to distribute marketing materials by zip code.

Response: States that permit marketing may oversee incremental distribution of marketing materials as long as the service area wide distribution requirements are observed.

Comment: Some commenters believe that States should ensure that when MCOs, PHPs, and PCCMs distribute marketing materials to the entire service area, the materials are in the languages spoken in that area, and proportional to the number of beneficiaries in the area with limited English proficiency. The commenters asserted that it is critical that the enrollment activities and the enrollment staff be capable of communicating effectively with those who have limited English proficiency and that there be adequate supplies of marketing materials in the appropriate languages. Several commenters contended that the regulation was too vague in this area, and should provide more concrete guidance.

Several comments, although not specifically addressing the service area distribution requirement, emphasized that MCOs, PHPs, and PCCMs (and their enrollment staff and written materials) be tailored to the needs of those with limited English proficiency. They also recommended that materials be appropriately translated throughout the service area. The recommendation was that this be required, and that guidelines be established for appropriate marketing to non-English and limited English-speaking individuals. One commenter observed that there are no cultural and linguistic requirements for marketers in the regulation and suggested that we require assurances of cultural and linguistic competency of marketers.

Response: We agree with the commenters that it is important for potential enrollees and enrollees with limited English proficiency have access to information in the appropriate language. Section 483.10(b) provides specific guidance regarding the language requirements applicable to information furnished to potential enrollees and enrollees. These requirements apply to all information, including marketing material, therefore, we do not believe that further guidance is needed in this section of the regulation.

Comment: One commenter urged that providers who contract with an MCO, PHP, or PCCM be able to market their program and services to other managed care entities inside and outside of their geographic area in order to fill vacancies. The commenter believed that the marketing restrictions might allow MCOs, PHPS, and PCCMs to unreasonably restrict the ability of providers to contract with other entities. The commenter recommended that the marketing restrictions not be applicable to marketing materials developed by a provider who contracts with an MCO, PHP, or PCCM to solicit services and fill vacancies.

Response: The marketing restrictions contained in this regulation apply to MCO, PHP, or PCCM marketing directly or indirectly to Medicaid enrollees and potential enrollees. The provision does not apply to certain providers or facilities marketing their services to MCOs, PHPs, or PCCMs.

Sale of Other Insurance

Proposed § 438.104(b)(2)(iv) required MCO, PHP, and PCCM contracts to assure that the entity does not seek to influence enrollment in conjunction with the sale of any other insurance. We stated in the preamble that we interpreted this provision to mean that MCOs, PHPs, and PCCMs may not entice a potential enrollee to join the MCO, PHP, or PCCM by offering the sale of any other type of insurance as a bonus for enrollment. However, we invited comment on this provision because we did not have any legislative history to consider when developing our interpretation.

Comment: Several commenters believed that language in this section was vague and needed clarification. Others expressed support for our interpretation prohibiting the offering for the sale of any other type of insurance as a bonus for enrollment and felt that the choice of an MCO, PHP, or PCCM must be unaffected by extraneous and conflicting incentives.

Some commenters encouraged us to prohibit other types of bonuses or gifts as inducements to enroll. These commenters noted that in the past, gifts have been offered to induce individuals to sign forms that they did not realize would change how they access their health care. Commenters recommended that, if we allow MCOs, PHPs and PCCMs to offer additional health care benefits for which they are not at risk, we should require minimum time periods during which the benefits must be offered, and require advance notice to members and an opportunity to change MCOs, PHPs, or PCCMs for cause if the benefits are discontinued. For example, commenters stated that some MCOs, PHPs, or PCCMs have offered extra benefits (eyeglasses) to induce enrollment and then discontinued these benefits after the initial enrollment period ended. Commenters indicated that Federal regulation was necessary in order to reduce the adverse impact of practices without entirely discouraging the provision of the extra benefits.

One commenter observed that inducements are generally ineffective, except when plans are essentially indistinguishable to beneficiaries. The commenter suggested that MCOs, PHPs, and PCCMs be encouraged to pursue market differentiation by offering better information about their quality and other attributes.

Response: In the past, we have provided guidance to States concerning incentives to enroll and the marketing of these incentives. However, we do not consider the expansion of the list of prohibited incentives to be within the purview of this regulation. States may permit MCOs, PHPs, and PCCMs to offer nominal incentives, similar to those commonly offered to commercial populations, or may choose to prohibit this practice entirely. States may also choose to set standards governing the offering of additional benefits. MCOs, PHPs, and PCCMs should be aware that practices such as offering additional benefits and the discontinuation of these benefits may, under certain circumstances, be considered deceptive, misleading or fraudulent activity and, therefore, could subject them to penalties. In response to commenters requesting clarification, we have revised the language to include situations where additional insurance is offered even if it is not offered for sale. This would include situations where, for example, an MCO offers a free burial insurance policy as an incentive to join that MCO.

State Agency Review

Proposed § 438.104(c) provided that, in reviewing the marketing materials submitted by MCOs, PHPs, and PCCMs, the State must consult with its MCAC or an advisory committee with similar

membership. In § 431.12 of our existing rules, we established the requirements for an MCAC. The MCAC must include Board-certified physicians and other representatives of the health professions who are familiar with the medical needs of low income populations and with the resources available and required for their care. The MCAC must also include the Director of the Public Welfare Department or the Public Health Department, whichever does not head the Medicaid agency, as well as members of consumer groups including Medicaid beneficiaries and consumer organizations such as labor unions, cooperatives, and consumer-sponsored prepaid group practice plans.

Comment: A commenter requested clarification as to whether, when neither the Director of the Public Welfare Department, nor the Director of the Public Health Department was not the head of the Medicaid agency, if both were required to serve on the MCAC. This commenter also asked if the director(s) could designate a staff member to serve on the MCAC.

Response: We recognize that in some States neither the Director of the Public Welfare Department nor the Director of the Public Health Department is the head of the Medicaid agency. In this case, the State has the flexibility to decide if only one of these departments is represented on the MCAC or both are included. We also believe that, as long as the basic requirements at § 431.12 are satisfied, the specific rules governing the administration of the MCAC are properly left to the State's discretion. For example, States may permit the Director of the Public Health Department or the Public Welfare Department to delegate their representation to other qualified individuals representing their Department.

Comment: Commenters suggested that the composition of the MCAC should be revised to include at least one MCO, PHP, or PCCM that provides services to beneficiaries. One commenter suggested that beneficiaries with disabilities be represented on the MCAC. Another commenter suggested that the MCAC membership and role be clearly stated and public.

Response: The State may always add to the current MCAC composition requirements to include representatives of any affected groups or entities, such as MCOs, PHPs, or PCCMs. We encourage States to have an MCAC membership that is diverse and represents groups served by the State's program, for example, minorities and individuals with special needs. With respect to the final comment, we note that § 431.12 requires that the State plan must ''provide for a MCAC meeting the requirements of this section'' and that the State plan is a public document. We would encourage States to ensure that the public is clearly and completely informed about the role and membership of the MCAC or any similar committee.

Comment: One commenter felt that HCFA went beyond the requirements of section 1932(d)(2)(A)(ii) of the Act in requiring consultation with a committee with specific composition since the statute refers only to a ''MCAC.''

Response: We believe that in using the term ''MCAC'' the Congress intended to refer to the requirements in § 431.12 governing MCACs. We recognize, however, that consultation regarding marketing materials is a new and distinct function, and that the State may wish to designate a separate committee to perform this function rather than require the existing MCAC to assume it. We want to afford States the flexibility to develop a second committee, but we require that any committee charged with this responsibility also comply with the existing MCAC requirements in § 431.12.

Comment: Some commenters believed that it was not appropriate to include Medicaid consumers on a MCAC charged with reviewing proposed marketing materials from competing HMOs.

Response: The requirement for consumer participation in the MCAC has been in the regulations for many years. When the Congress specifically identified a ''medical care advisory committee'' as a consultant in the review and approval of marketing materials, we believe that they intended to incorporate by reference the current composition requirements of the required advisory body with this name. We continue to believe that consumers are extremely helpful in this advisory capacity because they are the intended audience of marketing materials and can provide important feedback on the review and approval of materials.

Comment: Many commenters contended that the use of a MCAC to review and approve specific pieces of marketing material was impractical, burdensome, unrealistic, and an example of micro-management. Many States' MCACs meet monthly, bi-monthly, or quarterly. Several commenters believe that it would be difficult, if not impossible, to provide the quick turnaround, in some cases ten days or less, necessary for approval of marketing materials. Some States require that marketing materials be submitted sixty days prior to intended use and some commenters believed that adding another level of review would slow down the process. The regulation was also called, by one commenter ''unnecessary and bureaucratic'' and not in keeping with the guiding principles cited in the preamble.

Many commenters who objected to MCAC review of marketing materials suggested that the MCAC or similar body review generic marketing materials or approve guidelines instead of reviewing each individual MCO's, PHP's, or PCCM's materials. Some commenters stated that the committee could establish review standards and then State or local staff trained in those standards could perform the actual review. They indicated that the committee's role should be consultative and not decision making. Others suggested that marketing materials be reviewed retroactively.

Response: We do not intend to require that the committee itself review and approve marketing materials. Rather, we intend to reflect section 1932(d)(2)(A)(ii) of the Act, which requires the State to consult with the committee during the State's own process of review and approval. The State is not required to obtain the committee's approval or consensus on the materials. The State has tremendous flexibility in determining how to consult with the committee. A State may elect to require the committee to review the actual marketing materials. If so, then in order to expedite the total review time, the State could permit the committee members to conduct their review concurrently with the State's review.

States may also consult with the committee in the development of standardized guidelines or protocols that are intended to facilitate State review. States may consult with the committee to develop suggested language and deem approval of an MCO's, PHP's, or PCCM's materials if that language is used. MCOs, PHPs, and PCCMs could also use some of the suggested language and then identify areas where different language has been used, and States could then limit the review or consultation to that particular portion of the materials. In response to the last comment, we believe that the statutory language (''in the process of reviewing and approving'' marketing materials) precludes consulting with the committee retroactively.

Comment: One commenter suggested that the composition requirements of the MCAC could result in a conflict of interest between members and MCOs, PCCMs, and PHPs. Another commenter

suggested that the MCAC be held to confidentiality standards.

Response: The MCAC composition requirements have been in the regulations for over twenty years, and have always involved the potential for conflict between providers and beneficiaries who are served by the providers. We do not believe that this regulation raises any new concerns regarding conflicts of interest. Therefore, we are not revising the composition requirements in this final rule with comment period. We would not anticipate that the MCAC or any similar advisory body would have a need to review or have access to individually identifiable information about Medicaid beneficiaries, but if they did, then they would be governed by the same confidentiality standards that apply to the State Medicaid agency (Subpart F, Part 431).

Comment: Many commenters expressed strong support for requiring that marketing materials be reviewed by a committee to ensure that the materials are not false or misleading and to ensure that the information is understandable. One commenter stated that using established MCACs would not provide a level of consumer and advocate involvement sufficient to identify and resolve problems or develop appropriate policies. This commenter recommended that States be required to actively work with consumers on contract development, client protections, quality assurance, and problem resolutions.

Response: We appreciate the commenters' support. This provision, however, is intended to be limited to requiring consultation with a committee that includes consumer representation on the subject of the review and approval of marketing materials. This provision does not speak to the need for consumer participation in the development of the entire managed care system. We do require consumer involvement in other sections of this final regulation; for example, in § 438.202(c) we require the State to provide for the input of beneficiaries and other stake-holders in the development of the quality strategy, which must include making the strategy available for public comment before adopting the quality strategy. We encourage involvement by stakeholders during all phases of managed care implementation.

Comment: Commenters pointed out that neither the nature of the consultation nor its expected outcome was specified in the proposed rule.

Response: The legislative history do not indicates that the Congress intended for the consultation to be of any specific nature or have any specific outcome. Instead, it prescribe a Federal standard. We believe it is more appropriate to permit States to define the specific role of the committee.

Comment: A commenter pointed out that States that have adopted model legislation developed by the National Association of Insurance Commissioners (NAIC) have regulatory processes in place for the review of marketing materials and that MCAC involvement could lead to conflicts between the MCAC and the regulatory body.

Response: The NAIC's ''Advertisements of Accident and Sickness Insurance Model Regulation'' sets forth minimum criteria to ensure proper and accurate description of products and to protect prospective enrollees. The criteria are similar to the criteria for advertisements of Medicare supplemental insurance. States are free to use all or part of this model to craft their marketing standards and contract language. A State's use of NAIC or similar standards should neither conflict with nor complicate consultation with the MCAC or similar committee because the committee should be following standards adopted by the State.

4. Liability for Payment (§ 438.106)

Proposed § 438.106, consistent with section 1932(b)(6) of the Act, required MCOs to provide that their Medicaid enrollees will not be held liable for—(1) the debts of the MCO in the event of insolvency; (2) services provided to the enrollee for which the State does not pay the MCO or the MCO does not pay the individual or provider that furnishes the services under a contractual, referral, or other arrangement; or (3) payments for services furnished under a contract, referral, or other arrangement, to the extent that those payments are in excess of the amount that the enrollee would owe if the MCO provided the services directly.

Comment: We received several comments in response to our request for public guidance on § 438.106(c) that refers to beneficiary liability for payments to a provider ''in excess of the amount the enrollee would owe if the MCO provided the services directly''. Most commenters agreed with our position that Medicaid managed care enrollees should not be responsible for more than nominal charges for cost sharing. One commenter sought clarification of when the situation described in § 438.106(c) would apply, and another suggested that the amount owed by the Medicaid beneficiary should be any cost sharing required by the contract. Another commenter suggested that the provision may have been intended to address a recent trend in the managed care industry of establishing coverage options that allow enrollees to go out of network for services in exchange for higher premiums or co-pays (that is, ''point-of-service'' options), as there may have been concern that this type of coverage could be interpreted by MCOs as a non-Medicaid benefit for which they could charge.

Response: As we stated in the preamble to the proposed rule, Medicaid beneficiaries should not ''owe'' an MCO any payment amounts beyond nominal cost sharing. Section 1916 of the Act specifically prohibits States and plans from imposing additional cost sharing. We agree with the comment that § 438.106(c) would prohibit MCOs from offering a point-of-service option. This paragraph states that an enrollee may not be held liable for payment (for services furnished under a contract, referral, or other arrangement) in excess of the amount that the enrollee would owe if the MCO provided the services directly. In other words the enrollee may only be held liable for nominal cost sharing.

Under this regulation, enrollees may obtain out-of-network services under the following circumstances:

- Enrollees may always obtain family planning services out-of-network, as provided in our current regulations at § 431.51;
- Enrollees who reside in rural areas and are mandatorily enrolled in a single MCO, PHP, or PCCM may obtain out-of-network services as provided in § 438.52(b);
- Enrollees may obtain emergency and post-stabilization services from out-of-network providers as specified in § 438.114;
- Enrollees may obtain services out-of-network if the network is unable to meet an enrollee's medical needs as specified in § 438.206(d)(5).

The protection in § 438.106(c) would apply under all of these circumstances, therefore, the enrollee could not be held liable for costs in excess of the amount that the enrollee would owe if the MCO provided the services directly.

Comment: Several commenters were concerned that § 438.106 could be interpreted to require an MCO to pay its network providers for services that are not covered under the Medicaid State plan or are furnished by its network providers not in accordance with the provider's contract terms with the MCO. They suggested that we add language to clarify that the MCO's obligations are limited to those services that are covered under the contract between the

State agency and the MCO, as well as to those services covered under the contract between the MCO and the provider.

Response: In this section, we intend to protect beneficiaries against liability for payment of covered services. We agree with commenters that the proposed language could be interpreted as prohibiting enrollee liability for non-covered services or non-emergency or urgently needed services provided out of network, although this is not the intent. We therefore provide in this final rule with comment period at § 438.106(b) and (c) that enrollees cannot be held liable for ''covered'' services. ''Covered'' services would include any service that the State covers through its managed care program, whether it is a service that is covered under the contract between the State and the MCO (including additional or alternative services to traditional State plan services), or a service that is carved out of the capitation rate and paid fee for service, as long as the service is obtained appropriately. This provision does not preclude enrollee liability for non-covered services, or for covered services that are obtained inappropriately (for example, services obtained without a referral when one was required) unless, on appeal, it is determined that the services are covered.

Comment: One commenter requested that we add language that incorporates the ''hold harmless'' concept developed by the NAIC. Specifically, the commenter suggested that we revise the regulations to provide that beneficiaries should be ''held harmless'' for the cost of covered services except for applicable cost sharing.

Response: We believe that the provisions of § 438.106, as written, sufficiently convey that enrollees may not be held liable for the cost of covered services except for nominal cost sharing. We do not believe it is necessary to add additional language referencing the NAIC's ''hold harmless'' concept.

Comment: Several commenters suggested that we clarify that beneficiaries should not be held liable for family planning services covered under the Medicaid program, nor should they be held liable for reproductive services that are not provided by the health plan or its subcontracting providers or that are not reasonably accessible within the health plan.

Response: As stated above, we have revised § 438.106 to reflect that enrollees may not be held liable for ''covered'' services, which include family planning services. Section 431.51(a)(4), (5), and (6) provide that Medicaid beneficiaries enrolled in an MCO, PHP, or PCCM may not be denied freedom of choice for family planning services. This means that even family planning services that an enrollee obtains out of network are ''covered'' services for which the beneficiary may not be held liable. In addition, § 447.53(b)(5) states that cost sharing cannot be imposed for family planning services and supplies. Therefore, we do not believe it is necessary to specifically address family planning services in § 438.106.

5. Cost Sharing (§ 438.108)

Prior to the enactment of the BBA, MCOs were prohibited from imposing cost sharing on enrollees. The BBA eliminated this prohibition, and provided that copayments for services furnished by MCOs may be imposed in the same manner as they are under fee-for-service. In § 438.108 of the NPRM, we proposed that the contract must provide that any cost sharing imposed on Medicaid enrollees is in accordance with § 447.50 through § 447.58 of existing regulations.

Comment: One commenter recommended that we specify in § 438.108 that family planning services and supplies are excluded from cost sharing.

Response: This section specifies that any cost sharing imposed for services provided by an MCO must be in accordance with § 447.50 through § 447.58 of our rules. Because § 447.53(b)(5) states that cost sharing cannot be imposed for family planning services and supplies, we do not believe it is necessary to refer to this exclusion again under § 438.108.

Comment: Several commenters believed that it was important that contracts make clear that any cost sharing imposed under the contract must be nominal. Commenters also expressed concern that cost sharing could become a barrier to care, and that cost sharing requirements could be particularly problematic for enrollees who regularly use the health care system. The commenters believe that even nominal copayments, if consistently collected by MCOs, could deter enrollees from obtaining needed care.

Response: The regulation clearly requires that any cost sharing imposed for services delivered either by an MCO or under fee-for-service be nominal. We agree with the commenters that cost sharing may act as a deterrent to obtaining care. Therefore, in § 447.53, we are adding a new paragraph (e) that states: ''No provider may deny care or services to an individual eligible for the care or services on account of the individual's inability to pay the cost sharing.'' This language closely tracks the statutory language in section 1916(e) of the Act. This provision applies to services furnished either by an MCO or under fee-for-service.

Comment: One commenter suggested that we exclude enrollees receiving home and community-based waiver services from cost sharing.

Response: The BBA did not identify any new groups of enrollees to be excluded from cost sharing. The law only provided that cost sharing for MCO services may be permitted in the same manner as it is permitted under fee-for-service. Enrollees receiving home and community-based waiver services are not excluded under our current fee-for-service program and therefore, we are not excluding them from cost sharing for services furnished by an MCO. We note that States may always elect not to impose cost sharing on all enrollees or on specific groups of enrollees.

Comment: A few commenters stated that cost sharing creates a barrier to American Indian and Alaskan Native (AI/AN) participation in Medicaid programs, because they can access the Indian Health Service (IHS) and tribally-operated programs without paying for services. Further, the commenters noted that IHS and tribal providers are not authorized by the Congress to impose cost sharing for services provided to American Indians. These commenters recommend that we exercise the Federal trust responsibility to provide health care for AI/AN populations by exempting them from any cost sharing in Medicaid programs. Since the Federal government pays 100 percent FMAP for services delivered by tribally operated facilities, the commenters believe there should be a provision explicitly prohibiting States from imposing cost sharing on AI/AN Medicaid beneficiaries.

Response: The Congress has been very specific in section 1916 of the Act in specifying which categories of individuals or services are exempt from cost-sharing, and we believe that it would be inconsistent with Congressional intent to exempt additional groups. We note that under § 447.53(b)(1), all children (including AI/AN children) are exempted from cost sharing.

Comment: One commenter recommended that we eliminate the application of § 447.57 to cost sharing for services furnished by MCOs. The commenter stated that § 447.57 prohibits States from reimbursing providers for unpaid copayments. The

State Medicaid plan must specify that the State agency does not increase the payment it makes to any provider to offset uncollected amounts for deductibles, co-insurance, copayments, or similar charges that the provider has waived or are uncollectible. The commenter expressed concern that this provision inappropriately places the economic burden of unpaid copayments on health care providers, such as community pharmacies. The commenter stated that requiring pharmacies to absorb the cost of unpaid copayments discourages participation by pharmacies in Medicaid MCOs and discourages MCOs from participating in Medicaid.

Response: The BBA allows us to permit copayments under managed care in the same manner as we permit them under fee-for-service. At this time, we are not proposing to revise the rules that apply under fee-for-service to remove the requirement that States not reimburse providers for uncollected payments. Therefore, it will also apply to services furnished by an MCO. We encourage interested parties to work with States in developing their cost sharing policies.

Comment: One commenter felt that MCOs should be required to make cost sharing requirements clear in all cases, and enrollees should be informed of what constitutes ''good cause.'' The commenter recommended that if an MCO advertises that it does not require copayments, then it should be prohibited from charging copayments for two years. The commenter also stated that MCOs should make clear at the time of open enrollment whether they intend to charge copayments during the contract year.

Response: We agree with the commenter that enrollees should have clear information about cost sharing requirements. In § 438.10(d) and (e), we specify that information furnished to potential enrollees and enrollees, respectively, must include information on any cost sharing. MCOs are also required to inform potential enrollees and enrollees of any significant changes in the information that was furnished to them 30 days prior to the effective date of the changes. While the State will determine what qualifies as ''significant'', we assume that States would find that the introduction of new cost sharing requirements would constitute a significant change.

In addition, in § 438.56(d)(2)(iv), we specify that ''good cause'' for disenrollment by the enrollee includes poor quality care, lack of access to necessary specialty services covered under the contract, or other reasons satisfactory to the State agency. Under this provision, the State could determine that a change in the MCO's cost-sharing policy constitutes ''good cause'' for disenrollment.

Comment: One commenter expressed concern about the inappropriate use of hospital emergency rooms. The commenter recommended that we allow and encourage States to charge beneficiaries a $25 copayment per visit for inappropriate use of the emergency room. According to the commenter, MCOs could require that hospitals collect the copayment at the time of the visit and the enrollees would not be denied care because of inability to pay the copayment. If it was determined that a true emergency existed, the copayment would be refunded. The commenter believes that this would serve as an incentive to enrollees to seek care in the appropriate setting, at the appropriate time and would allow the primary care physician to establish a medical relationship with the beneficiary.

Response: Under § 447.53(b)(4), emergency services are exempted from cost sharing. Specifically, copayments may not be imposed on ''[s]ervices provided in a hospital, clinic, office, or other facility that is equipped to furnish the required care after the sudden onset of a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) that the absence of immediate medical attention could reasonably be expected to result in—(1) placing the patient's health in serious jeopardy; (2) serious impairment to bodily functions; or (3) serious dysfunction of any bodily organ or part.'' We emphasize that as long as the enrollee seeks emergency services that could ''reasonably be expected'' to have the above effects, a copayment may not be imposed, even if the condition was determined not to be an emergency.

The State may decide to impose a copayment for non-emergency services furnished in an emergency room in cases where the enrollee sought services in an emergency room when the standard under § 447.53(b)(4) was not met. Furthermore, the State may request a waiver of the requirement that cost sharing charges be nominal. Section 431.57 provides that for non-emergency services furnished in a hospital emergency room, the Secretary may grant a waiver to permit a State to impose a copayment of up to double the nominal copayment allowed under § 447.54.

Allowing payment of a copayment up front in a hospital emergency room as the commenter suggested would raise the implication of non-compliance with the standard in § 447.53(b)(4). However, enrollees should be aware that if they seek services in an emergency room when the standard in § 447.53(b)(4) is not met, they may be held liable for cost sharing.

6. Assurances of Adequate Capacity and Services (§ 438.110)

Under the authority of section 1932(b)(5) of the Act, proposed § 438.110 required that an MCO provide the State and the Secretary with adequate assurances that the MCO has the capacity to service the expected enrollment in its service area.

In proposed § 438.110, we interpreted the term ''assurances'' to require MCOs to submit documentation to both the State and us. While States were given the flexibility to decide the types of documentation to be submitted by MCOs, we specified that the documentation had to address the State's standards for access to care outlined under proposed § 438.306 (redesignated as § 438.206 in this final rule with comment period). In addition, we proposed that MCOs be required to submit documentation to the State and us, along with State certification, at least every two years, and at the time the MCO enters into or renews a contract with the State or when there has been significant change in the MCO's delivery network or enrollee population.

We received many comments on this section from State agencies, professional organizations, and advocates. A number of commenters appeared confused over this section's interface with proposed § 438.306, and argued that we need to be more detailed in both sections of this final rule with comment period. We recognize that the requirements relating to availability of services and assurances of adequate capacity are closely related and therefore, in this final rule with comment period, we have redesignated § 438.110 as § 438.207 so that these requirements may be read and applied together. We will respond to the comments that were received regarding proposed § 438.110 below.

Comment: Several commenters felt that proposed § 438.110, combined with proposed § 438.306, did not recognize the unique needs of homeless persons, women, children, and individuals with disabilities. Commenters believed we should require additional documentation, and establish standards that specifically recognize the needs of these populations.

Many recommendations were offered. With regard to the persons who are homeless, commenters recommended that MCOs and PHPs should create linkages with service providers offering a wide range of culturally appropriate

medical and social services, including case management. They recommended that the services be available at sites such as soup kitchens, drop-in centers, and shelters where homeless people congregate and are willing to receive care.

A few commenters suggested that we should respond to the needs of children by requiring that primary care pediatricians be available to provide care to children under 19 years of age. In addition, commenters suggested that we require pediatricians to serve as primary care providers, and require that such providers be available 24 hours a day, 7 days a week. Further, the commenters believed that we should require MCOs to include specialists with appropriate pediatric training and expertise, and require that they have arrangements with appropriate tertiary care centers. If an MCO fails to have an adequate number of pediatric providers, including primary and specialty care, the commenter urged that we require that these services be available to enrollees out of network at no additional costs.

Other commenters recommended that proposed § 438.110 be amended to require MCOs to document the availability of women's health specialists. Specifically, one commenter recommended that MCOs that do not contract with hospitals and health entities that provide a full range of reproductive services should be required to demonstrate access to alternative sites, which are medically appropriate and geographically, culturally, and linguistically accessible. In addition, if an MCO cannot demonstrate a full range of reproductive health services, the State should demonstrate to HCFA how individuals will be able to access those benefits without any undue burden.

Commenters also recommended that a provision be added to specifically address the needs of disabled individuals. One commenter recommended that we require MCOs to—(1) identify the populations that will be served, if disabled or unique; and (2) identify specialized professionals, DME, and related supply services that will be available to accommodate each population category. Another commenter suggested that MCOs should be required to document an appropriate range of services and networks, given that various communities may speak different languages. Other commenters suggested that we incorporate stronger requirements that address access to ancillary services, linguistic access, and physical access. Finally, one commenter recommended that we require physicians trained in mental illness to act as primary care providers for persons suffering from mental illness.

Response: The proposed rule was developed to address the needs of all Medicaid populations served under managed care. As we indicated in the preamble to the proposed rule, proposed § 438.110 was to address the procedural requirements for submitting assurances of adequate capacity and services, while proposed § 438.306 was to address the substantive requirements ensuring the availability of services. The intent behind both sections was that States be given flexibility to develop access standards and documentation requirements appropriate for the populations enrolled and specific to the unique circumstances in each State.

Although we therefore do not mandate all of the detailed requirements suggested by commenters, we do require in this final rule with comment period that States, MCOs, and PHPs, maintain an adequate delivery network under § 438.206(d)(1), pay particular attention to pregnant women, children, and persons with special health care needs. We added the last category of enrollees to recognize the special needs of individuals who, for example, disabled or homeless, and who require special attention from the MCO in order to access the health care system.

In addition, in this final rule with comment period, we require the State to identify to the MCO or PHP upon enrollment specific groups at risk of having special health care needs. We also require MCOs and PHPs to make a best effort attempt to identify and comprehensively assess pregnant women, and persons with special health care needs.

We believe that the above provisions ensure that the State, when developing its standards for access to care and when monitoring an MCO's or PHP's capacity and adequacy of services, pays particular attention to managed care enrollees who are vulnerable. Although this final rule with comment period does not include all recommendations offered by the commenters, States are free to consider them.

Comment: One commenter noted that neither States nor MCOs have developed a methodology to measure adequate capacity. The commenter states that while many States have required MCOs to submit a great deal of information with the intent to measure adequate capacity, that information for the most part has not been useful. Further, the commenter expressed concern that MCOs will be required to submit unnecessary data and information, thus wasting considerable resources. This commenter suggested that the most expedient and effective way to measure adequacy and access is to ensure that enrollees know how to contact the managed care plan for information and how to file complaints and grievances. The commenter recommended that States be allowed to use their judgment on these issues under their existing certification processes.

Response: Section 1932(b)(5) of the Act requires MCOs to provide the State and the Secretary with adequate assurances that the MCO has the capacity to serve the expected enrollment of Medicaid beneficiaries in its service area. The Congress specified that these assurances must demonstrate that each MCO has an appropriate range of services, and a sufficient number, mix, and geographic distribution of providers. Based on this statutory mandate, we are imposing detailed requirements on MCOs and States, including a requirement that MCOs submit documentation. We believe that States must have documentation in order to assess capacity and adequacy of services. We have clarified in this final rule with comment period that the documentation required under this section must be submitted by MCOs in a format specified by the State and acceptable to us. We recognize that MCOs may not be able to construct a provider network that anticipates all future needs of enrollees. Therefore, in this section we are requiring that the MCO have policies and practices in place to address unanticipated need for, or limitations in availability within their service area of, certain experienced providers when required by enrollees. We agree with the commenter that enrollees must know how to contact the MCO and know how to file grievances, appeals, and State fair hearings. Section 438.10 requires that this information be furnished to enrollees.

Comment: We received one comment questioning whether we should apply proposed § 438.110 to voluntary MCOs. The commenter believed that the provisions are burdensome for MCOs and PHPs in which enrollment is voluntary, especially when they are added to the proposed access requirements. The commenter recommended that this section be applied only to MCOs and PHPs in which enrollment is mandatory.

Response: Section 1932(b)(5) of the Act does not distinguish between voluntary or mandatory managed care organizations; rather, the statute generally references managed care organizations under section 1903(m) of the Act, which applies to both voluntary

and mandatory enrollment MCOs. Section 1903(m)(2)(A)(xi) of the Act requires that all MCOs meet applicable requirements in section 1932 of the Act. We have no discretion to exempt voluntary enrollment MCOs from the requirement in section 1932(b)(5) of the Act. We also do not see any justification for applying a lower standard under section 1932(b)(5) of the Act in the case of MCOs with voluntary enrollment. Under section 1903(m)(2)(A)(vi) of the Act, once an individual enrolls in a ''voluntary enrollment'' MCO, the enrollee may be ''locked in'' after the first 90 days for 12 months at a time. It is just as important to ensure adequate capacity in a case, as it is in the case of a ''mandatory enrollment'' situation.

Comment: We received one comment supporting proposed § 438.110(a), and the grievance and appeals provisions in proposed subpart E. The commenter noted that these provisions are consistent with the broader and more detailed obligations imposed on all health benefit plans in California.

Response: Our intent in the proposed and this final rule with comment period is not to prohibit a State from imposing more stringent standards concerning the adequacy of an MCO's network capacity and services. Our intent is to ensure that States, at a minimum, review MCO network capacity and services, and certify to us that the MCO satisfies the State's requirements for availability of services, as required under § 438.206. We are pleased that our standards are consistent with California's.

Comment: We received many comments suggesting that the documentation described in proposed § 438.110(b) should be sent to the State and not directly to HCFA. Although several commenters favored HCFA becoming more involved in reviewing MCO documentation justifying adequate capacity and services, a large number of commenters recommended that we delete the requirement for direct submission of documentation by MCOs to HCFA.

Specifically, commenters argued that States, and not HCFA, were responsible for entering into and monitoring contracts with MCOs, and ensuring that adequate capacity exists to serve enrollees. Other commenters argued that direct submission of documentation to HCFA would be redundant, unprecedented, and contrary to our stated intent to provide States flexibility wherever possible. A few commenters suggested that the proposed documentation requirements went beyond the statutory provisions in the BBA, which in the commenters' view only require that ''assurances'' be made to the Secretary.

Commenters also asserted that the proposed rule does not recognize the differences among the 50 states, and questioned what HCFA would do with the information once received, and whether we would be diminishing the management authority of the States. Finally, a number of commenters asked that we consider the administrative burden of this requirement, believing it would constitute unnecessary micro-management on the part of the Federal government.

Response: Based on comments received, we have re-evaluated proposed requirement that assurances be routinely and directly provided to us. This requirement was based on the fact that section 1932(a)(5) of the Act requires that MCOs provide adequate assurances to ''the State and the Secretary.'' We believe, however, that the requirement that the Secretary be provided with adequate assurances can be satisfied by requiring the State to provide assurances to us that it is satisfied that standards are met. In this final rule with comment period, we do not require the MCO to submit documentation directly to us. We agree that documentation should be submitted to the States that are the entities that contract with MCOs, and that it might be redundant for us to regularly receive all of the documentation. In this final rule with comment period, we require only that the State submit to us certification of an MCO's adequate capacity and services in accordance with State-established standards for access to care under § 438.206. We also added a provision that allows us to inspect the documentation submitted by MCOs.

We did not intend to interfere with the State's role in determining whether an MCO has demonstrated adequate capacity and services. We believe that the approach in this final rule with comment period satisfies our statutory requirements by providing us with sufficient flexibility to monitor State's actions and it also satisfies the commenters concerns by restoring the role of the States and reducing administrative burden. With respect to the commenters suggesting that our requirements go beyond the statute's requirement for ''assurances,'' we note that the title of section 1932(b)(5) of the Act is ''Demonstration of adequate capacity and services,'' and that the text requires ''adequate'' assurances. We believe it is reasonable, in order for the State to be ''adequately'' assured of an MCO's or PHP's capacity, and in order for the MCO or PHP to ''demonstrate'' such capacity, to expect documentation in support of the assurances it makes.

Comment: One commenter recommended that we request legislative action to eliminate the requirement in section 1932(b)(5) of the Act that assurances be submitted directly to HCFA. The commenter argued that direct submission by an MCO to HCFA would be unprecedented and redundant.

Response: A legislative change is not necessary in light of our decision to interpret our requirement as satisfied by the provision of assurances to us by States.

Comment: We received a number of comments on proposed § 438.110(b) asking that we provide additional clarification on the format of information to be received from MCOs and States assuring adequate capacity. Commenters questioned whether we would specify the electronic format to be used to submit information and whether we would require States to change current formatting requirements. One commenter reminded us that a change in formatting requirements could result in States and MCOs, PHPs, and PCCMs abandoning software already in use. Another commenter noted that for multi-state health plans, different electronic formatting requirements in each State would have enormous cost implications. This commenter suggested that States submit aggregate health plan information to HCFA.

Response: Because we no longer require direct submission of documentation from MCOs, it is not necessary to prescribe formatting requirements. We are requiring in this final rule with comment period that documentation be submitted in a format specified by the State and acceptable to us. We recognize that different States use different systems for collecting information. Accordingly, we permit a State to tailor the format of the documentation to its own unique system and resource capabilities. In meeting this requirement the State should submit to us its proposed format for approval. As we gain more experience in implementing this provision, we will provide formal guidance on acceptable formats. Although we are no longer requiring the direct submission of documentation from MCOs, we are requiring that States certify to us the MCO's assurances of adequate capacity and services. We wish to emphasize that the State certification must address how the MCO demonstrated compliance with the State's access standards developed under § 438.206.

Comment: We received a number of comments on proposed § 438.110(b)(1), which requires an MCO to submit documentation demonstrating that it offers an appropriate range of services for the enrollees in the service area, including access to specialty services. Many commenters supported the reference to specialty services. Several commenters noted that for many individuals with disabilities and mental illness, specialty care often amounts to primary care. In contrast, several commenters objected to this provision and argued that the BBA did not address specialty care as part of this requirement. One commenter indicated that there are no national standards to determine specialty care capacity and services.

Many recommendations were offered. A number of commenters recommended that we maintain this requirement in the final rule with comment period, with a few suggesting that we provide technical assistance to States. One commenter suggested that we only require MCOs to demonstrate that they have the capacity to provide specialty services in a timely and accessible manner, and that we require MCOs to disclose what provisions they have made for infrequently used tertiary care services. Another commenter suggested that the State agency obtain proof, as appropriate, that it furnishes health services required by enrollees as promptly as is appropriate and that the services meet the agency's quality standards. Finally, one commenter suggested that we incorporate into the regulation itself the preamble language discussing proposed § 438.306, which suggests that States consider the volume of services furnished to other enrollees, and reminds States to ensure that providers are accessible to those who rely on public transportation.

Response: Although section 1932(b)(5) of the Act refers expressly only to preventive and primary care services, it requires assurances of ''capacity to serve the expected enrollment,'' presumably including those enrollees who need specialty services. While it specifies expressly that these assurances should ''includ[e]'' assurances with respect to preventive and primary care, this does not mean that assurances about other types of services are not necessary. Indeed, the very clause that references preventive and primary care (section 1932(b)(5)(A)) of the Act also references ''an appropriate range of services,'' which we believe includes specialty services. Section 1932(b)(5)(B) of the Act refers to ''a sufficient * * * mix * * * of providers of services,'' which again in our view refers to having ''sufficient'' capacity for all types of providers, including specialists. We believe that section 1932(a)(5) of the Act, as we interpret it, provides authority for us to require assurances of specialty services. (We also have relied on our general authority under section 1902(a)(4)) of the Act.

We continue to believe that assurances with regard to specialists are important, and agree with the commenters that support this requirement. MCOs and PHPs must demonstrate access to specialty services based on the access standards established by the State under § 438.206. This reflects our recognition of the growing body of evidence showing that individuals secure positive health outcomes when treated by providers experienced in caring for significant numbers of individuals with a particular health care condition (for example HIV/AIDS). Also, in response to the above comments about the importance of specialty care which can serve as primary care for special populations, in § 438.206(d)(1)(iii), of this final rule with comment period, we have added a parenthetical statement to specify that in establishing the network, consideration of the types of providers needed must take into account the providers' ''training and experience''.

We emphasize that to demonstrate adequate access to specialty services, MCOs and PHPs need not contract with specialists in instances where a specialist provides infrequently used services or procedures. An MCO or PHP may satisfy this requirement in these types of cases, for example, by having appropriate arrangements with specialists, and allowing enrollees to go to these out-of-network providers to receive medically necessary specialty care. We note that in circumstances where an MCO's or PHP's provider network is unable to meet an enrollee's needs and the enrollee must seek care from an out-of-network provider, the enrollee may not be held liable for any additional expenses. In other words, for those services, enrollee liability must be the same regardless of whether they were received from in-network or out-of-network providers. Section 438.207(b)(4) of this final rule with comment period recognizes limitations in provider networks that may necessitate other arrangements, and provides for such alternative arrangements.

Although we believe examples in the preamble discussion of proposed § 438.306 referenced by the commenter are appropriate for State consideration, we have not incorporated them in this regulation. Given differences that may exist among States, it would be inappropriate to impose national ratio standards for access to specialty care.

Finally, in terms of providing technical assistance, we are always available to provide specific guidance to States upon request. We regularly provide technical assistance in a variety of different forms, including issuing letters to State Medicaid Directors, publishing Medicaid policy manuals, reviewing waiver applications and contracts, performing on-site monitoring reviews, and engaging in regular dialogue directly with State officials.

Comment: We received one comment requesting that we define the term ''mix'' in proposed § 438.110(b)(2), which stated that the MCO must submit documentation to demonstrate that it ''maintains a network of providers that is sufficient in number, mix, and geographic distribution to meet the needs of the anticipated number of enrollees in the service area.'' The commenter argued that the term ''mix'' is too vague. Further, as used in the context of the proposed regulation, the term could be interpreted to mean ethnic, language, and cultural diversity, or various types of specialties. The commenter recommended that we articulate this term to ensure that rights and protections are not restricted.

Response: The term ''mix'' is taken directly from the statute and we have retained it in this final rule with comment period. We believe that the term ''mix'' refers to provider types, for example, as we have just noted above, the appropriate types of specialists. We note, however, that States will be required to review documentation submitted by MCOs to ensure that each MCO has demonstrated adequate capacity and services in accordance with the State's standards for access to care. One of the requirements of the access provisions is that a State ensure that each MCO provides services in a culturally competent manner (§ 438.206(e)(2)).

Comment: We received a number of comments on proposed § 438.110(c), which required MCOs to submit the documentation described in paragraph (b) at least every two years, specifically at the time the MCO enters into or renews a contract with the State, and at the time the State determines that there has been a significant change in the MCO's delivery network or enrollee population. A number of commenters suggested that the two year time frame for assessing adequate capacity and services was insufficient and would not adequately protect enrollees. The commenters recommended that we

require an annual assessment of adequate capacity.

A number of other commenters suggested that States should have flexibility in determining when to require an MCO to provide assurances of adequate capacity. They argued that the two year time period specified in the proposed rule was too arbitrary and does not tie to existing contracts or waiver periods. Moreover, they noted that many States and MCOs assess adequate capacity within shorter intervals than the 2-year period proposed in the regulation. Their recommendations included a number of the following options: (1) shortening the time frame to one year; (2) revising the rule to allow for certifications to be submitted with waiver renewals, contract processes, or other administrative processes; and (3) requiring that assurances be sent at a time period agreed upon by HCFA and the State.

One commenter specifically noted that changes in reimbursement, limits on services, and the existence of closed panels affect provider composition. This commenter suggested that we require States to re-assess provider adequacy if changes in reimbursement policy or other factors require a change in network composition. Another commenter believed that if there is no substantial change in the delivery system, there is no need to re-submit information at each renewal. Finally, one commenter questioned how long it would take HCFA to review provider networks before approval can be given of a contract or contract amendment, since there were no time frames offered in the regulation for HCFA's review process.

Response: The time frames specified in proposed § 438.110 were never intended to prohibit a State from assessing adequate capacity at intervals shorter than two years. We proposed that, at a minimum, MCOs must submit the documentation at least every 2 years, and envisioned that States regularly would assess adequate capacity at the time it enters into or renews a contract with an MCO and when the State determines that there has been a significant change in an MCO's delivery network or enrollee population.

In response to commenters concerns, we have revised the provision in this final rule with comment period. We now require the MCO to submit documentation annually. The MCO is still required to submit the documentation at the time it enters into a contract and any time there has been a significant change in the MCO's operation that would affect capacity and services. We also in § 438.207(c)(2) provide examples of what constitutes a significant change in the MCO's operations. Although States are free to include other changes, we believe, at a minimum, significant changes include—(1) a significant MCO service or benefit change; (2) an expansion or reduction of the MCO's geographic service area; (3) the enrollment of a new population in the MCO; and (4) a significant MCO rate change. We also specify that after the State reviews the documentation from the MCO, the State must certify to us that the MCO has complied with the State's requirements for availability of services, as set forth in § 438.206.

Finally, we acknowledge that several commenters were confused over the interface of this rule with the section 1915(b) of the Act, waiver review process. Commenters should be aware that, if there has been a significant period of time between the State's assessment of adequate capacity at the time of a waiver renewal, we may ask the State to update its analysis of adequate capacity and services as part of the waiver review process, and may request documentation of an MCO's capacity at that time.

Comment: Several commenters expressed the view that § 438.110 did not have any enforcement mechanism. Citing problems encountered by American Indians in gaining access to specialists in voluntary Medicaid managed care programs, one commenter suggested that as an enforcement tool, we compare the rates paid for Medicaid beneficiaries by an MCO or PHP to those paid under fee-for-service Medicaid to ensure that a sufficient amount is paid to ensure access and availability. Further, the commenter suggested that we also direct detection and enforcement activity at providers that limit the number of appointments they make available to Medicaid enrollees. Another commenter argued that we did not discuss any consequences to the MCO should it fail to demonstrate adequate capacity and services. This commenter suggested that we address corrective action plans and other appropriate consequences in the regulation. Several other commenters recommended that the regulation explicitly describe HCFA's authority to determine whether States and MCOs or PHPs have adequately demonstrated capacity, and describe HCFA's ability to deny FFP if they have not.

Response: In addition to reviewing managed care contracts, we regularly monitor the operation of Medicaid managed care programs throughout the country. We have a variety of different monitoring tools, such as reviewing State reports and MCO or PHP documentation, interviewing representatives of the State, MCO or PHP, interviewing enrollees, reviewing provider agreements and contracts, and surveying participating providers.

We also have many mechanisms to enforce the provisions of this section. They range from issuing letters and corrective action plans to imposing terms and conditions under waiver programs, to conducting regular on-site monitoring reviews, and to withholding FFP under § 438.802(c) of this final rule with comment period (see section II. H. below). Our goal is to work with States to resolve problems and take action, as appropriate for the particular circumstances.

We note, in response to the commenter's concern regarding access to specialists under managed care, that section 1903(m)(1)(A)(i) of the Act requires an MCO to ''make services it provides to individuals eligible for benefits under this title accessible to individuals to the same extent as such services are made accessible to individuals (eligible for Medicaid assistance under the State plan) not enrolled with the organization.'' Accordingly, under managed care, States must ensure that MCOs provide Medicaid enrollees access to contracted services to the same extent such access is available under fee-for-service. Again, FFP could be disallowed in the case of a failure to comply.

Comment: We received a few comments questioning whether there is an adequate process for input and disclosure with regard to proposed § 438.110. One commenter recommended that we require public disclosure, upon request, of criteria used by an MCO or PHP to select and monitor the performance of health care providers, including those providing specialty services to persons with chronic diseases or disabilities. The commenter further recommended that the final rule with comment period require public disclosure of QISMC and accreditation surveys, arguing that we should require the same disclosure of quality assurance in Medicaid managed care as required under the Medicare+Choice program.

Another commenter recommended that we require States and HCFA to provide public access to documents, provide reasonable notice of pending review, permit public comment, and hold review hearings as appropriate. Finally, several commenters recommended that we require States to obtain input from consumers, consumer advocates, and medical providers, for

use in setting access standards. They suggested that States may do this through MCAC, proposed rulemaking, or public hearings on proposed State plan amendments.

Response: In § 438.202(c) of this final rule with comment period, we require the State to provide for the input of recipients and other stakeholders in the development of the quality assessment and performance improvement strategy, including making the strategy available for public comment before adopting it in final. We believe that the quality strategy required in § 438.202(c) is the appropriate venue for public input with respect to State requirements governing MCO assurances of adequate capacity and services.

In § 438.207 of this final rule with comment period, we do not impose specific requirements with respect to public disclosure of documentation. We hope that States, consistent with their own laws, will provide enrollees and other stakeholders access to all relevant documentation submitted by MCOs to demonstrate their capacity to deliver contracted services. We note that States and MCOs, PCCMs, and PHPs must comply with the enrollee information requirements in § 438.10.

Comment: A few commenters questioned whether we would consider granting waivers of the requirement under proposed § 438.110 that adequate capacity be assured. One commenter recommended that MCOs be granted waivers from this requirement if they can demonstrate that a good faith effort has been made to solicit providers to participate in the MCO's network. The commenter asserted that there may not be an appropriate mix or geographic distribution of providers in certain areas, and there may be a limited number of specialty providers. The commenter suggested that, if the MCOs can demonstrate that there are not enough Medicaid providers for a particular zip code, they should be permitted to allow enrollees to go out of the service area.

Response: The provisions of § 438.206, Availability of services, allow States flexibility in designing standards for access to care. States should take into consideration locations where certain provider types may not be available. In these cases, States may permit MCOs to make arrangements with other providers outside of an MCO's service area in order to ensure capacity and services adequate to meet the needs of the enrollee population.

As a general rule, § 438.206 requires the MCO to maintain and monitor a network of appropriate providers. We recognize, however, that geographic mail distribution of providers, limitations in the number of certain providers nationally, as well as other factors, may make it difficult for MCOs to always be able to construct a provider network that will be able to address all the health care needs of its enrollees. For example, we acknowledge that the MCO's providers may not always be experienced in providing care to an individual who has a rare condition. Consequently, in § 438.207(b)(4) we require MCOs to have policies and practices to address unanticipated scarcity of providers to meet the health care needs of the enrolled population. Specifically, these policies and procedures should address the following: (1) the unanticipated need for providers with particular types of experience; and (2) the unanticipated limitation of the availability of such providers. In addition, § 438.206(d)(5) provides that if MCO's network is unable to meet an enrollee's needs, the MCO must permit the enrollee to access out-of-network providers.

Comment: One commenter specified that since deeming is allowed under section 1932(c)(2)(B) and (C) of the Act, we should allow States to deem an MCO or PHP as having met the requirements of § 438.110, if the organization has been accredited by a recognized accrediting body or has been Medicare certified.

Response: Section 1932(c)(2)(B) of the Act provides that States have the option of substituting private accreditation for the external quality review (EQR) required under section 1932(c)(2)(A) of the Act when EQR activities would duplicate an accreditation review. Section 1932(c)(2)(C) of the Act provides States the option to forgo EQR under section 1932(c)(2)(A) of the Act when the Medicaid MCO also has a Medicare+Choice contract in effect, and has complied with Medicaid EQR requirements for at least two years. The deeming provisions cited by the commenter only applies to the EQR requirements in section 1932(c)(2)(A)of the Act, and have no applicability to the requirement for assurances of adequate capacity in section 1932(b)(5) of the Act implemented in proposed § 438.110 and § 438.207 of this final rule with comment period. This final rule with comment period requires that assurances of adequate capacity be made at the time of contract approval and annually thereafter. We believe that it is essential that an adequate provider network be in place when beneficiaries are first enrolled in an MCO. The EQR activities are retrospective, that is, they take place after the fact and review for adherence to standards. While we believe that the EQR review is important, it is not an appropriate substitute for an assurance of adequate capacity.

Comment: We received a few comments questioning our proposal to eliminate part 434, subpart E from the regulations; specifically, the requirements under § 434.50(b) and § 434.52. Under § 434.50(b), a State was required to obtain proof from each contractor, of the contractor's ability to provide services under the contract efficiently, effectively, and economically. Under § 434.52, a State agency was required to obtain proof that each contractor furnished the health care services required by the enrolled recipients as promptly as is appropriate, and that the services met the agency's quality standards.

Commenters argued that these sections contain important consumer protections that should be maintained. Further, commenters asserted that the proposed rule no longer requires the State to obtain assurances that the services meet the State's quality standards, and only addresses the theoretical availability of services as opposed to whether the services are provided in a timely fashion.

Response: We believe that it would be confusing and redundant to retain these requirements. In part 438, we incorporate and expand upon the requirements previously set forth in subpart E of part 434. We disagree that the provisions in the proposed and this final rule with comment period no longer require a State to obtain assurances that an MCO's services meet the State's quality standards, and only address the theoretical availability of services. In this final rule with comment period, States must develop a quality assessment and improvement strategy that requires MCOs to meet State standards for access to care and to submit documentation demonstrating adequate capacity and services. In particular, we note that one of the access requirements is that MCOs adhere to the State's standards for timely access to care (§ 438.206(e)(1)).

7. Emergency and Post-Stabilization Services (§ 438.114)

Section 1932(b)(2) of the Act provides that each contract with an MCO or PCCM must require the MCO or PCCM—(1) to provide coverage of emergency services without regard to prior authorization, or the emergency care provider's contractual relationship with the MCO or PCCM; and (2) to comply with guidelines established under section 1852(d)(2) of the Act (with respect to coordination of post-

stabilization services) in the same manner as those guidelines apply to Medicare+Choice plans.

In proposed § 438.114, we set forth the rules implementing these emergency and post-stabilization requirements. We proposed definitions of emergency medical condition, emergency services, and post-stabilization services. We proposed to require MCOs to provide specific information regarding emergency and post-stabilization services to enrollees at the time of enrollment and annually thereafter. We also outlined proposed rules for coverage and payment of these services.

We interpreted the term ''coverage'' to mean that an MCO that pays for hospital services generally must pay for emergency services obtained by Medicaid enrollees. We interpreted coverage in the primary care case management context to mean that the PCCM must allow direct access to emergency services without prior authorization. We applied different meanings to the term ''coverage'' because while PCCMs are primarily individuals paid on a fee-for-service basis, they receive a State payment to manage an enrollee's care. We determined that while PCCMs, unlike MCOs, are not likely to be involved in a payment dispute involving emergency services, they could be involved in an authorization dispute over whether a self-referral to an emergency room is authorized without prior approval of the PCCM. Accordingly, proposed § 438.114(d)(2) provided that enrollees of PCCM are entitled to the same emergency services coverage without prior authorization as is available to MCO enrollees under section 1932(b)(2) of the Act.

Section 1932(b)(2)(B) of the Act defines emergency services as covered inpatient or outpatient services that are furnished by a provider qualified to furnish services under Medicaid that are needed to evaluate or stabilize an emergency medical condition. Emergency medical condition is defined in section 1932(b)(2)(C) of the Act as a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) that a prudent layperson, who possesses an average knowledge of health and medicine could reasonably expect the absence of immediate medical attention to result in placing the health of the individual (or with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy, serious impairment to bodily functions, or serious dysfunction of any bodily organ or part. While this standard encompasses clinical emergencies, it also clearly requires MCOs to base coverage decisions for emergency services on the severity of the symptoms at the time of presentation and to cover examinations when the presenting symptoms are of sufficient severity to constitute an emergency medical condition in the judgment of a prudent layperson. The above definitions were set forth in proposed § 438.114(a). The identical definitions appear in the Medicare+Choice rules at § 422.113(b) and therefore, to avoid duplication, we incorporate those definitions by reference in this final rule with comment period.

Comment: One commenter stated that no protections now exist to require MCOs to cover ambulance services. The commenter cited proposed § 438.100(b), which states that Medicaid contracts with MCOs, PCCMs, or PHPs must either provide for all Medicaid services covered under the State plan or make arrangements to furnish those services. The commenter asserted that ambulance services should be covered in this regulation based on the authority in § 440.170(a), which states that transportation is a Medicaid covered service.

Response: Section 440.170(a) applies to non-emergency transportation, which is an optional Medicaid service that States may choose to provide or not to provide. Ambulance services are not included in the definition of ''emergency services,'' as that definition refers to ''inpatient or outpatient services.'' If a State covers ambulance services under its State plan, and these services are included in an MCO's contract, then the MCO must cover the ambulance services under the same terms they are covered under fee-for-service Medicaid. We recognize that the Medicare program has separate statutory authority to cover ambulance transportation when other transportation may jeopardize an enrollee's health, and that the Medicare+Choice statute thus obligates Medicare+Choice organizations to cover them. We do not, however, have that same statutory authority in the Medicaid program.

Comment: We received a number of comments on the rules governing post-stabilization care. Some commenters objected to requiring pre-approval from MCOs, PHPs, or PCCMs for post-stabilization services. Others opposed requiring an MCO, PHP, or PCCM with a risk contract that covers post-stabilization services to pay for those services without pre-approval if the MCO, PHP, or PCCM does not respond within one hour after receiving the provider's request or cannot be contacted for approval. The commenters believe that the requirement is too burdensome and the time frame is too short for an MCO, PHP, or PCCM to make an informed decision. Others thought the time period was too long for emergency physicians who must keep track of patient condition and be responsible for the stability of the patient. Some commenters believed that our preamble definition of post-stabilization was inconsistent with the definition in the regulation. They noted that the proposed definition in the preamble better described ''maintenance care,'' and that it should not be used in place of the regulation definition.

Response: We acknowledge that the definition of post-stabilization in the preamble differed from that in the proposed regulations text, and that the preamble definition was not consistent with the Medicare+Choice definition that we are required to apply to Medicaid under section 1932(b)(2)(A)(ii) of the Act. We regret any confusion that this may have caused.

Under the Medicare+Choice definition at § 422.113(c)(1), post-stabilization care services means ''covered services, related to an emergency medical condition, that are provided after an enrollee is stabilized in order to maintain the stabilized condition, or * * * to improve or resolve the enrollee's condition.'' The Medicare+Choice rules create a two-step process for post-stabilization care. The first step occurs during the one-hour time frame, while the hospital waits for a response from the MCO. The second step occurs after the first hour. When the MCO receives a call from the treating hospital requesting prior authorization or transfer, the MCO has one hour to make a decision on a course of treatment, and respond to the treating hospital. During that one hour, the MCO is responsible for services related to the emergency medical condition that are necessary to maintain stabilization. Any period of instability that rises to the level of an emergency medical condition that occurs during this time would be covered under provisions at § 422.113(b) related to emergency services.

The rule further establishes that if the MCO fails to respond within the one-hour time frame, or the MCO cannot be reached, the treating physician can proceed with post-stabilization services that are administered not only to ensure stability, but also to improve or resolve the patient's condition. If a nonphysician MCO representative and the treating physician cannot reach an agreement on a course of treatment, the MCO must allow the treating physician to speak with a plan physician and the

treating physician may proceed with care administered to improve or resolve the patient's condition until a plan physician is reached.

The MCO is financially responsible for post-stabilization services until the MCO and the treating physician execute a plan for safe transfer of responsibility. Safe transfer of responsibility should occur with the needs and the condition of the patient as the primary concern, so that the quality of care the patient receives is not compromised.

Comment: Many commenters recommended that we broaden the definition of emergency services to include coverage of ''urgently needed'' services. The commenters believe that expanding the definition would allow enrollees more leeway in seeking care in an emergency department for conditions that may benefit from earlier intervention. Some commenters stated that this policy would create a margin of safety for enrollees who may underestimate the severity of their illnesses and delay care if only the prudent layperson standard applies.

Response: The Congress has defined the obligations of an MCO to cover services received outside of an MCO's network. While MCO's are obligated to cover emergency services and post-stabilization services, there is no counterpart under the Medicaid statute for the obligation under section 1852(d)(C)(i) of the Medicare statute to cover ''urgently needed services.'' This latter obligation generally applies only when an individual is out of the Medicare+Choice organization's service area, since it only permits services to be covered when they were not available through the organization's network. Since Congress in the BBA chose to obligate Medicare+Choice organizations to cover ''urgently needed services, but chose not to do so in the same law in the case of Medicaid-contracting MCOs' we believe it would be inconsistent with Congressional intent to impose an obligation on MCOs to cover urgently needed services received out of area.

Comment: One commenter noted that some MCOs used a retrospective utilization review process to accept or deny an emergency claim based on a professional assessment of the nature of the emergency. The commenter believes that this violates the prudent layperson standard.

Response: Retrospective utilization review does not necessarily conflict with the prudent layperson standard as long as the MCO (or the State) reviews all documentation, takes into account the enrollee's presenting symptoms and applies the prudent layperson standard in making its determination. If the retrospective review reveals that the enrollee acted in a manner consistent with the prudent layperson standard, the enrollee may not be held liable for any additional costs even if it turned out that the case did not present a clinical ''emergency'' (that is, even if it turned out that the reasonable belief of a ''prudent layperson'' was incorrect). Section 438.114(e)(2) of this final rule with comment period expressly states that an enrollee who has an emergency medical condition may not be held liable for payment of subsequent screening and treatment needed to diagnose the specific condition and stabilize the patient.

Comment: Many commenters were concerned that requiring MCOs, PHP, and PCCMs to provide a list of emergency settings and any other locations at which MCO, PHP, or PCCM physicians and hospitals provide emergency services covered under contract would imply that enrollees may not use any hospital or other proper setting for emergency care, but rather are limited to using participating hospitals. They suggested that we require that the list be accompanied by a clear statement of the enrollee's right to use any hospital or other setting for emergency care consistent with this section. One commenter requested that we prohibit MCOs from using lists of examples in their instructional materials of when it is inappropriate to use an emergency room because people with certain disabilities may require emergency treatment for some conditions that would not be emergencies for the general population.

Response: We agree with the first comment and have revised § 438.114(b) of this final rule with comment period to include as item (5) of the information that must be provided to enrollees and potential enrollees, the fact that, subject to the requirements of the section, the enrollee has the right to use any hospital or other setting for emergency care.

We believe that it is appropriate for MCOs, as well as States, to educate enrollees as to when they should or should not access emergency care. However, we have deleted the requirement that information provided to enrollees and potential enrollees include appropriate use of emergency services. States and MCOs can best determine how and when to provide this education to enrollees. Further, to monitor the appropriateness of the information provided, we encourage States to establish information requirements and review enrollee emergency information from MCOs before it is released.

Comment: Some commenters suggested that information regarding access to and availability of emergency and post-stabilization services should be available to potential enrollees upon request at any time, and this information should be posted prominently in emergency rooms and in providers' offices.

Response: We agree that potential enrollees should receive information regarding emergency care access. We have revised the introductory text of § 438.114(b) to require that the information be furnished to potential enrollees upon request. We encourage States, MCOs, PHPs, and PCCMs to disseminate information on access to enrollees as broadly as possible. We do not agree that we should require that this information be posted in emergency rooms as this is more appropriately provided by the State or the MCO, PHP, or PCCM.

Comment: Some commenters suggested that the MCO, PHP, or PCCM or State should be required to provide the enrollee with information regarding the education and board certification and recertification status of the health care professionals staffing the emergency departments in the enrollees' geographical region. They noted that under proposed § 438.10(f)(2)(ii), this information is provided only upon request. The commenters explained that in emergencies, the enrollee will not have time to choose which emergency department to use and that unless the enrollees have the information on the education and board certification and recertification status ahead of time, they will not be able to use these markers of quality in an emergency situation.

Response: Under section § 438.10, enrollees may request information from MCOs, PHPs, and PCCMs regarding education and board certification status of its participating health care professionals and hospitals. If enrollees are particularly concerned about these issues, they may request the information immediately upon enrollment so that they have it available before they need emergency services.

Comment: Some commenters believed that the regulations should prohibit MCOs from developing lists of ''symptoms'' and diagnoses for coverage of emergency services under the ''prudent layperson'' standard. In these commenters' view, the development of such lists is an attempt to establish plan-specific ''prudent layperson'' standards in the commenters' view, and could have the effect of vitiating legislative intent. They believe that lists should be expressly prohibited, and that the prudent layperson standard requires

review on a case-by-case basis that considers not only the patient's complaint, but also age and medical history. The commenters suggest revising the regulation to prevent the use of lists under the prudent layperson definition. If such lists are permitted, these commenters believe that MCOs should be required to conduct broad scale enrollee education regarding the list of symptoms for coverage of emergency services. One commenter suggested that we add the following language to § 438.114: ''What constitutes an emergency medical condition with reference to the definitions in paragraph (a) of this section cannot be limited by lists of diagnoses or symptoms, or by retrospective audits based on such restrictive emergency lists, including refusal by the MCO, PHP, or PCCM, to process any claim which does not contain the primary care provider's authorization number.'' Another commenter also stated that some MCOs require the primary care provider's authorization number to appear on filed claims in order to receive reimbursement, and that this conflicts with the prudent layperson standard

Response: We believe that the use of authorization codes in the payment approval process may be an effective and efficient way for a State, MCO, or PHP to avoid the need to apply the prudent layperson standard on a case-by-case basis, in that it can be assumed that the primary care physician has already done so. However, the absence of such an authorization cannot be used to deny an emergency room claim. Denials must be based on a case-by-case review applying the ''prudent layperson'' standard. We agree with the commenter's suggestion that this final rule with comment period should state what constitutes an emergency may not be limited ''on the basis of diagnoses or symptoms,'' and have included a provision in § 438.114(e)(1)(i) of this final rule with comment period. We also agree that the regulations should expressly state that coverage of emergency room services cannot be denied based on the fact that it does not contain the primary care provider's authorization number. This suggestion is reflected in section 438.114(e)(1)(ii) of this final rule with comment period. With respect to the question of ''retrospective'' audits, we have addressed this above, and believe that this is addressed in the regulations in § 438.114(d)(1)(ii)(A) that makes it clear that coverage cannot be denied because the symptoms turned out not to be a ''real'' emergency in the sense that health was really at risk in the sense a prudent layperson might reasonably believe it would be. This should not be construed as mandating States, MCOs, or PHPs to pay a claim if the hospital or other provider has not submitted the pertinent documentation within either reasonable, or where applicable, legal time frames.

Comment: One commenter believed that the provisions of proposed § 438.114(f) that requires the attending physician to determine when an enrollee is stable, is an important safeguard to ensure that the person most knowledgeable about the enrollee's current condition will make this determination. Others disagreed, stating that allowing the attending physician to be the sole person to determine when an enrollee is stabilized enough for transfer may undercut the MCO's ability to manage inpatient services and has potential for abuse. These commenters recommended allowing the attending physician's decision to come under retrospective review.

Response: Once an emergency medical condition is acknowledged, the emergency physician is in the best position to decide when stabilization is achieved. As noted above, section 1932(b)(1)(2)(A)(ii) of the Act requires that MCOs and PCCMs follow the ''post-stabilization'' guidelines established for the Medicare+Choice program under section 1852(d)(2) of the Act. The Medicare+Choice regulations state that the emergency physician decides when a patient is stable, and that this decision is binding on Medicare+Choice organizations. Because Medicare+Choice post-stabilization rules govern Medicaid, we would have no discretion to adopt a different rule for Medicaid even if we agreed with the commenter.

Comment: Commenters expressed concern that MCOs will argue that in some cases, coverage of screening is not covered under the definition of emergency services in proposed § 438.114, even in cases in which a screening is required under the Emergency Medical Treatment and Labor Act (EMTALA). These commenters contended that MCOs frequently refuse coverage, relying on their own definitions of reimbursable emergency services, when these definitions are more narrow than what the hospital is required to cover under EMTALA requirements. This policy places physicians and hospitals in the position of being legally obligated to render treatment for which they will not be paid. Some commenters recommend adding in the emergency services definition that ''evaluate or stabilize,'' includes those services required under EMTALA. One commenter recommended adding ''within the meaning of 42 U.S.C. 1395dd'' at the end of the emergency services definition at proposed § 438.114(a)(2), and adding preamble language that states that the MCO must ''pay for the cost of emergency services obtained by Medicaid enrollees.'' However, one commenter stated that under such a definition, an emergency condition exists if certain acute symptoms are manifested even though the underlying condition may not be an emergency. The commenter asserted that EMTALA requirements are expansive, and would result in more emergency room services being approved for payment. This commenter believed additional benefits to Medicaid beneficiaries are appropriate, but that unless additional funding is provided, expanding emergency services effectively creates an unfunded mandate for additional services for which an MCO will have to pay.

Response: The definition of emergency services includes the evaluation necessary to stabilize a patient with an emergency medical condition. We believe that all screening (beyond the initial routine procedures for example, checking blood pressure and, temperature) used to determine whether an emergency medical condition actually exists involve medical screens and tests that would have to be covered. We do not agree that MCOs should be required to cover any screening required under EMTALA. The Congress only required MCOs to cover services if the ''prudent layperson'' standard is satisfied. Under EMTALA, a hospital would have certain screening obligations even in a case in which the prudent layperson standard clearly was not met, but an individual nonetheless presented themself for treatment at an emergency room. Because the Congress limited an MCO's obligation to situations in which the ''emergency medical condition'' definition containing the prudent layperson standard is met, we would have no authority to require MCOs to pay for services when this definition is not met, even if EMTALA would require the hospital to incur costs. Under this regulation, MCOs may not refuse coverage by relying on their own definition of reimbursable emergency services if the prudent layperson standard is met, regardless of EMTALA.

We are not addressing the issue of additional funding for emergency services in this regulation. We note, however, that under § 438.6(c) all capitation rates paid under risk contracts must be actuarially sound and

appropriate for the services to be furnished under the contract.

Comment: Some commenters were concerned that States will attempt to obtain a waiver of the emergency services provisions in the BBA under section 1915(b) of the Act or section 1115 of the Act, and require prior authorization for emergency services. They recommend not allowing the emergency services section to be waived through section 1915(b) of the Act or section 1115 of the Act.

Response: We view access to emergency services using the prudent layperson standard as an important enrollee protection and we do not foresee a circumstance under which we would exercise our authority under section 1115 of the Act to permit an MCO to engage in prior authorization. We note that section 1915(b) of the Act only permits waivers of section 1902 provisions, and would not provide authority to permit prior authorization even if we were inclined to do so.

Comment: Some commenters recommended that we establish a central contact point at HCFAs central and regional offices where individuals and entities could direct inquiries regarding State and MCO or PCCM activity with respect to emergency services, establish a process for obtaining a timely remedy for these concerns, and clearly set out penalties that States or HCFA can impose for violations of the regulations and statute.

Response: The appropriate HCFA regional office should be contacted regarding any concerns about application of the emergency services provision of the regulation. In turn, our regional office will contact the central office should they need policy guidance. This is the regular procedure within HCFA and we believe it appropriate to follow it for these issues as well as all others. We note, with respect to penalties, that a failure to comply with the requirements in § 438.114 would constitute a failure to comply with section 1932(b)(2) of the Act, and would be sanctionable under § 438.700(d) of this final rule with comment period.

Comment: One commenter recommended stating in § 438.114 that copayments not permitted under fee-for-service may not be imposed for emergency services under managed care.

Response: Restrictions on copays in managed care are by statute, the same as for fee-for-service. This issue is addressed in the comments on § 438.108, which incorporates the fee-for-service limits on cost-sharing in § 447.50 through § 447.58.

Comment: One commenter believed that the provision of information that describes or explains what constitutes an emergency should be the responsibility of the State and should not be left to the MCO. The commenter recommended allowing States to provide information on what constitutes an emergency service. Others stated that the provision at § 438.114(b) requires States, MCOs, and PHPs to provide information annually, especially on post-stabilization because it is burdensome, unnecessary, and potentially confusing to enrollees. Others suggested removing the annual requirement or making information available upon request of the enrollee.

Response: We have revised § 438.114(b) to require that the information must be furnished by the State or at State option, by the MCO, PHP, or PCCM. We believe that States should be permitted to delegate this dissemination responsibility to MCOs, PHPs, or PCCMs. We do not believe that it is too burdensome to require this information, including post-stabilization requirements to be furnished on an annual basis and therefore, we have retained this requirement. We note that under the Medicare+Choice program, we also require that information regarding emergency services be provided annually.

Comment: One commenter believed that HCFA should include in the regulatory text, rather than just the preamble, a statement that MCOs must pay for the cost of emergency services obtained by Medicaid enrollees. Some commenters felt that the language in proposed § 438.114(e)(1)(i) was confusing, and did not make clear that MCOs must pay for treatment at facilities outside its network. They suggested replacing paragraph (i) with ''(i) An enrollee had an emergency medical condition as defined at § 438.114(a).'' However, some commenters disagreed, stating that the language clearly articulates the requirement to cover and pay for emergency services that meet the prudent layperson standard.''

Response: While we have not changed the policy, we have clarified the requirements in this section by revising paragraph (d) to state that the specified entities must cover and pay for emergency services regardless of whether the entity that furnishes the service has a contract with the MCO, PHP, or PCCM. In addition, we specify that the entities may not deny payment for treatment obtained when either—(1) an enrollee had an emergency medical condition, including cases in which the absence of immediate medical attention would not have had the outcomes specified in the definition of emergency medical condition, or (2) a representative of the MCO, PHP, or PCCM instructs the enrollee to seek emergency services. This paragraph also outlines the coverage and payment rules that apply to PCCMs not responsible for payment.

Comment: One commenter believed that paragraph (b)(6) concerning preauthorization was confusing. The commenter noted that ''prior authorization,'' ''pre-authorization,'' and ''pre-approved'' are used synonymously throughout the regulation and that we should choose one word to be consistent. They recommend revising (b)(6) to read, ''* * * but payment is required if the MCO does not provide prior authorization within an hour * * *'' and choose one word for prior authorization throughout.

Response: We agree with the commenter and have adopted the term ''prior authorization'' throughout the regulation. In addition, we have revised § 438.114(b) to add to the list of required information the post stabilization rules set forth at § 422.113(c) of the Medicare regulations. Proposed paragraph (c) (coverage and payment for post-stabilization services) has been replaced by a paragraph (f) that provides for coverage and payment ''in accordance with § 422.113(c) of this chapter.''

Comment: Some commenters urged that the regulation make clear that the attending physician determines the point at which prior authorization must be sought for post-stabilization services. One of the commenters recommended changing ''attending physician'' to ''emergency physician'' to clarify who is actually physically present caring for the patient.

Response: We agree with the commenters' point, and in this final rule with comment period at § 438.114(e)(3), we use the term ''attending emergency physician'' to describe who determines that the patient's condition is stable.

Comment: One commenter suggested replacing ''MCE physicians'' in proposed § 438.114(b)(4) with ''MCO, PHP, or PCCM providers'' to accurately reflect the full range of qualified health professionals.

Response: We agree with the commenter and have revised paragraph (b)(4) as suggested (as noted above, we have also replaced references to ''MCEs'' with references to all entities subject to the rule, in this case, MCOs, PHPs, and PCCMs). In addition, we are changing ''practitioner'' in proposed § 438.114(f) to ''provider'' in § 438.114(e)(3) of this final rule with comment period. However, we want to make clear that an

emergency physician must provide oversight to those providers who are not physicians.

Comment: Some commenters suggested striking the phrase ''with an average knowledge of health and medicine'' from the definition of emergency services at § 438.114(a). The commenters believe the phrase is ambiguous and likely to invite legal challenge because what is average in one community or culture may be different in another.

Response: The language referenced by the commenters is in the statute and therefore we have retained it.

Comment: Some commenters question the meaning of proposed § 438.114(c)(4), specifying the circumstances under which the State must pay for post-stabilization services not covered under an MCE (that is, MCO or PCCM) risk contract. The commenters recommend stating, ''if post-stabilization services are not covered by an MCO, PHP, or PCCM risk contract, the State must pay for all medically necessary services.''

Response: We agree with the commenters that the language in proposed § 438.114(c)(4) was confusing. We have replaced this section with a reference to the post-stabilization requirements in § 422.113(b) of the Medicare+Choice regulations. We note that if the hospital contacts the MCO, PHP, or PCCM for prior approval, and the MCO, PHP, or PCCM determines that it is not at risk for that specific service because it is not obligated to cover the service under its contract, then it should refer the hospital to the appropriate payer. For example, if a hospital contacts an MCO for prior approval for mental health services after the enrollee has been stabilized and the MCO contract does not include mental health services, then the MCO should refer the hospital to either the State or the appropriate PHP.

Comment: Many commenters believed that the prudent layperson standard is not easily adapted to non-medical conditions such as behavioral health which is not generally evaluated based on impairment of bodily function or dysfunction of a bodily organ or part. The commenters felt that individuals with mental health problems should have the same protections as others who may experience a medical emergency. Other commenters stated that the concept of ''danger to others'' inherent in many definitions of emergent behavioral health conditions is absent and arguably is not easily assessed by a person untrained in the assessment of behavioral health risks. They suggested separately defining urgent conditions as mental health crises that require immediate treatment to avoid hospitalization, and suggested establishing authorization criteria similar to post-stabilization criteria in the proposed rule. One commenter believed that both the ''danger to others'' and ''prudent layperson'' standards could be used simultaneously without violating the regulations. Other commenters suggested that the emergency medical condition definition encompasses mental illness as well as physical illness because it states ''* * * could reasonably expect the absence of immediate medical attention to result in placing the health of the individual in serious jeopardy * * *''

Response: We agree that the emergency medical condition definition using the prudent layperson standard pertains to mental health as well as physical health. We note that this is also the case with EMTALA. We believe that the reference to ''placing the health of the individual in serious jeopardy'' is sufficient to cover mental health emergencies.

8. Solvency Standards (§ 438.116)

Section 4706 of the BBA added new solvency standards to section 1903(m)(1) of the Act, requiring that an MCO's provision against the risk of insolvency meet the requirements of a new section 1903(m)(1)(C)(i) of the Act unless exceptions in section 1903(m)(1)(C)(ii) of the Act apply. Under section 1903(m)(1)(C)(i) of the Act, the organization must meet ''solvency standards established by the State for private health maintenance organizations'' or be ''licensed or certified by the State as a risk-bearing entity.'' The exceptions to this new requirement in section 1903(m)(1)(C)(ii) of the Act apply if the MCO—(1) is not responsible for inpatient services; (2) is a public entity; (3) has its solvency guaranteed by the State; or (4) is controlled by FQHCs and meets standards the State applies to FQHCs. Section 4710(b)(4) of the BBA provided that the new solvency standards applied to contracts entered into or renewed on or after October 1, 1998. Proposed § 438.116 essentially reflected these statutory provisions. In addition to the specific comments addressed below, we received many comments indicating general support for the implementation of the new solvency exceptions.

Comment: One commenter expressed concern that proposed § 438.116(c)(5), which would exempt MCOs with contracts entered into on or before October 1998, will lead to the lack of beneficiary protection in the event of insolvency in these plans. The commenter questioned whether this exemption applies to contracts in effect in 1998 as well.

Response: The BBA specified contracts entered into or renewed on or after October 1, 1998, as the effective date of the new solvency requirements. At this time, all contracts are subject to the new requirements. In this final rule with comment period, we have removed paragraphs (c)(5) and (c)(6).

Comment: One commenter asked if all MCOs, PHPs, and PCCMs must be licensed or certified as risk-bearing entities, and if carve-out services provided by PHPs would be considered ''public entities,'' and be exempt from the solvency standards.

Response: This section does not require that all MCOs, PHPs, and PCCMs be licensed or certified as risk bearing entities. First, the solvency requirements in this section are only applicable to MCOs and PHPs, not to PCCMs. While § 438.116(b)(1) provides that subject to certain exceptions, an MCO or PHP must meet the solvency standards established by the State for private HMOs, or be licensed or certified by the State as a risk-bearing entity. The commenter is correct that this requirement does not apply to MCOs that are public entities. With respect to carve-out services provided by a PHP, if the PHP is a public entity, it does not have to meet the private HMO solvency standards or be licensed or certified by the State as a risk bearing entity. However, the PHP would still have to make assurances satisfactory to the State that it has adequate provision against the risk of insolvency.

Comment: One commenter questioned whether in a subcontracting situation, the subcontractor would be subject to the solvency standards. The commenter noted that it is important for all entities serving Medicaid beneficiaries be solvent.

Response: We agree that it is important for all entities serving Medicaid enrollees to be solvent. We believe that the responsibilities of subcontractors and MCOs with respect to their subcontractors are adequately addressed in other sections. We note that § 438.6(l) provides that all subcontracts must fulfill the requirements of this part that are appropriate to the service or activity delegated under the subcontract. In addition, § 438.230 requires that the State ensure that each MCO oversees and is accountable for any functions and responsibilities that it delegates to any subcontractor. It also requires that each MCO monitors the subcontractor's performance on an ongoing basis and subjects the subcontractor to formal review ''according to a periodic

schedule established by the State, consistent with industry standards or State MCO laws and regulations.''

Comment: One commenter noted that under the Medicare+Choice regulations, MCOs are permitted to apply for a Federal waiver (preemption) from State solvency requirements if such requirements are more stringent that the Federal PSO requirements. The commenter suggested that in light of the availability of waivers in Medicare, Medicaid regulations should recognize that some PSOs are not going to meet State solvency requirements, and permit their participation in Medicaid managed care without meeting the State requirements.

Response: We do not have the statutory authority to exempt PSOs from the Medicaid solvency requirements in section 1903(m)(1) of the Act. The waiver authority in the BBA for PSOs that wish to enter into Medicare+Choice contracts BBA applies only to the Medicare program.

Comment: One commenter does not believe that Federally Qualified HMOs should be exempt from solvency requirements.

Response: Federally Qualified HMOs from solvency requirements are subject to detailed solvency requirements under title XIII of the Public Health Service Act and part 417 of this chapter. The commenter is correct, section 1903(m)(1)(A) of the Act provides that ''an organization that is a qualified health maintenance organization as defined in section 1310(d) of the Public Health Service Act is deemed to meet the solvency requirements in section 1903(m)(1)(A)(i) and (ii) of the Act.'' Since this exemption is set forth in the statute, we do not have the authority to change it. This comment has prompted us to recognize that we did not provide for this exemption in proposed, § 438.116, therefore, we have revised this final rule with comment period.

Comment: Several commenters asserted that the basic rule of this section was confusing with respect to the solvency requirements an MCO must meet.

Response: In response to this comment, we have revised § 438.116 to separate the ''basic rule'' from the ''other requirements'' that must be met as required under section 1903(m)(1)(C).

Comment: One commenter believed that proposed § 438.116(c)(2) which provides that the State solvency requirements in paragraph (b) do not apply if the MCO is a public entity, would mean that a county consortium would not need to meet the State's financial solvency requirements. The commenter asked if these Federal regulations preempt the State statute.

Response: Section § 438.116(b)(2) in this final rule with comment period (§ 438.116(c)(2) in the proposed rule) does not exempt public entities from all solvency requirements under Federal regulation. Section § 438.116(b)(1) specifies that unless an exception in paragraph (b)(2) applies, an MCO must meet the solvency standards established by the State for private HMOs or be licensed or certified as a risk bearing entity by the State. While paragraph (b)(2) exempts public entities from this requirement, under § 438.116(a), these entities must still make assurances satisfactory to the State showing that they have adequate provision against the risk of insolvency. States retain the flexibility to determine what assurances must be provided.

Comment: Several commenters supported the provision that exempts public entities from solvency standards imposed on private HMOs.

Response: While we acknowledge the support of this comment, we would like to reiterate that public entities are not exempt from all solvency standards. Public entities must still provide assurances satisfactory to the State showing that they have adequate provision against the risk of insolvency in accordance with § 438.116(a).

Comment: One commenter recommended that Federal requirements for capitalization should apply to all managed care organizations. In addition, the commenter suggested Federal and State governments should pre-approve all contracts with managed care organizations whose enrollees are primarily Medicaid insured, and require both Federal and State governments to guarantee provider payments if organizations become insolvent.

Response: We do not have statutory authority to establish Federal requirements for capitalization to guarantee payments to providers, or to require States to do so. However, under § 438.6 (Contract requirements), our Regional Office will review and approve all MCO and PHP contracts, and under § 438.806(b), prior approval by us is required for all MCO contracts with a value in excess of $1,000,000. While there is no Federal requirement that States guarantee provider payments, if, under § 438.116(b)(2)(iv), an MCO has its solvency guaranteed by the State, the State would be liable for all of the MCO's debts, including provider payments, if the MCO became insolvent.

Comment: One commenter noted that proposed § 438.116(c) provided that public entities are not required to meet the standards a State imposes on its private HMOs. The commenter questioned how this policy would affect a State that imposes the same or similar requirements on both private and public HMOs. In addition, the commenter asked if this provision applies to tribal governments.

Response: Even though public entities are not required to meet the solvency standards established by the State for private HMOs, public entities are still required to make adequate assurances satisfactory to the State that they have adequate provision against the risk of insolvency. States still have the flexibility to determine what assurances they consider adequate. Therefore, a State may require that public entities meet requirements that are the same or similar to those it imposes on private HMOs. With respect to tribal governments, if the MCO operates outside of the reservation, State solvency standards apply. But a State does not have jurisdiction to impose solvency standards on an on-reservation tribal MCO as a general operating condition.

Comment: One commenter expressed concern that we intend to accept State solvency standards rather than imposing Federal solvency standards.

Response: We do not have statutory authority to require a Federal solvency standard because the BBA specifically provides for State flexibility in this area.

D. Quality Assessment and Performance Improvement (Proposed Subpart E Recodified as Subpart D)

Background

Section 4705 of the BBA created section 1932(c) of the Act, paragraph (1) which requires State agencies that contract with Medicaid MCOs under section 1903(m) of the Act to develop and implement quality assessment and improvement strategies. Proposed subpart E (recodified as subpart D in this final rule with comment period) implemented section 1932(c)(1 of the Act), and set forth specifications for the quality assessment and performance improvement strategies that States must implement to ensure the delivery of quality health care through contracts with MCOs and (where applicable) PHPs.

Proposed § 438.302 established standards for State contracts with MCOs and PHPs, and required that each State must have a strategy for continually monitoring and evaluating MCO and PHP compliance with those standards. Proposed § 438.304 set forth minimum elements required in each State's quality improvement strategy. Proposed § 438.306 set forth standards for

availability of services addressing: (1) Beneficiary choice of entities; (2) services not covered by the MCO or PHP; (3) the MCO or PHP delivery network including: assurance of adequate capacity and services; the right to access to a women's health care specialist; credentialing requirements; 24 hour, seven day per week access; and convenient hours of operation; (4) coordination of care including screening and assessment; (5) procedures designed to identify and treat pregnancy and complex and serious medical conditions, and (6) a cultural competency requirement.

Proposed subpart E also contained rules regarding coverage and authorization decisions (proposed § 438.310), provider selection (proposed § 438.314), enrollee information (proposed § 438.318), enrollee rights (proposed § 438.320), confidentiality and accuracy of enrollee records (proposed § 430.324), and enrollment and disenrollment requirements (proposed § 438.326).

Additionally, proposed § 438.328 required an effective grievance system that meets the requirements of subpart F of this part; and proposed § 438.330 provided for oversight and accountability by the MCO or PHP of functions and responsibilities delegated to subcontractors.

Proposed § 438.340 required that MCOs and PHPs have an ongoing quality assessment and performance improvement program for the services it furnishes to enrollees; that the performance improvement programs achieve any minimum performance levels required by the State; and that the MCO or PHP achieves significant and sustained improvement in significant aspects of clinical care and non-clinical care areas that can be expected to have a favorable effect on health outcomes and enrollee satisfaction. The State also would be required under proposed § 438.336 to ensure that each MCO and PHP uses practice guidelines meeting specified criteria and under proposed § 438.342 to maintain a health information system that collects, analyzes, integrates, and reports data on the achievement of the objectives of this subpart.

1. Scope (Proposed § 438.300)

Proposed § 438.300 set forth the scope of subpart E.

Comment: Several commenters found the provisions in subpart E on Quality Assessment and Performance Improvement to be overly prescriptive. One commenter believed that the lack of flexibility would prevent States from accommodating new approaches and standards in a rapidly changing marketplace. One commenter contended that the provisions do not make allowances for resource limitations of States, while another suggested that the provisions of this part are unnecessary because of our review and approves MCO contracts.

Response: We understand the concern that this rule establishes substantial new requirements for States, MCOs, and PHPs. However, we believe that these provisions are important beneficiary protections, and reflect the intent of the Congress in enacting the quality and beneficiary protections of the BBA. As required by a directive from President Clinton, we also sought to incorporate the provisions of the Consumers Bill of Rights wherever permissible under our legal authority. When drafting the proposed rule, we spoke to States as well as representatives of beneficiaries to inform ourselves as to their views. We then tried to strike an appropriate balance that would reflect the Congressional intent, but also maintain flexibility for States, where possible, and avoid unreasonable burden and costs on MCOs and PHPs. Public comment on the proposed rule provided us an additional opportunity to hear the opinions of stakeholders. In this final rule with comment period we make many of the changes suggested by commenters.

Comment: Several commenters believed that these regulations would discourage or prevent State innovation in designing managed care programs, especially as States would fear the loss of Federal financial participation.

Response: We hope that these regulations will not have the effect of discouraging State innovation in managed care, because we recognize the important contributions made by States who have led the way in the past. We will continue to encourage and support State innovation in the future. However, we believe that a formal approach to quality assessment and improvement is an essential component of all successful health care delivery programs, including managed care programs, and that it is appropriate to incorporate such formal quality approaches into Medicaid managed care programs. We note that the approaches to quality assessment and improvement that are contained in this regulation are consistent with quality measurement and improvement activities currently in use throughout the health care industry

Comment: Several commenters contended that the quality provisions of subpart E are so burdensome to MCOs that this will discourage their participation in Medicaid managed care.

Response: We are concerned that some MCOs have decided to leave the Medicaid market and we have seriously considered the burden these regulations carry as we developed this final rule with comment period. While we have made some changes in recognition of this burden, we must balance this concern with beneficiary concerns raised by numerous commenters. This is especially important because the Medicaid population includes many individuals with special health care needs.

Comment: One commenter stated support for the comprehensive quality assessment framework of the proposed rule.

Response: We believe that the statute intends that State quality strategies be sufficiently broad to ensure a high quality of care for Medicaid managed care enrollees. This is the reason why we proposed a comprehensive strategy, and are retaining it in the final rule with comment period.

Comment: Several commenters discussed the provision of the BBA that requires us to conduct a study of the protections (if any) that may be needed when enrolling individuals with special health care needs into managed care. The commenters believed that we should have begun the study promptly following enactment of the BBA so that the results of the study could be reflected in the final rule with comment period.

Response: The research, analysis, and writing of this BBA-mandated study was underway during the public comment period for the proposed rule. As a result, in analyzing and responding to the comments, we were able to consider the comments in light of the findings and evidence resulting from this study. While we believe that the proposed rule addressed the needs of all Medicaid enrollees, including those with special health care needs, we have made revisions to the proposed rule in response to comments that have been informed by the findings in the BBA special needs study.

Comment: Numerous commenters raised questions about the relationship of the requirements of subpart E to our standards and guidelines for Medicaid and Medicare managed care organizations contained in our Quality Improvement System for Managed Care (QISMC) document. Several commenters interpreted the regulation to incorporate QISMC requirements. One commenter contended it was unrealistic to expect a small State to implement QISMC without allowing for incremental implementation over an extended period of time. Another

commenter suggested that the regulation should require the use of QISMC, and that QISMC should be modified and strengthened by incorporating ideas contained in our document titled ''Key Approaches to the Use of Managed Care Systems for Persons with Special Health Care Needs.'' Another commenter asserted that not requiring States to use QISMC for Medicaid, when we are using it for Medicare, discriminates against Medicaid beneficiaries. Another commenter asked how future improvements to QISMC will be incorporated into the regulations. Another commenter asked how we will review State strategies when States choose not to use QISMC. One commenter felt that QISMC was inadequate to improve the health care provided to vulnerable populations.

Response: All these comments reflect some confusion about the relationship of this BBA regulation to QISMC. The quality provisions of the BBA regulation and QISMC are similar, but not identical.

In 1996, before the BBA was enacted, we began an initiative that aimed, in part, to—

- Develop a coordinated Medicare and Medicaid quality oversight system that would reduce duplicate or conflicting quality requirements for Medicaid and Medicare managed care and send a uniform message on quality to managed care organizations and beneficiaries; and
- Make the most effective use of existing quality measurement and improvement tools, while allowing sufficient flexibility to incorporate new developments in the rapidly advancing state of quality measurement.

This initiative was QISMC. The most prominent products of the QISMC initiative were standards and guidelines for Medicaid and Medicare-contracting MCOs. For Medicaid, these standards updated and replaced earlier standards sent by us to States as part of the Quality Assurance Reform Initiative (QARI). The QARI standards were provided to States as technical assistance tools for their discretionary use although most States with MCO contracts used them, in part or in whole. QISMC was intended to replicate the success of QARI, in part by disseminating revised standards that reflected advances in private sector accreditation standards, as well as advances in quality measurement and improvement in both the public and private sectors.

After the BBA was passed in 1997, our development of the regulations to implement the quality assessment and improvement provisions of the law was informed by our prior work in developing QISMC. From the QISMC work, we identified those fundamental activities that formed the essence of quality measurement and improvement. These activities and standards were revised as necessary to reflect a level of detail appropriate for regulations and included in our proposed rule. For this reason, many of the regulations implementing the BBA quality provisions reflect QISMC standards. However, while QISMC was developed as a set of standards that address MCOs and PHPs, the legal requirements set forth in this final rule with comment period address States as well as MCOs and PHPs.

QISMC has been offered to States as a tool to use to the extent the State wishes, as long as the State complies with the requirements in this final rule with comment period. While full compliance with QISMC would help satisfy the quality requirements in subpart D that were based in part on QISMC standards, a State may meet the minimum standards in the regulation without requiring the use of QISMC. If a State requires MCOs and PHPs to follow QISMC, this will promote compliance with the regulatory requirements that overlap the QISMC standards. However, compliance with QISMC is not sufficient to meet all the provisions of the regulation because this regulation includes a much broader range of topics than is covered by QISMC. For the foregoing reasons, we will not use QISMC to monitor States, but rather monitor against the regulatory requirements.

Comment: Several commenters questioned the relationship of Medicaid quality provisions and those used by private accrediting organizations for the commercial managed care market. Two commenters suggested that private sector standards be used for Medicaid, either at State direction or through deeming. Another commenter recommended against use of private sector standards because he believes that they are geared to a generally healthy population while the Medicaid population includes populations with special health care needs.

Response: The Medicare+Choice statute, at section 1852(e)(4) of the Act, provides authority for Medicare+Choice organizations that are reviewed by private accreditation bodies to have a broad range of Medicare+Choice requirements ''deemed'' satisfied based on such private accreditation (if the private accreditation body applies standards at least as stringent as Medicare's). This authority includes the authority to ''deem'' compliance with QISMC standards, which is mandatory for Medicare+Choice organizations. There is no comparable broad deeming authority provided for MCOs or PHPs under the Medicaid statute. The only Medicaid authority for ''deeming'' by private accreditation bodies relates to the deeming of external review requirements under section 1932(c)(2)(A) of the Act. This rulemaking does not address these requirements, or provisions for the deeming of these requirements in section 1932(c)(2)(B) and (C) of the Act. These are being addressed in a separate rulemaking, in which a notice of proposed rulemaking was published on December 1, 1999, 64 FR 67223.

Comment: Several commenters questioned the applicability (or non-applicability) of subpart E to entities other than MCOs. One commenter agreed with applying the provisions of this subpart to PHPs. Another commenter suggested that we extend these requirements to all MCEs, including PCCMs. Another commenter suggested that the provisions of subpart E not be applied to capitated PCCMs. Lastly, another commenter suggested that PHPs be excluded from external quality review, because the commenter believed that this imposes an undue burden on States for contracts that are limited in scope.

Response: In section 1932 of the Act, the Congress included provisions that apply to all MCEs (that is, to MCOs and PCCMs), provisions that apply only to MCOs, and provisions that apply only to PCCMs. Since the Congress thus addressed PCCMs in section 1932 of the Act, we believe that where it applied a requirement only to MCOs, this reflects a clear and expressed intent that the requirement not apply to PCCMs. We therefore are not applying the regulations implementing section 1932(c)(1) of the Act to PCCMs. With respect to PHPs, as we have noted above, the Congress was silent, in section 1932 of the Act and its legislative history, concerning what requirements should be applied to these entities. At the time the Congress acted, we had longstanding regulations in place applying selected section 1903(m) of the Act requirements to PHPs. We believe that given that PHPs are paid on a risk basis, the concerns that caused the Congress to impose the quality requirements in section 1932(c)of the Act on MCOs apply with equal force to PHPs, and that the extension of these requirements to PHPs under our authority in section 1902(a)(4) of the Act is appropriate. With respect to the comment on risk-based PCCMs, they are not subject to these requirements by virtue of their status as PCCMs, since as

we have just noted, we are not imposing these requirements on PCCMs. Rather, as a risk contractor, they also meet the definition of PHP, and are subject to these requirements by virtue of their status as PHPs. Only PCCMs that fall in both categories would be subject to the requirements in subpart D.

Comment: Several commenters questioned the relationship of the quality provisions to waiver approval requirements. One contended that the relationship is unclear and duplicative. Another questioned if waivers of any of the quality provisions will be approved in light of the proposed rule's preamble language which states that waivers will only be granted if the quality requirements in this regulation are met or exceeded.

Response: We believe that the BBA quality requirements that are addressed in this subpart should apply to managed care provided through MCOs and PHPs regardless of the authority used to establish these programs. Quality is equally important whether the managed care program is established through a waiver granted under section 1115 or 1915(b) of the Act or as a State plan amendment under section 1932(a) of the Act. Therefore, generally, States will be required to follow these provisions as a condition for approval of a waiver. However, the Secretary has the discretion to waive these requirements if quality is addressed in the waiver program in a manner that equals or exceeds the quality requirements contained in this subpart. We believe that to do less would deny beneficiaries important protections and be counter to Congressional intent.

Comment: One commenter believed that the most important quality standard for persons with disabilities is that these individuals be served in the least restrictive setting, and that the standard for outcomes should include the achievement of the highest level of functioning for each individual.

Response: We agree that it is important to serve persons with disabilities in the setting that they desire. We further agree that achievement of the highest level of functioning is a desirable outcome for this population. This is consistent with the provisions of the proposed regulation. However, we are not specifying in the regulation particular performance measures for any of the populations served by the Medicaid program. The strength of each particular performance measure is dependant upon the specifications for calculating the measure. Performance measure specifications typically change over time as information systems, coding, survey instruments and other methods of data collection change over time. For this reason, we do not believe it is appropriate to establish specific performance measures in regulation.

Comment: One commenter noted that the proposed rule only addresses requirements that States and MCOs must meet, and suggested that these requirements will be effective in improving the quality of health care only if they are acted upon by external sources.

Response: Subpart D of this final rule with comment period interprets and implements section 1932(c)(1) of the Act and sets forth required quality standards. We agree that these new provisions must be executed well to have the desired impact of improving the health care provided to Medicaid beneficiaries. In this regard, States play a key role. They establish the provisions of MCO and PHP contracts and are primarily responsible for ensuring that the regulatory requirements are effectively implemented by MCOs and PHPs. We are responsible for overseeing the States' adherence to these rules. To this end we have revised, and will be further revising (based on this final rule with comment period), protocols that HCFA Regional Offices use to monitor State compliance with statutory and regulatory requirements.

Comment: Several commenters questioned the consistency between Medicaid and Medicare quality requirements. One suggested that the Medicaid requirements should be the same as those for Medicare. The other commenter suggested that the Medicaid subpart be reworked because it is not appropriate to apply the Medicare standards to Medicaid due to differences in the populations covered by each program.

Response: As stated in the introduction, the proposed Medicaid rule is consistent with the Medicare+Choice regulations wherever we believe it is appropriate. We believe that quality provisions should be consistent for all of our programs unless the statutory requirements differ, or program or population differences necessitate different standards. In creating this consistency, we carefully considered the needs of both Medicaid and Medicare beneficiaries and, where possible, proposed quality provisions that meet the needs of both. We believe that this approach best meets the needs of our beneficiaries (many of whom are eligible for both programs), and reduces burden on MCOs that contract with both programs. In subpart D, the regulatory requirements are consistent with those that apply to Medicare+Choice organizations. As noted above, however, under Medicare, Medicare+Choice organizations are all required to comply with QISMC, while States have the option of using all or part of QISMC in the case of Medicaid-contracting MCOs and PHPs.

Comment: Several commenters suggested that particular quality measures be incorporated into the regulation. One commenter wanted to ensure use of quality standards for patients with end stage renal disease, including a specific standard identified by the commenter. Another commenter suggested that all States measure quality against objectives contained in ''Healthy People 2000 and 2010,'' publications of the Department of Health and Human Services that outline a comprehensive health promotion and disease prevention agenda for the nation. Another commenter suggested that we establish, for children and adults with disabilities, a distinct set of quality standards (that is, performance levels) to ensure that these persons obtain the quality health care and health-related services necessary for them to lead full lives.

Response: We do not believe that particular quality measures should be specified in the regulation. Performance measures and quality standards change over time and it is important that the most current and useful measures can be quickly adopted. However, in response to these comments we have added a provision at § 438.204(c) that requires States to use performance measures and levels prescribed by us, as part of their State quality strategy. We also have provided in § 438.240(c)(2)(ii)(A) of the final rule with comment period that States must require their contracting MCOs and PHPs to meet these specific performance levels. This allows us to establish performance measures and levels for subsets of the Medicaid population, such as persons with end stage renal disease or other disabilities. We plan to use performance measures and levels that are widely accepted, standardized, and have undergone validity and reliability testing. At the present time, we are not aware of large numbers of such measures specific to persons with disabilities such as end stage renal disease that would meet these requirements. However, we expect measures to be developed over time that will meet these criteria. In the meantime, in response to the comment concerning the disabled population, we have added a new § 438.240(b)(4) to require States to have procedures to identify enrollees with special health care needs and to assess the quality and

appropriateness of care provided to these individuals. Also in response to this comment, we have in § 438.204(e)(2) required that the number of MCO and PHP enrollees with special health care needs be reported to us. The identification of these individuals and the assessment of their care and services is an essential step in assuring high-quality health care for them. We note that we also provide, in § 438.240(c)(1), for States to specify performance measures for their MCOs and PHPs to support quality improvement.

Comment: Several commenters suggested that we establish quality performance levels for States and MCOs.

Response: We agree with these commenters, and in response to these comments, and as noted above, we have added a new § 438.204(c) that requires that State quality strategies include our-prescribed performance measures and levels that States must require their MCOs and PHPs to meet. We believe that by requiring States to require their MCOs and PHPs to meet a specified level of performance on specific measures, we are carrying out its responsibility to ensure quality in the Medicaid program. We intend to use widely-recognized measures and establish levels through a public process, or based on statutory requirements. We have retained the States' authority to set minimum performance levels for MCOs and PHPs.

Comment: Several commenters suggested that States and MCOs be required to have vision and mission statements.

Response: We do not agree that it is essential for each State and MCO to have a vision and mission statement to support its quality strategy, nor do we believe it would be appropriate for us to mandate such a statement. While this approach can be an effective management tool, we believe that States should have the discretion to decide whether to adopt this approach, as long as they meet the elements for a comprehensive quality strategy set forth in this final rule with comment period.

Comment: Several commenters suggested that State quality strategies be required to address all statutory and regulatory requirements, not only those addressed in subpart E.

Response: We believe that the scope of this subpart is sufficiently broad to include the wide range of areas related to quality. We note that none of the commenters provided any specific examples of additional areas that they believe would be appropriate for inclusion. Therefore, we are not broadening the scope of the State quality strategy beyond the areas covered in the proposed rule.

2. State Responsibilities (Proposed § 438.302)

Proposed § 438.302 set forth the State's responsibilities in implementing its quality strategy. Specifically, § 438.302 required that each State: (1) have a strategy for assessing and improving the quality of services provided by an MCO and PHP; (2) ensure compliance with standards established by the State agency; and (3) conduct regular, periodic reviews to evaluate the effectiveness of its strategy, as often as the State agency determines appropriate, but at least every 3 years.

Comment: We received a large number of comments suggesting that the regulation require States to involve stakeholders in the development of their quality strategies, as is recommended in the preamble to the proposed rule. One commenter suggested that the Medical Care Advisory Committee perform this function. Another commenter suggested that the proposed State quality strategy should be published and comments from the public should be considered before the plan is made final.

Response: As stated in the preamble of the proposed rule, we expect that State agencies will consider the input of stakeholders when developing performance goals that are clear, fair, and achievable. We also believe that it is reasonable and appropriate for States to consider the ideas of stakeholders and other members of the public in the design of their quality strategies. Therefore, in response to this comment, and earlier comments on § 438.110 discussed in section II. C. above, in § 438.202(c) of the final rule with comment period we require States to provide for input of beneficiaries and other stakeholders regarding their quality strategies, and specifically, to make the strategies available to the public before adopting them. We do not specify what process States must use to obtain public input, because we wish to allow States flexibility to structure this process as they find appropriate. For several years, States with section 1115 demonstration projects have been required to have a process for public input. States with 1115 demonstrations may want to use this process for receiving comments on their quality strategy or choose another process.

Comment: Several commenters suggested that we add more specificity to the requirement for a State quality strategy. Most of the commenters suggested that the regulation should require that the strategy be put in writing. Two commenters suggested that standards be established to measure the success of the strategy. One commenter suggested that we incorporate in the regulation the language contained in the preamble that the strategies should be ''well considered,'' ''well coordinated,'' and ''overarching.'' Another commenter suggested that the regulation require State strategies to address all statutory and regulatory standards, identify each component of the strategy, address how the components are coordinated, ensure adequate monitoring and oversight, and be effective.

Response: We agree that the State quality strategies should be in writing, and in response to this comment, we are including this requirement in the final rule with comment period, in § 438.202(b). We believe that this new requirement, along with the requirement at § 438.202(c) that States consider the input of stakeholders in the design of their strategies, the requirement at § 438.202(e) that States conduct periodic reviews of the effectiveness of their strategy, and the requirement in § 438.204(g) that the State strategy include standards at least as stringent as those set forth in subpart D, provide the best mechanisms to ensure that the strategies will (1) be well considered, well coordinated, and overarching; (2) identify each component of the strategy and how components are coordinated; and (3) be effective. Therefore, we have not added the specific requirements suggested by the commenter to the regulation.

Comment: Several commenters considered the proposed maximum three year period between State reviews of the effectiveness of their quality strategies to be too long. The commenters instead suggested an annual review of MCO or PHP compliance with contract requirements. One commenter believed that the three year time period was inconsistent with QISMC requirements, and certification and licensing procedures. Another commenter expressed support of the three year time frame.

Response: The commenters who objected to the three year maximum period between reviews of the State quality strategy appear to have misunderstood the intent of § 438.202(e). Section 438.202(e) does not apply to State review of MCO and PHP compliance with contracts, but to review of the effectiveness of the *State's* quality strategy. State monitoring and review of MCOs and PHPs is addressed, in the context of the State's quality strategy, in § 438.204(b)(2), which requires States to continuously monitor and evaluate MCO and PHP compliance with the standards specified in the

subpart. The evaluation of the State's quality strategy under § 438.202(e) is intended to be a broad review of the interrelationship of all the elements that the State is required to include in its quality strategy to determine the effectiveness of this strategy as a whole. We believe it is particularly important for States to step back and review the ''big picture'' at least every three years because the field of quality review and measurement is rapidly evolving, making it important for States to reassess their approach at regular intervals. Requiring periodic review on a more frequent basis may not provide the State with sufficient time to effectively implement its strategy. For this reason, we are retaining the provision requiring review at least every three years.

Comment: Several commenters suggested that the final regulation require that beneficiaries be provided information about the State quality assurance program and MCO and PHP quality. In particular, the commenters wanted enrollees and potential enrollees to receive information on quality indicators, quality improvement topics, external review results, compliance audits, summarized complaint and grievance data, and disenrollment counts.

Response: We agree that beneficiaries, upon request, should have access to information concerning the State quality strategy and MCO and PHP performance. In § 438.202(b) and (c) of the final rule with comment period with comment period we require that the States' quality strategies be in writing and that stakeholders have an opportunity to make suggestions and comment on the strategy. We believe that this requirement will also serve the purpose of ensuring that beneficiaries can obtain information on that strategy. Section 438.10 of the regulation specifies what information must be furnished to enrollees and potential enrollees by the State, the MCO or PHP, and the enrollment broker. For MCOs, PHPs, and as appropriate PCCMs that enroll beneficiaries under a State plan program under section 1932(a) of the Act, this includes quality and performance indicators that can be used to compare plans. In addition, the proposed rule implementing the external quality review (EQR) requirements in section 1932(c)(2)of the Act, published in the **Federal Register** on December 1, 1999 (64 FR 67223), identifies EQR results that it proposes must be made available to enrollees. We believe that these requirements will ensure that enrollees and potential enrollees have access to information that will enable them to compare the performance of MCOs and to make an informed choice.

Comment: One commenter suggested that we add a new paragraph to proposed § 438.302 that would require that State strategies address all covered services, including midwifery services.

Response: We do not believe it is appropriate to specify that all covered services be included, since all covered services may not be included under an MCO or PHP contract. We also believe that the existing regulations already cover all services that are covered under the contract, as § 438.202(a) refers to ''managed care services offered'' by MCOs and PHPs. This would include any services they offer. Under § 438.206(c) of the final rule with comment period, the State is responsible for making available to the enrollee any Medicaid service not covered under the MCO or PHP contract, and these thus would not be included in an MCO or PHP quality strategy.

Comment: One commenter believed that furnishing quality oral health services requires planning and treatment decisions that are made by the dentist and the patient together.

Response: We agree with the commenter, and believe that the final rule with comment period addresses this issue. Paragraphs (b)(5) and (b)(6) of § 438.100 (previously designated as § 438.320(b)(4) and (5) in the proposed rule) specify the right of enrollees to receive information on available treatment options, and to participate in decisions regarding their health care.

Comment: One commenter asked what criteria we will use to review and evaluate State quality strategies.

Response: Since the requirement that States develop and follow State strategies is new, we have no experience with reviewing and evaluating these strategies. In response to the commenter's concern, however, we have added a new paragraph (f) to § 438.202 requiring States to submit to us a copy of their initial strategies and all significant revisions thereafter. We also in paragraph (f)(2) specify that States must regularly report to us on the implementation and effectiveness of their strategies.

3. Elements of State Quality Strategy (Proposed § 438.304)

Proposed § 438.304 set forth the minimum elements of a State quality strategy, including contract provisions that incorporate the standards specified in this subpart. Specifically, quality strategies would include procedures for assessing the quality and appropriateness of care and services provided, including but not limited to: (1) contract provisions that incorporate the standards specified in this subpart; (2) procedures for assessing the quality and appropriateness of care and services, including, but not limited to continuous monitoring and evaluation of MCO and PHP compliance with the standards; (3) annual, external independent reviews of quality outcomes, and timeliness of, and access to services covered under each MCO and PHP contract; (4) appropriate use of intermediate sanctions that at a minimum, meet the requirements in subpart I; (5) an information system sufficient to support initial and ongoing operation and review of the State's quality strategy; and (6) standards, at least as stringent as those required under proposed §§ 438.306 through 438.342, for access to care, structure and operations, and quality measurement and improvement. In developing a strategy, we communicated our expectations that each State will work with beneficiaries and their advocates, quality experts, managed care organizations, and other stakeholders to develop performance goals that are clear, fair, and achievable.

Comment: As proposed, § 438.304 required States to ''continuously monitor'' MCO and PHP compliance with the quality standards. Many commenters urged that we revise this requirement. Several commenters suggested that the regulation require an annual audit of each MCO for compliance with the standards; that the requirement include monitoring of grievances and logs of calls to beneficiary ''hotlines''; and that a medical records review be required of catastrophic events, random records, and persons with disabilities. Other commenters suggested replacing the continuous monitoring requirement with a more flexible standard related to the MCO's or PHP's contract cycle or to the need for monitoring based on the plan's performance.

Response: We continue to believe that States should be required to continuously monitor and evaluate MCO and PHP compliance with quality standards. States may choose, as part of their quality strategies, to conduct a comprehensive audit of MCOs and/or PHPs on an annual or other basis, but this should not relieve them of the ongoing responsibility to ensure that MCOs and PHPs are meeting the standards at all times. States are in the best position to decide how best to accomplish this activity and may vary their requirements according to their knowledge of particular MCOs and

PHPs. We believe the requirement in § 438.416(d) requiring MCOs and PHPs to submit to the State summaries of their handling of grievances and appeals is sufficient to address the comments regarding monitoring of grievances. However, we have not required MCOs and PHPs to have a ''hotline'', therefore, including a monitoring requirement for hotlines would not be appropriate. With respect to medical records, we do not believe that we should specify what records States should review or the frequency with which they should perform review. Rather, we believe that this should be left to States to determine as part of their overall quality strategies. With respect to persons with disabilities, we have added new requirements for monitoring. New § 438.204(b)(1) requires States, as a part of their quality strategies to have procedures to identify, and assess the quality and appropriateness of care furnished to, enrollees with special health care needs.

Comment: One commenter suggested that, as part of the State quality strategy, States should be required to evaluate the effectiveness of services provided to beneficiaries with limited English proficiency. Another commenter suggested that States should collect and analyze data on cultural competency. This commenter further suggested that States conduct demonstration projects related to cultural competency to better understand this new and critical area of quality assessment.

Response: We agree that in order for States' MCOs and PHPs to effectively address cultural competency, they all must have basic information on the cultural characteristics of their Medicaid enrollees. We therefore have revised § 438.204(b)(1) of the final rule with comment period to require States, as a part of their quality strategies, to include procedures to identify the race, the ethnicity, and primary language spoken of each MCO and PHP enrollee and to provide this information to each MCO and PHP at the time of each Medicaid beneficiary's enrollment in the MCO or PHP. Further, § 438.306(e)(4) of the proposed rule has been modified as § 438.206(e)(2) of the final rule with comment period to require the State to ensure that each MCO and PHP provides services in a culturally competent manner to all enrollees, including those with limited English proficiency and diverse cultural and ethnic backgrounds. This means that, as part of its quality strategy, the State must monitor and evaluate the effectiveness of these provisions. We would welcome State demonstrations or other strategies to develop effective means of evaluating cultural competency in the provision of services.

Comment: Several commenters recommended that we add a State quality strategy element requiring the State to have an information system capable of managing the data that MCOs are required to report under proposed § 438.342. Another commenter stated that the regulation should require compatibility between the MCO's and the State's information systems.

Response: Section 438.204(g) of the final rule with comment period includes, as an element of the State quality strategy, that the State provide for ''structure and operations'' standards (among other standards) at least as stringent as those of this subpart. Because the health information systems requirement is included in the subpart, it is unnecessary to add this as an element of the State quality strategy. Likewise, the information systems requirements in § 438.242 are sufficient. While this section does not specify that MCO and PHP systems must be compatible with those of the State, we believe that it is in the State's best interest to require this. If a State chooses not to impose this requirement on an MCO or PHP, the State remains responsible for obtaining from the MCO or PHP the information specified in § 438.242 and incorporating into its information system. Some States may choose this option for MCOs or PHPs that need time to acquire a compatible system or to modify an existing system to make it compatible.

Comment: Numerous commenters requested information concerning the EQR element of the State quality strategy. Several commenters felt that requiring States to review quality outcomes, timeliness, and access to care under the EQR would be expensive and excessive; and that therefore, review of all three of these areas should not be required annually. One commenter suggested that States should be allowed to conduct an in-house review. Another commenter believed that well performing MCOs and PHPs should not be required to undergo an annual review. One commenter wanted additional information about how EQR fits into the State quality strategy and QISMC. Another commenter suggested that we should establish criteria for EQR organizations. One commenter suggested that we publish interim standards for EQR that would allow States to access the 75 percent matching rate established by the BBA.

Response: As noted above, on December 1, 1999, we published in the **Federal Register** a proposed rule to implement the BBA provision that requires an annual, external independent review of the quality outcomes and timeliness of, and access to, services covered under each MCO contract. 64 FR 67223. This proposed regulation includes information that will address the comments made concerning § 438.304(c) of the proposed rule. The statute requires that we contract with an independent quality review organization to develop protocols to be used in the reviews. That work is now underway. Until that work is completed, we cannot publish standards to permit States to access the 75 percent matching rate provided by the BBA. We note, however, that States may currently receive a 75 percent Federal match under section 1903(a)(3)(c) of the Act for EQR activities conducted by Peer Review Organizations (PROs) and entities that meet the requirements for contracting as a PRO.

Comment: One commenter suggested that we add the word ''items'' before ''services'' in § 438.304(c) of the proposed rule, as it is included in the statute. The commenter also suggested that we include a list of examples of such items, such as durable medical equipment, assistive devices, certain birth control items, and prescriptions.

Response: Ordinarily, we do not use the term ''items'' in our regulations because the term ''services,'' as used in the regulations, includes covered ''items'' as well. While only the Medicare regulations expressly specify that ''services'' includes ''items'' (42 CFR 400.202), section 1905(a) of the Act uses the term ''care and services'' to encompass all services or items for which Medicaid payment may be made. References in the regulations to ''services'' therefore, include covered ''items'' as well. Because of this, we are not adding the word ''items'' before ''services'' in § 438.204(d) (§ 438.304(c) in the proposed rule).

Comment: One commenter expressed the need to clarify that appeals on coverage and claims are handled through the State fair hearing process, and not through complaints to the EQR.

Response: The commenter is correct that appeals on coverage and claims decisions by enrollees are properly addressed through the internal appeals process of the MCO and PHP and the State fair hearings process. The proposed EQR regulation makes clear that handling enrollee appeals is not an EQR function.

4. Availability of Services (Proposed § 438.306)

Section 1932(c)(1)(A)(i) of the Act, as added by section 4704 of the BBA,

requires each State that contracts with MCOs under section 1903(m) of the Act to develop and implement standards for access to care under its quality assessment and improvement strategy. Section 438.306 of the proposed rule established standards for access to care. Paragraph (a) required that States ensure that all covered services are available and accessible to enrollees. Paragraph (b) specified that if a State agency limits freedom of choice, the State agency must comply with the requirements of proposed § 438.52, which specify the choices that the State agency must make available. Paragraph (c) specified that if an MCO or PHP contract did not cover all services under the State plan, the State agency must arrange for those services to be made available from other sources, and instruct all enrollees on where and how to obtain them, including how transportation is provided. In § 438.306(d) we proposed new requirements for the delivery networks of MCOs and PHPs to ensure that all covered services under a contract are available and accessible to enrollees. These requirements would be imposed on State agencies, which in turn would enforce these requirements on MCOs and PHPs. Specifically, paragraph (d)(1) proposed that the State agency require all MCOs and PHPs to maintain and monitor a network of appropriate providers that is supported by written arrangements and is sufficient to provide adequate access to covered services. In this context, adequate access generally means that all contracted services, other than out-of-area emergency care services, are available within the MCO's or PHP's network. In establishing and maintaining such a network, the proposed rule required that MCOs and PHPs consider (1) anticipated enrollment, with particular attention to pregnant women and children; (2) the expected utilization of services, considering enrollee characteristics and health care needs; (3) the numbers and types of providers required to furnish contract services; (4) the number of network providers who are not accepting new patients; (5) the geographic location of providers and enrollees, considering distance, travel time, the means of transportation ordinarily used by enrollees, and whether the location provides physical access for enrollees with disabilities.

In § 438.306(d)(2) we proposed that the State be required to ensure that MCOs and PHPs allow women direct access to a woman's health specialist for women's routine and preventive services, and in paragraph (d)(3) we proposed that MCOs and PHPs seeking an expansion of their service area demonstrate that they have sufficient numbers and types of providers to meet the anticipated additional volume and types of services the additional enrollee population may require. Proposed § 438.306(d) also required that: (1) the State agency ensure that each MCO and PHP demonstrate that its providers are credentialed as described in proposed § 438.314, (2) when medically appropriate, each MCO and PHP make services available 24 hours a day, 7 days a week, (3) as part of the State quality strategy, the State must ensure that each MCO and PHP requires its providers to meet the State-established standards for timely access to care and member services, taking into account the urgency of need for services; and (4) that each MCO and PHP establish mechanisms to ensure compliance and monitor continuously for compliance, and take corrective action in cases of non-compliance.

In § 438.306(e) we proposed that each MCO and PHP be required to provide each enrollee with an initial health assessment within 90 days of the effective date of enrollment, and that pregnant women and individuals with complex and serious medical conditions receive this baseline health risk assessment within a shorter period of time. We further proposed that each MCO and PHP have in place State-approved procedures to identify and furnish care to pregnant women and individuals with complex and serious medical conditions; and that appropriate medical procedures be implemented to address and monitor their care, including specifying an adequate number of direct access visits to specialists as required by the treatment plan.

Finally, proposed § 438.306(e)(4) required that the State ensure that each MCO and PHP provide services in a culturally competent manner, including satisfying the language requirements in § 438.10(b).

Comment: We received several comments in support of the proposed rule, but a few commenters suggested that we revise it to include more specific wording. For instance, one commenter recommended that we expand the rule to make clear that access includes receiving services in a timely manner. Another commenter suggested that we change the language to ensure that all covered services are available to each enrollee as medically necessary. Another commenter suggested that the regulation be revised to reflect that both services and ''items'' were available and accessible to enrollees. This commenter was concerned that the proposed language did not address access to medical equipment, drugs, and other supplies covered by a State Medicaid plan.

Response: Paragraph (a) was intended to convey the broad general intent of the subsequent provisions. Subsequent provisions of the final rule provide more detailed specifications for what access standards must include, including timely access to care and medical necessity. As noted in a previous response, we have not added the word ''items'' to explicitly address access to ''items and services'' covered by an MCO or PHP contract because the term ''services,'' as used in the regulations, includes covered ''items'' as well. While only the Medicare regulations expressly specify that ''services'' includes ''items'' (42 CFR 400.202), section 1905(a) of the Act uses the term ''care and services'' to encompass all services or items for which Medicaid payment may be made. References in the regulations to ''services'' therefore, include covered ''items'' as well.

Comment: We received numerous comments in response to proposed § 438.306(c), which requires a State—

- To arrange for State plan services not covered under an MCO or PHP contract to be made available from other sources; and
- To instruct enrollees on where and how to obtain these services, including how transportation is provided.

Most of the commenters supported the inclusion of this provision, indicating that distribution of information on out-of-plan services has been unsatisfactory in the past. However, a few commenters requested clarification of this provision and wondered whether States could delegate this responsibility to MCOs. In contrast, one commenter disagreed that MCOs should have the responsibility to advise enrollees on where and how to obtain services not provided by the MCO.

Response: We recognize that States have discretion to contract with MCOs or PHPs to provide a specific set of services that may not include all services covered under a Medicaid State plan. Our intention in proposing this provision was to ensure that enrollees in managed care have access to services covered under a State plan but not provided by an MCO or PHP. We believe that the duty to inform enrollees on how to obtain those services rests primarily with the State. However, we agree that a State may delegate this responsibility to an MCO or PHP as part of its contract.

Comment: One commenter believed that we have gone beyond our authority

in proposing § 438.306(c). The commenter suggested that our use of the words ''arrange for services to be made available from other sources'' expands the State's responsibility to a greater degree under managed care than under a fee-for-service arrangement. In light of such concerns, the commenter recommended that the clause be deleted, and argued that States should only be responsible for guaranteeing payment for State plan services not covered under an MCO contract.

Response: States continue to have the same responsibility they have always had to ensure that covered benefits are available to eligible beneficiaries in accordance with a Medicaid State plan. In proposing § 438.306(c), it was never our intent to imply that States act as case managers in ''arranging for services to be available from other sources.'' Therefore, we agree that some change to the proposed rule is necessary to clarify the State's responsibility. In the final rule with comment period, § 438.206(c) requires that, if the MCO or PHP does not cover all of the services under the State's plan, the State must make available those services from other sources and provide enrollees with information on where and how to obtain them, including how transportation is provided.

Comment: We received several comments on proposed § 438.306(c) with regard to the provision of transportation. One commenter noted that transportation has been an issue in certain counties within its State. Another commenter noted that transportation is particularly important for adolescents. Several commenters made specific recommendations. For example, one commenter recommended that we clarify how transportation is reasonably provided, and require that it be subject to the availability of public transportation in the region. Other commenters recommended that we make the transportation requirement a separate provision.

Response: Under § 431.53 of our regulations, a State Medicaid agency is required to specify in its State plan that the agency will (1) ensure all necessary transportation for recipients to and from providers, and (2) describe the methods that the agency will use to meet this requirement. Proposed § 438.306(c) was intended to ensure that, under managed care, enrollees still receive necessary transportation services consistent with what is described in the Medicaid State plan. We do not believe any changes are necessary to further require access to transportation services under managed care.

Comment: Several commenters requested that § 438.306(c) specifically refer to services excluded from a contract because of religious beliefs. In addition, commenters requested that we address the knowledge and expertise of providers with respect to the scope of services provided by the MCO.

Response: We believe that the information requirements in §§ 438.10(e)(2)(xii) and 438.102 specifically address the commenters' concerns. Section 438.10(e)(2)(xii) requires that, either the State or the MCE, as appropriate, must furnish enrollees and potential enrollees with information on how to obtain services covered under a State plan. This encompasses information on services not covered under an MCO or PHP contract because of moral or religious objections and information on the education, licensure, and board certification of providers. Section 438.102(c) requires that MCOs or PHPs that elect on moral or religious grounds under § 438.102(b)(3) not to provide, reimburse, or provide coverage of a counseling or referral service that they would otherwise be required to under § 438.102(b)(1), must furnish information about the services it does not cover to the State and to potential enrollees and enrollees at certain times.

Comment: We received several comments suggesting that proposed § 438.306(d)(1), which set forth requirements for establishing, maintaining, and monitoring a network of appropriate providers, imposed an undue administrative burden on States. Commenters objected to the general requirement for the State to ensure that MCOs maintain and monitor a network of appropriate providers ''that is supported by written agreements and is sufficient to provide adequate access to all services covered under the contract.'' One commenter believed that documentation referenced in the general requirement was rarely available to the Medicaid agency, much less to MCOs. The commenter viewed the requirement as impractical, and believed that there was potential for large implementation problems. Another commenter suggested that, although it is the duty of the State to monitor MCO contracts, it would be a huge administrative burden to verify that a written agreement exists with each provider.

Response: We do not agree that this requirement is impractical or imposes an undue burden on States. This provision is consistent with § 438.230, which requires written agreements that specify the delegated activities and reporting responsibilities of a subcontractor. We believe that, without written agreements, MCOs and PHPs cannot assure their enrollees sufficient access to network providers. Therefore, States must obtain assurances from and monitor MCOs and PHPs, as appropriate, to verify that such agreements exist.

Comment: Numerous commenters suggested that we revise proposed § 438.306(d)(1) to add a requirement that States and MCOs make available, as part of their network, providers experienced in serving individuals with certain conditions, and providers with specialty training. For example, commenters suggested that we require MCOs to contract with providers experienced in serving individuals with HIV/AIDS, children with special health care needs, individuals with chronic diseases, and individuals with physical and developmental disabilities. One commenter recommended that the final regulation establish minimum standards for a provider's experience in serving persons with chronic diseases and disabilities in managed care plans. Minimum standards suggested by commenters include: (1) current caseload of persons with certain chronic diseases or disabilities, (2) provider training in treating persons with certain diseases or disabilities, (3) extent or duration of experience serving persons with certain chronic diseases or disabilities, and (4) measures of successful outcomes in treating persons with chronic diseases or disabilities.

Response: We agree that States should ensure that MCOs make available, as part of their network or through other arrangements, access to providers experienced in treating conditions such as HIV/AIDS and access to specialty providers for certain chronic conditions. Therefore, in response to this comment, in § 438.206(d)(1)(iii), we have added ''training and experience'' to the list of attributes MCOs and PHPs must consider when establishing their provider networks. We also have added, in § 438.206(d)(1)(i) ''persons with special health care needs'' as a category of enrollees to whom States, MCOs ans PHPs should pay particular attention in meeting this requirement.

We do not believe it is appropriate to further specify in regulation the types of specialists that must be included in an MCO's or PHP's provider network, nor do we believe it appropriate to define what constitutes an experienced provider for certain types of conditions. Because the evidence base regarding how to precisely define all types of ''experienced providers'' is still limited, we believe that States are in a better position to impose specific requirements on MCOs and PHPs,

consistent with their standards for access to care and the population enrolled in managed care. However, also in response to the concerns raised in this comment, we have added a requirement at § 438.206(d)(5) that if the network is unable to provide necessary medical services, covered under the contract, to a particular enrollee, the MCO or PHP must adequately and timely cover these services out of network for the enrollee, for as long as the MCO or PHP is unable to provide them. We intend that the inability to provide medically necessary services would extend to a situation in which the enrollee needs related and covered services (for example, a Cesarean section and a tubal ligation) to be performed at the same time; not all related and covered services are available within the network; and the enrollee's primary care provider or another provider determines that receiving the services separately would subject the enrollee to unnecessary risk. We further specify at § 438.206(d)(8) that the State must ensure that use of out-of-network-providers incurs no greater cost to the enrollee beyond what he or she would have paid had the services been received from a network provider.

We emphasize that § 438.206 is integrally linked to § 438.207, which requires MCOs and PHPs to give the State assurances of adequate capacity and services to serve the MCO's and PHP's expected Medicaid enrollment, including access to specialty services. In meeting the requirements of the final rule with comment period, each MCO and PHP will have to submit assurances of its capacity to States, and States will have to submit certification to us, annually and at any time there has been a significant change in the MCO's and PHP's network that would affect adequate capacity and services. We reserve the right to inspect documentation submitted by MCOs and PHPs to the State. With these requirements, we believe that appropriate checks are in place to ensure that States are monitoring MCOs and PHPs against the State's standards for access to care.

Comment: We received several comments suggesting that proposed § 438.306(d)(1)(i) should specifically consider other populations with special health care needs in addition to pregnant women and children. Commenters recommended that we revise § 438.306(d)(1)(i) to also consider people with disabilities, adults with special health needs, persons with mental illness, persons with substance abuse problems, persons with developmental disabilities, and persons with functional disabilities or complex problems involving multiple medical and social needs such as HIV/AIDS and homelessness.

Response: We agree and have revised this provision. As noted above, § 438.206(d)(1)(i) of the final rule with comment period requires that each MCO and PHP, in establishing its provider network, take into consideration ''persons with special health care needs,'' as well as pregnant women and children. Also, in response to this comment, § 438.208(b) of the final rule with comment period requires that States implement ''mechanisms to identify to the MCO or PHP, upon enrollment'' categories of enrollees at risk of having special health care needs, children under age 2, and other enrollees known to be pregnant or have special health care needs.

''Persons with special health care needs'' is the terminology used by the Congress at section 4705(c)(2) of the BBA that called for the Secretary to conduct a study of the safeguards needed when such individuals are enrolled in Medicaid managed care. In undertaking this study, we conceptualized individuals with special health care needs as persons who either (1) have functional disabilities (e.g., difficulty bathing, dressing, eating, communicating, or problems with mobility) or (2) live with health or social conditions that place them at risk of developing functional disabilities (for example: mental retardation; serious chronic illnesses such as HIV, schizophrenia, or degenerative neurological disorders; disabilities resulting from many years of chronic illness such as arthritis, emphysema, or diabetes; and certain environmental risk factors such as homelessness or family problems that lead to the need for placement in foster care). From this conceptual framework, our study identified six groups of individuals with special health care needs:

(1) children with special health care needs;

(2) children in foster care;

(3) individuals with serious and persistent mental illness/substance abuse;

(4) individuals who are homeless;

(5) older adults (individuals 65 years of age and older) with disabilities; and

(6) adults under 65 who are disabled or who have a chronic condition, whether physical or mental. As noted above, under new § 438.208(b)(1), States are required to identify enrollees in these categories to their MCO or PHP.

Subsequent to the passage of the BBA, we also began to explore the concept of ''persons with complex and serious medical conditions.'' This category of persons was referenced in the proposed rule because they are a group of individuals addressed in the Consumer Bill of Rights and Responsibilities (CBRR). On August 31, 1999, the Institute of Medicine (IOM) submitted a report to us entitled ''Definition of Serious and Complex Medical Conditions.'' This study was requested in order to provide guidance to Medicare M+C organizations (who do not have a BBA mandate with respect to ''persons with special health care needs''). While the IOM recommended that the establishment of an administrative definition for serious and complex medical conditions would be premature at this time, it also described a ''serious and complex condition'' as: * * * one that is persistent and substantially disabling or life threatening that requires treatments and services across a variety of domains of care to ensure the best possible outcomes for each unique patient or member.''

In examining the similarities and differences between the concepts of ''special health care needs'' and ''serious and complex medical conditions'' as articulated in our work for its Report to the Congress and the IOM, respectively, it is clear that individuals with, ''persistent and substantially disabling * * * [conditions] that require treatments and services across a variety of domains of care to ensure the best possible outcomes for each unique patient or member,'' are included in our conceptual framework of ''persons with special health care needs.'' The only component of the IOM description of persons with serious and complex medical conditions that is not readily apparent as included in our conceptual description of persons with special health care needs are those health conditions that are ''life threatening.'' However, we believe that persons with life threatening conditions can reasonably be considered to have a special health care need. Therefore, the provisions of this final rule with comment period require States to ensure that each MCO and PHP establish and maintain a network of providers that considers the MCO's or PHP's anticipated enrollment, with particular attention to pregnant women, children, and persons with special health care needs. We have also, throughout this final rule with comment period, deleted the language, ''individuals with serious and complex health care needs'' where used in the proposed rule, and replaced

it with ''persons with special health care needs.''

Comment: We received numerous comments that generally supported the requirement in proposed § 438.306(d)(1)(iii) that MCOs consider the numbers and types of providers needed to furnish contracted services. Many commenters recommended that, instead of providing examples in the preamble, we establish in regulation specific enrollee-to-provider ratio standards. While several commenters suggested that we incorporate the examples from the preamble into the regulation itself, other commenters suggested that we apply other enrollee-to-primary care provider ratios ranging from 1200:1 to 2500:1. Some providers believed that primary care assignments should be discontinued when a patient load reaches 3,000. Several believed that enrollee-to-provider ratios should encompass all patients treated by a provider, and not just Medicaid patients. Finally, some commenters also believed that specific ratios for specialists should be established in regulation, such as ratios for pediatric specialists and providers serving persons with HIV/AIDS.

Response: We do not believe it is appropriate to set national standards that specify maximum enrollee-to-provider ratios. We believe that the inclusion of such ratios in regulations would be too prescriptive, and would not be appropriate for all Medicaid managed care programs across the country. The variation in the comments we received attests to this. Because of such variation, we believe that States are in a better position to establish specific standards to ensure that an adequate number of providers is maintained within MCO and PHP networks.

Comment: Some commenters requested that we establish specific standards in the final rule with comment period outlining the types of providers that must be included in an MCO's network. One commenter specifically recommended that the term ''provider'' be defined when establishing standards for the various disciplines and specialty areas of practice. Other commenters recommended that an MCO be required to include in its network specified types of providers such as nurse-midwives, obstetricians and gynecologists, pediatric specialists, and providers with demonstrated competence in serving enrollees with mental illness, substance abuse problems, developmental disabilities, functional disabilities, and complex problems involving multiple medical and social needs such as homelessness and HIV/AIDS.

Response: We do not believe it appropriate to impose national standards requiring specific numbers and types of providers. States have implemented varying and often unique programs that cover a variety of benefits. Some of these programs serve a broad spectrum of Medicaid enrollees; while others serve a narrower group. One set of standards may not be appropriate in every circumstance. However, we have required at § 438.206(d) that each State must ensure that each MCO and PHP maintain and monitor a network of providers that is sufficient to provide adequate access to all services covered under the contract, and that in constructing this network, each MCO and PHP must consider (among other requirements): (1) the anticipated enrollment, with particular attention to pregnant women, children and persons with special health care needs, and (2) the numbers and types (in terms of training and experience) of providers required to furnish the contracted services.

Comment: We received a number of comments suggesting that we establish in the final rule with comment period a national geographic access standard. Section 438.306(d)(1)(v) of the proposed rule required MCOs and PHPs, when establishing and maintaining their provider networks, to take into account the geographic location of providers and enrollees, considering distance, travel time, the means of transportation ordinarily used by enrollees, and whether the location provided physical access for enrollees with disabilities. Commenters offered a variety of recommendations to supplement this provision. Some commenters suggested that geographic standards be based on travel time and not distance, and others urged that we liberalize geographic access standards to take into account allowable public transportation time. Several commenters recommended that we require a general time of 30 minutes from an enrollee's residence, and others recommended an exception for frontier areas. Further, other commenters suggested varying standards, such as 30 miles or 30 minutes for rural areas, 20 miles or 30 minutes for urban areas, and 45 minutes for specialty care; whereas other commenters suggested a 30 minute or 30 mile standard, with a 60 minute or 60 mile standard for rural areas.

Response: We do not believe it is appropriate to set national geographic access standards in these regulations. We recognize that there are unique circumstances which exist in each State for which a national standard could be inappropriate. This is reflected in the comments received and in the preamble to the proposed rule in which we noted that a provider network should be structured so that an enrollee residing in the service area does not have to travel an unreasonable distance to obtain a covered service, beyond what is customary under a Medicaid fee-for-service arrangement. The preamble to the proposed rule also acknowledged that many Medicaid enrollees may use public transportation. We stated that ''in areas where Medicaid managed care enrollees rely heavily on public transportation, the State should ensure that providers are accessible through these means within the same time frames as enrollees who have their own means of transportation.'' Because of this, we believe that States are in a better position to establish access standards, including geographic access standards, as part of their States' quality assessment and improvement strategy. Our availability of services requirements under § 438.206 of the final rule with comment period allow States sufficient flexibility to develop access standards that are appropriate for their own circumstances, and ensure that States take into consideration important factors such as distance, travel time, and the means of transportation normally used by enrollees.

Comment: We received several comments requesting that we be more specific with respect to our requirement that MCOs and PHPs take into account a location's physical accessibility for enrollees with disabilities. While the commenters generally supported inclusion of this provision, they also believed that we should be more specific in our final rule with comment period. Several commenters believed that we should require States, at a minimum, to ensure that sites are physically accessible and comply with the Americans with Disabilities Act. One commenter suggested that States and MCOs ensure access not only to locations, but also to all aspects of medical treatment. Other commenters stressed that in addition to physical access, it is just as important for populations with special health care needs, such as persons with mental retardation, to have access to knowledgeable and trained staff, to receive understandable information, to be able to communicate with a provider if he or she is hearing impaired, and to have longer appointment times. They recommended that we reflect these adaptations in the final rule with comment period.

Response: We believe that several of the requirements in this final rule with comment period address many of the commenters' concerns. We specifically refer commenters to the following:

- Sections 438.206(d)(1)(i) and (d)(1)(ii) require each MCO and PHP, when establishing their provider networks, to take into consideration their anticipated enrollment, with particular attention to persons with special health care needs, and their expected utilization of services, considering the enrollees' characteristics and health care needs.
- Section 438.206(d)(1)(iii) requires each MCO and PHP to also consider the numbers and types (in terms of training and experience) of providers needed.
- Section 438.206(d)(1)(v) requires MCOs and PHPs to consider distance, travel time, means of transportation ordinarily used by enrollees, and whether the location provides physical access for enrollees with disabilities.
- Section 438.100 requires the State to ensure that MCOs, PHPs, and PCCMs, comply with applicable Federal and State laws that pertain to enrollee rights. The Americans with Disabilities Act is explicitly mentioned as one of these Federal laws. Section 438.100 also requires States to ensure that enrollees receive information on available treatment options and alternatives, presented in a manner appropriate to the enrollees' conditions and ability to understand.
- Section 438.102(b)(2)(ii) requires that steps be taken to ensure that enrollees with disabilities have effective communication with all health system participants in making decisions with respect to treatment options.

All these requirements were designed to ensure that States address issues such as physical access and composition of provider networks. We have not required in this final rule with comment period that populations with special health care needs always have longer appointment times because it is not yet possible to precisely define all individuals with special health care needs, and because all such individuals may not always require longer appointment times.

Comment: We received several comments on proposed § 438.306(d)(2), which requires that female enrollees have direct access to women's health specialists within the network for women's routine and preventive services, notwithstanding that the MCO maintains a primary care provider for each enrollee.

Overall, many commenters supported inclusion of this provision. However, a few commenters requested clarification of regulatory terms. For example, several commenters expressed concern over what they viewed as the ambiguity of the term ''women's health specialist.'' They requested that we expand the definition of that term in the final regulation to include specific provider types, such as nurse-midwives or obstetricians/gynecologists. Others felt that this provision could be construed to include non-licensed practitioners or laypersons.

Response: We do not define ''women's health specialist'' in this final rule with comment period, because different types of health professionals may, through education and/or clinical experiences, be appropriately thought of by a contracting MCO or PHP or enrollee as a ''women's health specialist.'' However, we intend for the term to refer to licensed health professionals with specific clinical education and training in women's health care, including obstetricians, gynecologists, nurse midwives, and nurse practitioners, consistent with State licensing requirements.

Comment: Several commenters felt that the term ''routine and preventive services'' in proposed § 438.306(d)(2) should be excluded from this provision, while other commenters felt that we should define the term further. One commenter felt that we should define the term based on existing professional guidelines. Others requested that we define the term to include specific services, such as prenatal care, labor and delivery services, breast exams, mammography, and pap smears.

Response: We agree that some clarification is needed. In § 438.206(d)(2) of the final rule with comment period, an MCO or, as appropriate, a PHP is required to provide female enrollees with direct access to a woman's health specialist within the network for covered care necessary to provide women routine and preventive health care services. This would include initial and follow-up visits for services unique to women such as prenatal care, mammograms, pap smears, and for services to treat genito-urinary conditions such as vaginal and urinary tract infections and sexually transmitted diseases.

Comment: Several commenters requested that we expand proposed § 438.306(d)(2) to clarify whether the requirement applies to both adult females and to minor adolescent females. Other commenters suggested that we add language that would allow direct access to a women's health specialist for pregnant enrollees of any age, but otherwise would set a limit for access to a women's health specialist to age 15 or older.

Response: We used the term ''female enrollees'' to include minor females. Thus, we believe that if there is a medical need to see a women's health specialist, there should be no impediment based on the age of the enrolled female.

Comment: One commenter believed that proposed § 438.306(d)(2) would conflict with recent insurance legislation in the State which allows MCOs to require a women's health specialist to have a referral arrangement with, but not actual referrals from, an enrollee's primary care physician. Another commenter stated that it is unclear whether a female enrollee would be able to choose any women's health specialist within the network.

Response: We believe that, within MCO and PHP networks, female enrollees must have direct access to a women's health specialist for covered care necessary to provide women's routine and preventative health care services. We believe that this means that each woman should have access to any women's health specialist within the network, unless some network providers are not accepting new enrollees or there are other network restrictions based on the enrollee's choice of primary care provider. (For example, a woman may choose a primary care provider that is part of a subnetwork of providers within an MCO. As long as the woman was informed of the consequences of choosing a primary care provider that is a part of a subnetwork, at the time of her enrollment, she can be restricted to using only those specialists, including women's health specialists that are part of the subnetwork—although provisions for using out-of-network providers would still apply.) This provision was proposed consistent with statutory authority requiring States to develop standards for access to care ''in a manner that ensures continuity of care and adequate primary care and specialized services capacity'' (section 1932(c)(1)(A)(i) of the Act). Moreover, this provision is consistent with the beneficiary rights in the CBRR.

Comment: We received several comments recommending that proposed § 438.306(d)(2) be applied to all managed care entities, including PCCMs, HIOs, and PHPs. Commenters also suggested that we should apply this provision to individuals in managed care plans with 6-month eligibility.

Response: Section 438.206(d)(2) is based on authority in section 1932(c)(1)(A)(i) of the Act. As noted above, with respect to the quality assurance requirements implementing

section 1932(c)(1) of the Act generally, the Congress chose to apply this provision only to MCOs, while other provisions in the same section were made applicable to both MCOs and PCCMs (*i.e.,* to ''MCEs''). The Congress thus expressed a clear intent that these requirements not apply to PCCMs. With respect to HIOs, if they are required to meet the definition of MCO and comply with section 1903(m) of the Act requirements, these requirements would apply to them. If, however, they have a specific statutory exemption from section 1903(m) of the Act, again, the Congress has spoken directly to the question of whether these requirements should apply, and determined that they should not. We therefore believe it would be inconsistent with clearly expressed Congressional intent to subject PCCMs or section 1903(m) of the Act-exempted HIOs to requirements based on the authority in section 1932(c)(1) of the Act. Also as noted above, however, in the case of PHPs, the Congress was silent as to what standards should apply, and based on our authority under section 1902(a)(4) of the Act, we have applied the requirements in subpart D (including the woman's health requirement in § 438.306(d)(2)) to PHPs, as appropriate. We do not believe that we need to explicitly reference individuals with six-month eligibility because the provision applies to all women regardless of their length of eligibility or enrollment.

Comment: One commenter suggested that § 438.306(d)(2) should not apply to behavioral health organizations, since women's health specialists do not exist in such settings.

Response: We agree with the commenter that this requirement may not apply to PHPs that deliver a limited set of services under a capitated arrangement. PHPs of this type typically include organizations contracted to provide mental health or substance abuse services and organizations that provide dental services. Section 438.8(a) of the final rule with comment period specifies that the quality assessment and performance improvement requirements apply to PHPs ''to the extent that they are applicable to the services furnished by the PHP.'' In the example of a behavioral health organization, access to a women's health specialist for covered care necessary to provide women's routine and preventive health care services would not be applicable.

Comment: Several commenters believed that § 438.306(d)(2), pertaining to women's direct access to a women's health specialist, as proposed, would impede continuity of care. They recommended that this provision be eliminated. Another commenter recommended that we delete the phrase ''notwithstanding that the MCO maintains a primary care provider for each enrollee.''

Response: As we have stated, we believe that female enrollees must have direct access to a women's health specialist within an MCO's and PHP's network as applicable and PHP's network as applicable. This provision was proposed in order to provide access in a manner that ensures adequate specialized services as required under section 1932(c)(1)(A)(i) of the Act and in order to implement the CORR. To make this purpose and the provision more clear, we have replaced the words ''notwithstanding that the MCO maintains a primary care provider for each enrollee'' with the sentence, ''This [direct access to a women's health specialist] is in addition to the enrollee's designated source of primary care, if that source is not a women's health specialist.'' This change of wording also emphasizes that a female enrollee's right to directly access a women's health specialist cannot be satisfied, under Medicaid, by simply offering the opportunity to choose a women's health care specialist as a primary care case manager. We believe that in the case of the Medicaid population, direct access for these services is critical, and that the opportunity to choose a primary care case manager who provides these services is not sufficient, since a woman may not wish to see a woman's health specialist for general care.

Comment: We received one comment referencing § 438.306(d)(2) which suggested that OB/GYNs be able to serve as primary care physicians. The commenter expressed concern that women may not receive information about when they are entitled to self-refer to OB/GYNs. The commenter recommended that such information be required.

Response: Our intent in the proposed rule was not to require States and MCOs or PHPs to allow (or preclude States and MCOs or PHPs from allowing) OB/GYNs, or other specialists, to serve as primary care providers. The final rule with comment period, as amended, provides flexibility for States to determine the appropriate specifications to impose on MCOs and PHPs regarding the types of primary care providers, depending on the nature of the managed care program in the State and the enrollee population being served. Moreover, the information requirements at § 438.10, as amended, are written to ensure that enrollees receive adequate information on procedures for obtaining all benefits, including information on the right of female enrollees to directly access a women's health specialist within the MCO or PHP network for covered care necessary to provide women's routine and preventive health care services.

Comment: We received a comment on the grievances and appeals provisions urging that enrollees faced with an adverse decision have the right to a second opinion, and that this right be mentioned in the adverse action notice. The commenter felt that enrollees should have the right to out-of-network, unbiased, second opinions, and this right should be specified in the regulations.

Response: We agree that enrollees should have access to an unbiased second opinion. We believe that this right extends beyond an adverse action notice to any instance in which the enrollee requests a second opinion. Therefore, we have added requirements in the regulation, both in Enrollee rights (§ 438.100) and in the Availability of services provisions (§ 438.206(d)(3)), with regard to second opinions. Contrary to the commenter's suggestion, we believe that an enrollee can receive an unbiased opinion from another qualified health professional in the network. Accordingly, we have specified that the MCO or PHP must provide for an enrollee to have access to a second opinion from a qualified provider *within the network* or arrange for the enrollee to obtain a second opinion outside of the network if an additional qualified health care professional is not currently available within the network.

Comment: We received many comments on proposed § 438.306(d)(5), which required the State to ensure that, when medically appropriate, the MCO or PHP makes services available 24 hours a day, 7 days a week. The proposed regulations stated that this provision applies, at a minimum, to emergency services and post-stabilization services, and to non-emergency services that are required immediately because of unforseen illness. A majority of the comments requested further clarification of terms and standards. Specifically, several commenters requested that the term ''unforseen illness'' be clarified or deleted. Many commenters argued that the term is too restrictive, invites legal controversy over its interpretation, and is contrary to managed care's emphasis on prevention, early detection, and treatment. Other commenters urged that we adopt and apply specific standards for urgent care of 24 to 48 hours depending on the day of the week an

unforseen illness occurs. One commenter specifically recommended that we add an additional standard of 24 hour, 7 day ''crisis services'' for beneficiaries with mental illness. Another commenter felt that MCOs should have a mechanism to conduct triage and assessment, but should not have to make available non-emergency, non-urgent care 24 hours a day, 7 days a week. Finally, one commenter stated that the availability of services under this provision should be based on medical necessity and not medical ''appropriateness.''

Response: Our intent in proposing § 438.306(d)(5) was to ensure that individuals who require home health services or other types of non-hospital based services receive care, when medically necessary, during non-business hours. After further review and consideration of comments received, we have revised the policy so that the final rule with comment period requires MCOs and PHPs to ensure that services are available 24 hours a day, 7 days a week, when medically necessary (§ 438.206(e)(1)(iii)). We believe this change ensures access to care without using potentially ambiguous terms such as ''unforseen illness'' and ''medically appropriate.'' We further believe that this requirement is consistent with our overall intent as reflected in other provisions in the final rule with comment period, including § 438.114, Emergency and post-stabilization services, and § 438.210, Coverage and authorization of services.

Comment: Several commenters felt that proposed § 438.306(d)(5) was too prescriptive and costly. One commenter believed that the provision was likely to increase the number of providers who refuse to see Medicaid patients, and suggested that normal physician practice standards should be acceptable for all populations. Other commenters recommended that the provision be deleted.

Response: As we have indicated above, we believe this provision is important to ensure that enrollees have access to medically necessary care during traditional, non-business hours.

Comment: We received numerous comments on proposed § 438.306(d)(6), which required MCOs and PHPs to ensure that its providers' hours of operation are convenient to enrollees, and do not discriminate against Medicaid enrollees. One commenter supported the provision, but suggested that we reference populations with special health care needs. Other commenters believed that the term ''convenient'' in the proposed regulation was too ambiguous and subjective, and that this term required further clarification. One commenter specifically argued that we were imposing a new requirement in Medicaid managed care that we have not imposed in Medicaid fee-for-service. Finally, other commenters suggested that this particular provision, if included in the final rule with comment period, would have widespread implications for the program. They argued that we have exceeded our statutory authority in proposing this provision.

Response: Upon further consideration, and based on comments received, we agree that the term ''convenient'' needs clarification. As a result, we have moved this requirement to § 438.206(e), because we believe that it more appropriately falls under the ''provision of services'' paragraph. Under paragraph (e)(1)(ii), the MCO or PHP must ensure that its providers' hours of operation are convenient for the enrollees, as determined by a State-established methodology, and that they are at least comparable to Medicaid fee-for-service.

We believe that the State should establish standards for what is convenient for enrollees in terms of provider hours of operation. Those standards should be at least comparable to Medicaid fee-for-service. Thus, an enrollee who was able to schedule weekend or evening appointments under the Medicaid fee-for-service program should have access to appointments during those hours under Medicaid managed care.

We continue to believe that the State and MCO or PHP must ensure that providers do not discriminate against Medicaid enrollees. Thus, we retain this requirement in § 438.206(d)(7).

Comment: One commenter suggested that we apply proposed § 438.306(d)(6) to MCEs, and not just MCOs.

Response: We proposed § 438.306(d)(6) under the authority of section 1932(c)(1)(A)(i) of the Act. As discussed above in connection with proposed § 438.306(d)(2), the Congress expressed a clear intent that requirements under section 1932(c)(1) of the Act apply to MCOs, but not PCCMs. When the Congress wanted to apply requirements to PCCMs as well as MCOs, it did so by referencing ''MCEs,'' which includes MCOs and PCCMs. We thus believe it would be inconsistent with clearly stated Congressional intent to apply requirements under section 1932(c)(1) of the Act to PCCMs.

Comment: We received numerous comments on proposed § 438.306(e)(1)(i), which required MCOs and their providers to meet State-established standards for access to care and member services, taking into account the urgency of the need for services. Several commenters recommended that we incorporate into the final regulation the suggested standards outlined in the preamble to the proposed rule. The commenters' rationale for incorporating the suggested standards in the final rule with comment period is that the standards reflect existing managed care contracts and there appears to be no reason for State flexibility regarding maximum wait times for care. The same commenters argued that the BBA gives us the authority to establish minimum standards for quality assessment and improvement strategies. Several other commenters noted the importance of establishing standards for in-office waiting times, especially for mental health services.

Commenters offered a number of recommendations that included standards in addition to, or as alternatives to, those presented in the preamble to the proposed rule. Moreover, the recommendations referenced both in-office waiting times and appointment scheduling times. Specifically, the additional standards included referral appointments to specialists within 30 days for routine care, 72 hours for urgent care, and 24 hours for emergency appointments. Other additional standards included routine, prenatal visits within 2 weeks for the first trimester, 1 week for the second trimester, and 3 days for the third trimester. Recommended alternative standards included in-office waiting times of no longer than 45 minutes or 1 hour, and appointment times for routine appointments ranging from 2 weeks to 30 days.

Response: Section 1932(c)(1)(A)(i) of the Act provides that ''the State shall develop * * * a quality assessment and improvement strategy,'' that shall include ''[s]tandards for access to care.'' Under the authority of section 1932(c)(1)(A)(i) of the Act, we have proposed regulations to ensure that States take into consideration certain requirements when developing their standards for access to care. One of these requirements (contained in § 438.306(e)(1)(i) of the proposed rule) is that MCOs and PHPs and their providers meet State-established standards for access to care.

We disagree with commenters who suggest that national standards should be established in the final regulation. First, as just noted, the statute calls for ''the State'' to ''develop'' such standards, not us. This suggests that the Congress contemplated that standards

be State-specific. Secondly, patterns of care delivery typically vary across the country. Because of this, a single national standard may not be appropriate in all localities. Therefore, we only included suggested standards in the preamble to the proposed rule as examples for States to consider. The various additional and alternative suggestions offered by commenters may also be appropriate for States to consider. However, we will not mandate any of them in this final rule with comment period.

Comment: Several commenters suggested that proposed § 438.306(e)(1)(i) was too burdensome, and not consistent with the common practice of wait times for appointments of six to eight weeks. Further, commenters suggested that if more stringent standards are imposed for Medicaid managed care enrollees than commercial enrollees, providers may avoid serving Medicaid members.

Response: We do not agree with commenters who suggest that we are imposing more stringent standards for Medicaid enrollees than commercial enrollees. In this final rule with comment period, we require MCOs and PHPs to meet State-established standards. Further, we require that provider hours of operation be at least comparable to fee-for-service. We included examples in the preamble of the proposed rule for State consideration only. These examples were not mandatory requirements. In fact, we specifically indicated that States should evaluate a number of factors, including common waiting times for comparable services in the community. We believe that this statement reflects our intent that, in designing standards for timely access to care, States consider existing practice patterns.

Comment: We received one comment that we should revise proposed § 438.306(e)(1)(i) to add the word ''subcontractors'' after providers, to ensure that subcontractors are required to meet State-established standards for timely access to care and member services.

Response: We do not believe that such a change is necessary for the final rule with comment period. Section 438.230 of the final rule with comment period establishes requirements for subcontractual relationships and delegation. It ensures that each MCO and PHP oversees and is held accountable for any functions and responsibilities that it delegates to a subcontractor. In addition, § 438.6(l) requires that all subcontracts meet the contracting requirements that are appropriate to the service or activity delegated under that subcontract. We believe that these provisions are adequate to ensure that subcontractors are held to the same access standards imposed on MCOs and PHPs by the State.

Comment: Several commenters took issue with the examples contained in the preamble for proposed § 438.306(e)(1)(i), which requires States to establish mechanisms to ensure MCO compliance with standards for timely access to care. Several commenters expressed concern that documenting in-office waiting times would be administratively burdensome, would lead to increased costs, and may reduce the willingness of HMOs to participate in Medicaid. One commenter believed that satisfaction surveys would be sufficient to indicate if a problem exists, which can then be explored with audits of individual providers. Another commenter suggested that our preamble discussion on compliance include methods for gaining consumer feedback in addition to mail and telephone surveys.

Response: In the preamble to the proposed rule, we offered a number of mechanisms that States, MCOs and PHPs could use to monitor compliance with timeliness standards, including the use of surveys, analysis of complaints and grievances, provider self-reports, random audits, and test calls. While we cautioned States on the use of general surveys of its enrolled population, we did not discount the use of surveys all together. For example, the Agency for Healthcare Research and Quality's (AHRQ's) Consumer Assessment of Health Plans Study (CAHPS) survey tools are reliable and valid survey instruments that can be used to assess many aspects of health care, including access to quality and timeliness of care. We believe that States should consider all appropriate mechanisms for measuring MCO and PHP performance against State standards, and rely on those mechanisms which are most effective.

5. Proposed § 438.306(e)(2) (Initial Assessment) and (e)(3) (Pregnancy and Complex and Serious Medical Conditions)

Paragraph (e)(2) of proposed § 438.306 required States to ensure that MCOs and PHPs provide initial assessments of each enrollee within 90 days, and within a shorter period of time for pregnant women and enrollees with complex and serious medical conditions. Paragraph (e)(3) of proposed § 438.306 set forth specific requirements for dealing with the two groups and for their treatment plans. We received a great many comments on these proposed provisions which, in the final rule with comment period, are redesignated under § 438.208, and incorporate several additional groups and time frames.

Comment: Many commenters requested clarification on what constitutes an initial assessment as proposed. Several commenters questioned whether a telephone call or questionnaire might suffice. Other commenters suggested that initial assessment should be face-to-face, and should cover both health and social issues. Several commenters suggested that, particularly for enrollees with complex or serious medical conditions, and populations such as the homeless, pregnant women, newborns, and children, assessments should be conducted face-to-face. One commenter specifically recommended that we define initial assessments to include the following services: a comprehensive health and developmental history, a comprehensive unclothed physical exam, laboratory tests including blood level assessments appropriate for age and risk factors, and health education.

Response: We agree that the term ''initial assessment'' is misleading. While our original intent was that this term be analogous to the term ''screening,'' we are persuaded by comments that certain individuals require a more thorough and timely assessment by an MCO or PHP provider after enrollment. Accordingly, in § 438.208(d) and (e) we are now requiring that the MCO or PHP make a best effort to identify, screen, and comprehensively assess pregnant women, children under the age of 2 years old, and enrollees with special health care needs.

In order to assist MCOs and PHPs in conducting the types of assessments suggested by the commenters, in section 438.208(b) we are requiring States to identify to MCOs and PHPs populations ''at risk'' of having special health care needs, children under age 2, and other enrollees known by the State to be pregnant or to have special health care needs. The ''at risk'' populations include: (1) Children and adults receiving SSI benefits; (2) children in title IV–E foster care; (3) enrollees over age 65; (4) enrollees in relevant, State-established, risk-adjusted, higher-cost payment categories; and (5) any other groups of enrollees identified by us (§ 438.208(b)(1)).

Also in order to address the commenters' concerns about ensuring appropriate assessments, in § 438.208(e) of the final rule with comment period,

we require the MCO or PHP to implement mechanisms to ensure the ongoing screening of its enrolled population to identify and comprehensively assess persons who become pregnant or who develop special health needs following enrollment in the MCO or PHP.

We believe that a State and MCO or PHP should have the flexibility to choose the form and substance of the initial screen or screens. Initial screens may take the form of a phone call, mailed questionnaire, home visit or physical examination; however, it must be sufficient to identify individuals with special health care needs. Further, the initial screen should also attempt to collect information on any languages or TTY requirements, and needs for accessible medical facilities and/or transportation services. The comprehensive health assessment, on the other hand, should include a physical examination by an MCO or PHP provider. In fulfilling the screening and assessment requirements, the MCO or PHP must ensure that its providers have the information required for effective and continuous patient care and quality improvement.

Comment: We received many comments with respect to time frames. Commenters varied in their opinions. Several commenters believed that 90 days was too long to wait for an initial assessment (now referred to as ''screening'' in the final rule with comment period), particularly for enrollees with serious and complex medical conditions. Many other commenters expressed concern over whether an MCO or PHP could perform an initial assessment (screening) on each enrollee within 90 days. These commenters noted the difficulty in contacting an enrollee and ensuring the cooperation of an enrollee in seeing a physician in order to have an assessment (screening) completed. They felt that initial assessments (screening) within 90 days was unrealistic and longer time frames were needed. One commenter suggested that the issue of timing can better be addressed in the contract between the State and the MCO or PHP. The commenter believed that the 90 day requirement should not be a Federal mandate.

Many recommendations were offered. One commenter suggested that a health assessment (screen) need only take place once a year, with an initial assessment (screening) occurring within 180 days if (1) the member has not used the emergency room within the last 90 days, (2) the member is in good health, and (3) the member has reported to the MCO or PHP that it has had a health assessment. Other commenters recommended a shorter time frame of 30 days, and recommended special time standards for specific populations, such as requiring an initial assessment (screening) within 15 to 30 days from enrollment for newborns and young children and within 72 hours for enrollees with HIV. Other commenters suggested more general standards of no more than 60 days to complete initial assessments (screening), to 180 days for adults and 90 days for children. One commenter recommended that MCOs or PHPs only be required to make a good faith effort to contact each new member at least two times to schedule an appointment with his or her primary care provider. Other commenters recommended that we revise the final rule with comment period to require MCOs and PHPs to meet a variation of the following language: (1) Make a good faith effort to conduct an assessment (screening), (2) make available within 90 days of enrollment an initial assessment (screening), (3) inform enrollees of the need for an initial assessment (screening), or (4) make a substantial attempt to provide initial assessments (screenings). One commenter suggested that an assessment for a child under the age of 21 should meet the requirements of the EPSDT guidelines set forth in §§ 441.50 through 441.62.

Response: We agree with many of the comments received. Specifically, we agree with the comment that an MCO or PHP should only be required to make an ''effort'' to perform a screening or assessment. We agree that, through no fault of its own, an MCO or PHP may not be able to achieve full compliance with the proposed initial assessment (screening) requirement. We therefore have revised the requirement to provide, in § 438.208(d) of the final rule with comment period that MCOs and PHPs must make a ''best effort'' to perform the screening and assessment required in this section. A ''best effort'' means that the MCO or PHP should follow-up on unsuccessful attempts to contact an enrollee. With this change, we wish to make clear that the MCO or PHP is not relieved of the obligation to screen all enrollees. Rather, we only wish to acknowledge that an MCO or PHP may not be able to achieve 100 percent compliance with the screening and assessment requirements. We also recognize that some enrollees may be unable to cooperate with the MCO's or PHP's efforts to screen and assess them. In these cases, MCOs and PHPs should document the attempt to screen and (as applicable) assess individual enrollees.

We also agree with the commenters who believed that a 90 day time frame was too long, and specifically with the suggestion of a 30 day time frame in connection with enrollees with special needs. Because of this, we have revised the rule to include different time frames for screening the especially vulnerable groups of pregnant women and persons who either have been identified as having special health care needs, or have been identified by the State under § 438.208(b) as being in categories at risk for having special health care needs. Although we have not identified children under 2 years of age as enrollees ''at risk,'' we recognize the importance of timely screening and assessment of young children and have added them to the groups requiring quicker screening. Specifically, under § 438.208(d), we require MCOs (and PHPs as determined by the State in accord with § 438.208(a)(2)) to make a ''best effort'' to screen and comprehensively assess pregnant women, children under 2 years of age, and persons determined to have special health care needs in accordance with the following timeframes:

(1) For enrollees identified by the State as at risk of having special care needs, screening within 30 days of receiving the State's identification, and for those the screening identifies as being pregnant or having special health care needs, comprehensive health assessment as expeditiously as the enrollee's health requires but no later than 30 days from the date of identification through screening.

(2) For enrollees identified by the State as being children under age 2, and for other enrollees who are identified by the State or who identify themselves as being pregnant or having special health care needs, comprehensive health assessment as expeditiously as the enrollee's health requires, but no later than 30 days after the date of identification.

(3) For all other enrollees, screening within 90 days of enrollment and for those the screening identifies as being pregnant or having special health care needs, comprehensive health assessment as expeditiously as the enrollee's health requires, but no later than 30 days after the date of identification.

We believe that these standards are reasonable to ensure that persons requiring special medical attention from MCOs and PHPs receive services as expeditiously as possible. Because we agree with the commenters recommending these shorter time frames that such time frames are necessary to help ensure the health of vulnerable beneficiaries, we are not accepting the comments that suggested

longer time frames, or abandoning this requirement altogether.

Comment: Several commenters suggested that an initial assessment (now referred to as ''screening'' in the final rule with comment period) not be required for enrollees who are continuing patients of the MCO or provider, or when a prior assessment (screening) is available to the MCO.

Response: We recognize that in some situations it would be duplicative and unnecessary to require screening of an enrollee. For instance, we would not expect an MCO to screen enrollees for whom current health care information is available, such as enrollees already under the care of providers with the MCO's network, or who maintain the same primary care provider when enrolling in a different MCO. In such a case, the screening required under this rule could be considered to have been performed. To ensure compliance with the revised requirements for enrollee screening, MCOs and PHPs should document in the enrollee's health record why screening is not necessary.

Comment: We received a few comments that the proposed initial assessment (screening) requirements should not apply to PHPs, such as managed behavioral health organizations. The commenters recommended that this provision apply only to managed care organizations that provide primary and preventive care services.

Response: As previously indicated, § 438.8 makes the subpart D rules applicable to PHPs to the extent that they are applicable to the services furnished by the PHP. Some PHPs provide services to the most vulnerable Medicaid enrollees, many of whom are diagnosed with chronic conditions or who are determined to have long-term care needs. Thus, timely screening and assessment of these individuals by PHPs, in relationship to the scope of services provided by the PHP, is necessary to ensure that those requiring special attention receive necessary medical care.

We acknowledge, however, that a State might design a managed care initiative that involves PHPs for which an initial screening by the PHP might be duplicative. For example, a State may utilize a separate ''carve-out'' program for mental health services in which an enrollee may require referral by the MCO contracted to provide physical health services. In such a case, a State might design its managed care initiative to have the MCO screen for both physical and mental health. The MCO could screen the enrolled population to identify enrollees who likely require mental health services, and could share the results of the screen with the PHP. The PHP, in turn, would conduct a comprehensive health assessment through appropriate health care professionals. States must determine the most effective and efficient strategy for assuring that all Medicaid MCO and PHP enrollees are screened.

While the State is responsible for ensuring that a screening is carried out on all Medicaid managed care enrollees by some combination of the enrollee's MCO and PHP, in response to this comment, we are under § 438.208(a)(2) of this final rule with comment period providing the State with the flexibility to decide how this responsibility will be carried out, and whether PHPs will be required to perform screenings and assessments in cases in which an enrollee is enrolled in both an MCO and a PHP or more than one PHP.

Our decision in response to the comment to permit State flexibility with respect to PHP screening raises issues of coordination between MCOs and PHPs and responsibilities for screening, assessment and treatment planning for Medicaid enrollees who also receive Medicare and are enrolled in a Medicare +Choice plan. The commenter presumably was concerned about possible duplication of efforts in urging that only the single entity furnishing primary care perform screenings. We believe that this concern about duplication can be addressed, while still providing for PHP screening where appropriate, by requiring in a new § 438.208(h)(3), that each MCO or PHP share the results of its screening or assessment of an enrollee (or both, if the MCO or PHP performs both) with other entities serving the enrollee, so that those entities need not duplicate the MCO's or PHP's screening or assessment (or both). To address the issue of Medicaid enrollees also receiving Medicare and enrolled in a Medicare+Choice plan, we have added a new provision at § 438.208(a)(3) requiring the State to determine the extent to which each MCO is to perform initial screening, assessment and treatment planning for such enrollees, consistent with the services the State requires the MCO to provide.

Comment: We received a number of comments on proposed § 438.306(e)(3)(iii) which required the MCO to develop treatment plans that are appropriate for the conditions identified, specify an adequate number of direct access visits to specialists, and are updated periodically by the physician responsible for the overall coordination of the enrollee's health care. Some commenters suggested that MCOs and physicians need to be given the flexibility to evaluate each enrollee's circumstance. Other commenters urged that the regulations require that enrollees participate in treatment planning. Several commenters believed that enrollees with complex and serious medical conditions should be permitted direct access to specialists, even if they are out-of-network providers. Other commenters suggested that this provision be deleted because it can be interpreted to permit unlimited access to specialists. One commenter expressed the view that direct access to specialists is a benefit that has just begun to evolve in commercial plans, and accordingly should not be applied until MCOs and PHPs can further manage a direct access system.

Response: We disagree with commenters who suggest that this provision permits unlimited access to specialists. It was never our intent to guarantee unlimited access. Proposed § 438.306(e)(3)(iii) was drafted to ensure that enrollees with complex and serious medical conditions (now referred to as enrollees with special health care needs) be permitted a sufficient number of direct access visits to specialists as required by the treatment plan. Our overall intent in the final rule with comment period remains the same. We continue to believe that enrollees with special health care needs who are undergoing an approved course of treatment should be able to access specialists within the MCO's or PHP's network without having to obtain numerous authorizations from their primary care providers, and that this is necessary in order to meet the ''access to care'' standard in section 1932(c)(1)(A)(i) that services be available ''in a manner that ensures * * * adequate * * * specialized services capacity.'' In recognition of varying MCO and PHP practices, the final rule with comment period, requires the treatment plan to specify either an adequate number of direct access visits to specialists or a standing referral to specialists. However, we continue to require that the treatment plan be time-specific, and updated periodically to determine whether continued access to a specialist for a course of treatment is necessary. To avoid confusion, in this final rule with comment period, we also have added a specific requirement that we believe was implicit in the proposed rule. Section 438.206(f)(6) now expressly requires that the treatment plan ensure periodic reassessment for each enrollee as his or her health requires. In addition, in response to the comments

on the need for enrollee participation and that treatment planning consider the needs and preferences of the enrollee, at § 438.206(f)(5) we added a requirement that treatment plans be developed with enrollee participation.

Comment: We received a number of comments urging that we revise proposed § 438.306(e)(3) to further address and consider populations with special health care needs. Many commenters wanted us to further clarify and define the term ''complex and serious medical conditions.'' Specifically, one commenter recommended that we revise the wording of proposed § 438.306(e)(3)(ii) to state: ''Timely identifies individuals with complex and serious medical conditions or mental disabilities, assesses those conditions, and identifies appropriate health care services for monitoring, treatment, or rehabilitation.'' Another commenter recommended that the regulation include a list of conditions that mandate the actions spelled out in proposed § 438.306(e)(3)(ii) and (iii). Although the commenter recognized that it would be impractical to include an exhaustive list, he argued that there are some chronic conditions that should be listed, particularly where continuing attention and monitoring are vital. Some of the populations that commenters recommended include persons with mental disabilities, cancer patients, persons with end stage renal disease, persons awaiting organ transplants, persons with HIV/AIDS, children with special health care needs, and persons with cerebral palsy or other conditions related to the presence of a developmental disability. In contrast to identifying an exhaustive list of conditions, one commenter suggested that we develop a definition for complex and serious medical conditions based on patient requirements for higher levels of resources. This commenter argued that such a definition would require MCOs that enroll persons whose needs exceed normal actuarial physical and mental utilization estimates for a working age population to demonstrate higher capacity both in their networks and with respect to their access standards.

Response: We agree that clarification is needed and, as previously discussed, have revised this provision to require that MCOs and—where applicable—PHPs, screen and comprehensively assess ''enrollees with special health care needs,'' which, as noted above, is how we now refer to individuals with complex and serious medical conditions. As we discussed previously, ''persons with special health care needs'' is the terminology used by the Congress at section 4705(c)(2) of the BBA. We have conceptualized this term to include:

(1) children with special health care needs;

(2) children in foster care;

(3) individuals with serious and persistent mental illness/substance abuse;

(4) individuals who are homeless;

(5) older adults (individuals 65 years of age and older) with disabilities; and

(6) adults under 65 who are disabled or who have a chronic condition, whether physical or mental.

We note that this listing of individuals with special health care needs is not an operational definition of persons with special health care needs and that health services research is still in the process of developing conceptual models, screening tools and approaches to identifying individuals with special health care needs.

Comment: We received a number of comments suggesting that under proposed § 438.306(e)(2) and (3), we should require continuing coverage of on-going treatment, even if it is out-of-network, until the time of an initial assessment when a primary care physician, in consultation with a specialist, establishes a new care plan. Commenters believed that unless an MCO is given prior information, it will not know if an enrollee is pregnant or has a complex medical condition to provide an assessment prior to 90 days. Other commenters noted that the disruption of services can be particularly harmful for enrollees with complex and serious medical conditions. To facilitate the initial assessment, one commenter recommended that we require the State Medicaid agency to provide the MCO with information on age, eligibility category, and whether a child is in foster care or is in an out-of-home placement.

Response: We believe that most States already have mechanisms in place to transition enrollees with ongoing health care needs to managed care. However, we acknowledge the commenters' concerns that our proposed regulation did not address the potential disruption of services, even for a short period of time, between enrollment and the time of assessment by the new primary care physician/specialist in the receiving MCO or PHP. To address this concern, as discussed in section II. B. above, we have added a new paragraph (b) to proposed § 438.62 to require a State to have a mechanism to ensure continued access to services when an enrollee with ongoing health care needs is transitioned from fee-for-service to an MCO, PHP or PCCM; from one MCO, PHP or PCCM to another; or from an MCO, PHP or PCCM to fee-for-service. We believe this provision, plus the requirements in § 438.208 for (1) State identification of enrollees with special needs or at risk for special needs, and (2) MCO and PHP screening and assessments, respond to commenters' concerns that MCOs have the means to identify, in an expedient fashion, enrollees who require immediate attention, and provide needed services to such enrollees.

Comment: One commenter objected to the fact that proposed § 438.306(e)(3) required an MCO to implement and update a treatment plan. Specifically, the commenter suggested that requiring an MCO to implement a treatment plan for specific enrollees is not appropriate for such an administrative entity, as such plans should be developed and implemented only by a patient's physician or other health care professional.

Response: We agree with the commenter. Section 438.208(g) of the final rule with comment period, requires MCOs and PHPs to use appropriate health care professionals to perform comprehensive health assessments and to develop and implement treatment plans.

Comment: A commenter suggested that proposed § 438.306(e)(3) be revised to require the MCO to timely provide effective EPSDT screens and mandated EPSDT services.

Response: EPSDT screenings are required in current regulations. We believe it would be duplicative to restate those requirements in this final rule with comment period.

Comment: One commenter believed that proposed § 438.306(e)(3)(iii)(C) is unclear, and recommends that the final rule with comment period be changed to read ''a treatment plan that specifies an adequate number of direct access visits to specialists as appropriate to the enrollee's condition.'' Further, the commenter suggests that we add the phrase ''or, when required by the condition, the names of specialists to whom the enrollee shall have direct access for the duration of the treatment plan.''

Response: We agree that the proposed language was unclear. We have revised the cited provision, which is now redesignated as § 438.208(f), to require MCOs and PHPs to implement a treatment plan that: (1) is appropriate to the enrollee's conditions and needs identified by screening and assessment, and (2) specifies either a standing referral or an adequate number of direct

access visits to specialists. We expect that the treatment plan will specify the specialist(s) to whom the enrollee has direct access, but do not believe it necessary to require in regulations text that the treatment plan must specify the actual names of specialist to whom the enrollee shall have direct access for the duration of the treatment plan.

Comment: Several commenters expressed concern with proposed § 438.306(e)(3)(iii)(D). Commenters suggested that requiring physicians themselves to update a treatment plan is unrealistic and administratively burdensome. One commenter recommended that the final rule with comment period, be revised to permit the updating of a treatment plan by a specialist instead of a primary care provider.

Response: We agree on the need to allow for situations in which a specialist or other health care professional within an MCO or PHP assumes the responsibility for updating an enrollee's treatment plan. While we believe that a treatment plan should be developed in coordination with an enrollee's primary care provider, we recognize that MCOs or PHPs may permit professionals other than the enrollee's primary care provider to update the enrollee's treatment plan. Accordingly, in the final rule with comment period, § 438.208(g) requires MCOs and PHPs to use ''appropriate health care professionals'' to develop, implement, and update any required treatment plan.

Comment: We received a number of comments on proposed § 438.306(e)(4), which required that MCOs and PHPs ensure services are provided in a culturally competent manner, including at least meeting the language requirements of § 438.10. Overall, the majority of commenters supported this provision, but many suggested that we clarify the provision in the final rule with comment period. Several commenters requested that we define cultural competency and strengthen the regulation to require that MCOs include in their networks providers that have an understanding of enrollees' customs and traditions.

Commenters offered many recommendations. One commenter suggested specific language: ''the MCO ensures that services are provided in a culturally competent manner to all enrollees, by providers with appropriate knowledge and skills to treat enrollees who are members of linguistic or ethnic minorities, and adults and children with special health care needs, including recipients with mental illness, substance abuse problems, developmental disabilities, functional disabilities, or complex problems involving multiple medical and social needs (for example, HIV/AIDS and homelessness).'' Several other commenters recommended that we add requirements such as: (1) full attention by the MCO to racial and ethnic minorities, (2) interpreter services, including braille and sign language, (3) an appropriate number of caregivers properly trained in cultural competency, and (4) provider awareness of medical risk related to racial, ethnic, and socioeconomic factors. Finally, other commenters recommended that we: (1) mandate California's standards for cultural competency, (2) limit providers who are culturally aware to 5 percent or 200 in number to combat recruitment or other training burdens, (3) revise the rule to require that MCOs identify enrollees who belong to ethnic minority groups that may have special barriers in accessing care, and make continued efforts to improve accessibility, or (4) mandate that the National Committee for Quality Assurance (NCQA) require MCOs to collect ethnicity data to ensure quality so that appropriate educational, screening, and treatment programs can be developed.

Response: We do not believe it is appropriate to add all of the specificity suggested by the commenters, however we do agree that further strengthening and clarification is needed. As a result, we have added a provision at § 438.204 that requires States, as an element of their State quality strategies, to identify and provide MCOs and PHPs with information, on, the race, ethnicity, and primary language spoken by each Medicaid beneficiary at the time of their enrollment in an MCO or PHP. We will provide technical assistance to States on implementing these requirements. Our final rule with comment period also has been revised at § 438.206(e)(2) to require MCOs and PHPs to ensure that services are provided in a culturally competent manner to all enrollees, including those with limited English proficiency, and diverse cultural and ethnic backgrounds.

While we decline to add a definition of cultural competency in regulation text because the state of the art with respect to standards for cultural competency is still evolving. States should undertake efforts to further define cultural competency in their contracts and in standards for access to care under their quality assessment and performance improvement strategies. We offer the following statement as one that States may consider using in any definition of cultural competency: ''Cultural competency in health care is a set of attitudes, skills, behaviors, and policies that enable organizations and individuals to work effectively in cross-cultural situations. It reflects an understanding of the importance of acquiring and using knowledge of the unique health-related beliefs, attitudes, practices, and communication patterns of beneficiaries and their families to improve services, enhance beneficiary understanding of programs, increase community participation, and eliminate disparities in health status among diverse population groups.''

Comment: Several commenters believed that we needed to further clarify proposed § 438.306(e)(4) to ensure appropriate linguistic access. One commenter recommended that the comment period be strengthened to require, at a minimum, that MCOs and PHPs have a means of communicating during medical and administrative encounters.

Response: We agree that some clarification in the final rule with comment period is needed. As noted above, we have provided in § 438.206(e)(2) that MCOs and PHPs must provide services in a culturally competent manner to all enrollees, including those with limited English proficiency, and diverse cultural and ethnic backgrounds. Further, as noted above in section II.A., we require in § 438.10(b) that States and MCOs, PCCMs and PHPs make interperter services available to meet the needs of all enrollees. We believe that § 438.10(b) is sufficient to ensure that enrollees have means of communication during medical and administrative encounters.

5. Continuity and Coordination of Care (Proposed § 438.308)

Proposed § 438.308 set forth a series of requirements to ensure that a State require MCOs and PHPs to maintain continuity and coordination of care for its enrollees. Proposed § 438.308(a) required that MCOs and PHPs have in place written policies that provide each enrollee with an ongoing source of primary care appropriate to the enrollee's needs, as well as, formally designating a practitioner who is responsible for coordinating the enrollee's overall health care.

In proposed § 438.308(b), MCOs and PHPs were required to ensure coordination of services, both internally and with services available from the community.

Proposed § 438.308(c) required MCOs and PHPs and their providers to have the information necessary for effective and continuous patient care and quality improvement, including procedures to ensure that each provider maintains

health records that meet requirements established by the MCO or PHP, taking into account professional standards, and there is appropriate and confidential exchange of information among providers.

Proposed § 438.308(d) required procedures to ensure that providers inform enrollees of specific health conditions that require follow-up, and if appropriate, provide training in self care, and deal with factors that hinder enrollee compliance with prescribed treatment or regimens.

Comment: We received a number of comments urging that proposed § 438.308 address the continuation of an enrollee's ongoing treatment when transitioning to managed care. (Similar comments, discussed above, were also received on proposed § 438.306(e)). Although many commenters commended us for addressing the issue of continuity and coordination of care once a beneficiary has been enrolled in managed care, many also expressed concern that the proposed regulation did not highlight the need for identification and continuation of an enrollee's treatment when transitioning from fee-for-service into managed care or from one managed care organization to another. Several commenters stated that the interruption of treatment for only a short period of time could have serious and possibly irreversible consequences on a individual's health. Other commenters suggested that ongoing treatment without interruption was especially critical for persons suffering from mental illness, substance abuse, and chronic conditions such as HIV/AIDS.

A number of recommendations were offered. Some commenters recommended that we require continued coverage of ongoing treatment until a new care plan is established as a result of an initial assessment in the receiving MCO. Other commenters suggested that we define continuing treatment to include equipment, medical supplies, and prosthetic and orthotic appliances. Several commenters also recommended specific regulatory language that would permit an enrollee to continue to be covered for a course of treatment for a specified transition period. These commenters suggested that State agencies or the MCO or both be required to notify enrollees of the right to have treatment continued. In addition, the forwarding MCO should be required to share all medical files on a transferring enrollee with the receiving MCO.

Response: As noted above in this section, and as discussed more fully in section II. B., in response to the large number of comments on this issue, we have added to § 438.62 a new paragraph (b) that requires States to have a mechanism to ensure continued access to services when an enrollee with ongoing health care needs is transitioned from fee-for-service into a MCO, PHP or PCCM; from one MCO, PHP or PCCM to another MCO, PHP, or PCCM; or from an MCO, PHP, or PCCM to fee-for-service. We further have specified minimum requirements that the State transition mechanisms must address, and have identified specific population categories that State transition mechanism must cover.

Comment: Several commenters believed that proposed § 438.308 did not adequately address the issue of prior existing relationships. Commenters voiced concerns about the impact on enrollees when existing relationships have to be discontinued as a result of mandatory managed care programs, or as a result of providers leaving the network. These commenters specifically referenced populations with special health care needs and pregnant women as particular populations who would suffer an adverse impact. Some commenters recommended that pregnant women have the option to continue care with their OB/GYN until completion of post-partum care and others recommended that women who have already initiated prenatal care be exempted from the mandatory enrollment requirement. Other commenters focused their recommendations on other populations with special health care needs, with some recommending that we require MCOs to contract with providers currently serving Medicaid beneficiaries, and others requesting that we exempt populations with special health care needs from managed care entirely, particularly children with special health care needs.

Response: In section 1932(a)(2) of the Act, the Congress specifically exempted certain categories of children with special needs and Medicare eligible beneficiaries from mandatory enrollment under section 1932(a)(1) of the Act. Given the level of specificity in the statute, we believe that it would be inconsistent with Congressional intent to exempt additional categories of beneficiaries. With respect to the suggestion that MCOs be required to cover out-of-network services, once again the Congress has specified in detail those circumstances (e.g., post-stabilization services), for which an MCO is required to pay for out-of-network services or those circumstances (e.g., family planning services) for which an MCO cannot limit an enrollee to its network of providers. We do not believe that we would have authority to require MCOs to cover non-emergency services furnished by a provider with whom the MCO has no relationship. However, we understand the commenters' concerns that an existing relationship may be disrupted as a result of a beneficiary enrolling in managed care, and as discussed in the previous comment response, we believe we have addressed this problem in § 438.62(b). We wish to make clear that the requirements in § 438.62(b) are not intended to preempt State laws that require continuation of care outside the network.

Comment: We received numerous comments on proposed §§ 438.308(a)(1) and (a)(2). Several commenters argued that certain individuals with disabilities and other chronic conditions may require a specialist or other qualified and experienced practitioner as their primary care provider. Some commenters recommended that the final regulation explicitly provide for the designation of a specialist as the primary care provider in certain instances, such as for persons with complex and serious medical conditions. One commenter suggested that an MCO be required to refer chronic renal disease patients to a nephrologist for primary care services before a patient develops end stage renal disease. Another commenter suggested that we add language to allow residents, under supervision, to serve in the role of ''continuing physician.'' Finally, one commenter recommended that primary care systems not be allowed as care managers for complex behavioral needs.

Response: We agree that there may be instances where a specialist would be an appropriate choice for a primary care provider, particularly for individuals with special health care needs. However, we decline to impose that degree of specificity in regulation because: (1) the existing evidence base regarding better health outcomes for individuals whose primary care provider is a specialist is limited; and (2) it is not possible at present to specify in this regulation all the decision rules to direct when a given individual must have a specialist as a primary care provider. We believe that States, MCOs, and PHPs have sufficient flexibility under the final rule with comment period to permit specialists or other experienced providers to serve as primary care providers, as appropriate.

We also do not believe that it is appropriate to revise this final rule with comment period, to prohibit primary care systems from acting as care managers for persons with complex

behavioral needs. Again, States have the flexibility to decide the appropriate specifications to impose on MCOs and PHPs regarding the types of primary care providers, depending on the nature of the managed care program in the State and the population being served.

Comment: One commenter recommended that we revise proposed §§ 438.308(a)(1) and (a)(2) to allow an MCO or enrollee to designate a medical group or provider entity, instead of an individual, for primary care and overall coordination.

Response: We agree that the MCO should have the flexibility to include medical groups and other provider entities as sources of primary care and overall coordination. Our intent in drafting the proposed rule was to ensure that enrollees have an ongoing source of primary care and a designated person or entity responsible for coordinating their health care. Section 438.208(h) in the final rule with comment period, now requires the State to ensure that each MCO and each PHP: (1) provide each enrollee with an ongoing source of primary care appropriate to his or her needs; and (2) have a mechanism to identify the person or entity formally designated as primarily responsible for coordinating the enrollee's health care. While we thus have added flexibility to designate a medical group or entity as the primary care source, we urge MCOs and PHPs to make every effort to promote a relationship between an enrollee and a single primary care provider.

Comment: Several commenters requested that we clarify whether we are proposing a ''case-manager'' or ''point-of-entry'' care coordination model in proposed § 438.308(a). One of these commenters stated that under either model, the entity must be intimately familiar with the varied needs of the enrollee, and stressed that appropriate safeguards must be in place to ensure effective coordination among care providers. One commenter specifically recommended that we modify the proposed rule to indicate that, based on the initial assessment under proposed § 438.306(e)(2), the type of care coordination for each enrollee be determined by an analysis of individual need.

Response: Our intent was not to propose a ''case-manager,'' ''point-of-entry,'' or any other particular model of care coordination. Rather, our intent was to ensure that MCOs and PHPs, regardless of the model of care coordination, make every effort to promote a relationship between the enrollee and the primary care provider source. We recognize that some MCOs and PHPs might have systems of care coordination under which a person or entity, other than the enrollee's primary care provider, coordinates services. We believe that our revised language in § 438.208(h) better reflects our intent.

With respect to the specific comment that the type of care coordination for each enrollee be determined by an analysis of individual need, we believe that the comprehensive assessment, treatment plan, and coordination program requirements in § 438.208 sufficiently address this issue.

Comment: A commenter found proposed § 438.308(a)(1) unclear, and thought that it could be interpreted to mean that an MCO must provide each enrollee with a primary care provider, and allow self-referral to a specialist on an as-needed basis. This commenter recommended that we delete this provision because, as the commenter interpreted it, it was unworkable in a managed care environment.

Response: We have clarified our final rule with comment period so that each MCO and each PHP must provide an enrollee with an ongoing source of primary care appropriate to his or her needs, and have a mechanism to identify the person or entity who is formally designated as primarily responsible for coordinating the enrollee's health care. We believe that this language is clear and cannot be interpreted to allow self-referral to a specialist.

Comment: We received several comments supporting the proposed provision in § 438.308(b), which requires an MCO to ensure coordination of services internally and with services available from community organizations and other social programs. Many of these commenters requested that we expand the coordination of services list. In contrast, several other commenters stated that they felt that the proposed regulation was unclear and questioned whether it was practical for an MCO to serve as a gatekeeper for non-medical services. Some commenters questioned our authority in proposing this provision, with a few stating that this provision was a major expansion of State and MCO responsibility. Several of these commenters indicated that this provision would be difficult for States to monitor, and recommended either that we clarify the regulatory language or delete the provision entirely. In addition, one commenter referenced the cost-effectiveness test under 1915(b) of the Act waiver programs, noting that such a test is based on a comparison to historic fee-for-service costs that does not include costs associated with coordinating services with other social programs.

Response: We agree that the extent to which an MCO can coordinate all health and health-related services that are needed by an individual enrollee is variable, and that effective approaches to care coordination has not been well addressed to date by health services research. MCO responsibility for care coordination can range from: (1) coordination of all Medicaid services included in the contract between the MCO and the State; (2) coordination of all Medicaid services regardless of whether they are included in the MCO's contract with the State; and (3) coordination of all health, social, educational, and other services needed to maintain optimal health of an enrollee. Determining the appropriate level of responsibility for the MCO for care coordination is complex. The ability of the MCO to coordinate care is determined, in part, by the authority the MCO has to coordinate care provided by entities not a part of the MCO and by the MCO's available resources. Further, social or community organizations external to the MCO may not desire the MCO to coordinate care out of concern that care will be ''medicalized'' or that the authority of other agencies for care coordination will be weakened.

Since these are complex issues, we encourage all State Medicaid agencies to work with beneficiaries, MCOs and PHPs and other stakeholders in their State to determine the appropriate responsibilities of MCOs and PHPs in the State for care coordination. We accordingly have, in response to the above comments, deleted the requirement in proposed § 438.308(a)(2) that MCOs and PHPs coordinate services available from community organizations and social programs. We note, however, that an MCO or PHP may still have responsibilities for coordination that exist under fee-for-service Medicaid. Under § 431.615, State Medicaid agencies are required to establish, as part of their State plan, ''arrangements'' with State health and vocational rehabilitation agencies and Title V grantees. These arrangements must include coordinating plans for health services provided or arranged for recipients. In addition, similar arrangements are required under § 431.620, between a State Medicaid agency and State mental health authority or mental institutions. Section 431.635 also outlines requirements for the coordination of Medicaid with Special Supplemental Food Programs for Women, Infants, and Children (WIC). While these requirements are imposed on States, we believe that States may

delegate some of these coordination responsibilities to MCOs and PHPs. To the extent that these responsibilities are delegated, MCOs and PHPs must ensure coordination of health-related services with community and other social groups. This is now a State option, however.

In response to comments, § 438.208(h) of the final rule with comment period, thus requires that: ''Each MCO and PHP must implement a coordination program that: (1) Meets the requirements specified by the State; (2) Ensures that each enrollee has an ongoing source of primary care appropriate to his or her needs and a person or entity formally designated as primarily responsible for coordinating the health care services furnished to the enrollee; (3) Coordinates the services it furnishes to enrollees with the services the enrollee receives from any other MCOs and PHPs; (4) Ensures that the results of its screen or assessment of an enrollee (or both, if the MCO or PHP performs both) are shared with other entities serving the enrollee, so that those entities need not duplicate the MCO's or PHP's screening or assessment or both; (5) Ensures that in the process of coordinating care, each enrollee's privacy is protected consistent with the confidentiality requirements in § 438.224; (6) Ensures that each provider maintains health records that meet professional standards and that there is appropriate and confidential sharing of information among providers; (7) Has in effect procedures to address factors (such as a lack of transportation) that may hinder enrollee adherence to prescribed treatments or regimens; and (8) Ensures that its providers have the information necessary for effective and continuous patient care and quality improvement, consistent with the confidentiality and accuracy requirements of § 438.224 and the information requirements of § 438.242. We are further requiring in § 438.10(d)(2)(i)(C) that the scope of MCO and PHP coordination be disclosed to potential enrollees by adding ''MCO and PHP responsibilities for coordination of enrollee care'' as an additional type of information that must be provided to potential enrollees.

Comment: Several commenters suggested that proposed § 438.308(b) would not achieve continuity and coordination of services if an MCO contract does not cover all medically necessary services included in a State plan. These commenters believed that an MCO should take responsibility for coordinating all Medicaid services that are not part of its contract. One commenter requested that we clarify whether a State may determine that a State entity, local organization, or community organization is more appropriate to fulfill the coordination role. As an alternative, the commenter recommends that we revise the final rule with comment period to state, ''With the permission of the enrollee, or when consistent with the State's confidentiality laws, the MCO must provide that its providers release information concerning the enrollee's medical treatment to community organizations and other social programs when so requested by such organizations or programs.''

Response: Consistent with our response to the prior comment, and with our revisions to this section, we do not believe that § 438.208(h) prevents a State Medicaid agency from delegating the responsibility for coordinating health-related services to entities other than the MCO or PHP, such as other State and local organizations. Under the final rule at with comment period, § 438.208(h), States have the discretion to contract with MCOs and PHPs to provide a specific set of services that may not include all services covered under a Medicaid State plan. In a situation where the State has assumed a coordination function or delegated it to an entity other than the MCO or PHP, the MCO or PHP must still coordinate care and services to the extent and manner specified by the State and ensure that in the process of coordinating care, each enrollee's privacy is protected consistent with the confidentiality requirements in § 438.224.

Comment: We received several comments on proposed § 438.308(c)(2), which would require an appropriate and confidential exchange of information among providers. One commenter indicated that he or she was pleased to see the importance of confidentiality stressed. However, several comments suggested that proposed § 438.308(c)(2) lacked specificity about what information should and should not be shared between primary care and behavioral health providers. Several of these commenters recommended that enrollees be provided informed consent before information is shared. One commenter specifically noted that existing confidentiality requirements, especially those related to substance abuse treatment, severely limit the practitioner's ability to exchange treatment information. Another commenter stated that it is difficult to know what proposed § 438.308(c)(2) means without a definition of the term ''confidential.'' This commenter recommended that we reference applicable State law in the final rule with comment period.

Response: Our intent in drafting this provision was to ensure that MCOs and PHPs and their providers have the information necessary for effective and continuous patient care and quality improvement. In proposed § 438.308(c), we referenced the need for providers to maintain health records consistent with the requirements established by MCOs and PHPs, taking into account professional standards. In proposed § 438.308(c)(2), we also referenced the need for confidential exchange of information among providers. Both of these requirements were included in an effort to reinforce the confidentiality requirements in proposed § 438.324. We did not intend that the proposed rule be interpreted to require informed consent or to supersede relevant State law governing the exchange of information between providers.

We decided to revise the requirement to provide further clarification and to avoid confusion over the interface of this provision with § 438.224. Accordingly, § 438.208(h)(7) of the final rule with comment period, specifies that each MCO and PHP must ensure that its providers have the information necessary for effective and continuous patient care and quality improvement ''consistent with the confidentiality and accuracy requirements of § 438.224 and the information requirements of § 438.242''. In addition, at § 438.208(h)(4), we require that MCOs and PHPs have coordination programs that ensure that each enrollee's privacy is protected consistent with the requirements of § 438.224. Based on these revisions, we believe that there is no need to define the term ''confidential.''

Comment: We received several comments in support of proposed § 438.308(d), which would require MCOs and PHPs to have procedures in place to ensure that providers: (1) Inform enrollees of specific conditions that require follow-up and, if appropriate, provide training in self-care, and (2) deal with factors that hinder enrollee compliance with prescribed treatments or regimens. One commenter noted that the proposed rule recognizes the value of disease management programs. Another commenter supported the rule but felt that we should further clarify it to ensure that MCOs take responsibility to educate patients as to when they may go to emergency rooms. Another commenter asked that we recognize that there are limits on self-care requirements due to the nature of an enrollee's disability.

Other commenters objected to the proposed rule. One commenter opined that self-care cannot be legislated. This commenter believed that by making this a compliance issue, we were exceeding her authority. Another commenter felt that this provision was not practical and would lead to increased administrative costs.

Response: We continue to believe in the value of providing information and training on conditions that may improve with self-care, and encourage MCOs to provide for this. However, we are persuaded by commenters that some of the conceptual language on ''specific health conditions that require follow-up'' and ''if appropriate, provide training in self-care'' are unclear and subjective. We note that potentially all health conditions that require a visit to a health care practitioner require some degree of ''follow-up.'' Accordingly, in § 438.208(h)(6) of the final rule with comment period, we only require that MCOs and PHPs have in effect procedures to ''address factors (such as lack of transportation) that hinder enrollee adherence to prescribed treatment regimens.''

With regard to the comment that MCOs and PHPs should have the responsibility to educate beneficiaries on the proper use of the emergency room, we encourage MCOs and PHPs to undertake this type of education. However, any training effort must be consistent with the emergency services requirements in § 438.114.

6. Coverage and Authorization of Services (Proposed § 438.310)

Proposed § 438.310 set forth requirements to ensure that each contract with an MCO or PHP identify all services offered under the contract and follow written policies and procedures for processing requests for services in a manner that ensures access to these services. Further, the proposed requirements would ensure that utilization management activities are not structured in a manner that is detrimental to enrollees. These standards implement section 1932(b)(1) of the Act, and to the extent appropriate and applicable, are consistent with Medicare+Choice regulations at § 422.112.

In paragraph § 438.310(a) we proposed that the State ensure through its contracts with MCOs and PHPs that each MCO or PHP identifies, defines, and specifies the amount, duration, and scope of all Medicaid benefits that the MCO or PHP must furnish. Furthermore, the contract must specify what constitutes medically necessary services to the extent they are described in the State plan, and provide that the MCO or PHP furnishes the services in accordance with that provision. We believe these requirements are essential, as it is a concern that an MCO's or PHP's authorization procedures, if unduly burdensome, can prevent an enrollee from having access to, or receiving services to which they are entitled under the State plan. In addition to serving as a protection for enrollees, these requirements support the provider's needs and desires to know what is required for authorization determinations.

In § 438.310(b) we proposed to require that, in processing requests for initial or continuing authorization of services, the MCO or PHP and its subcontractors: (1) follow written policies and procedures that reflect current standards of medical practice; (2) specify the information required for authorization decisions; (3) have in effect mechanisms to ensure consistent application of review criteria; (4) consult with the requesting provider when appropriate; and (5) observe time frames specified in paragraph (d) of proposed § 438.310.

In paragraph (c), we proposed that MCO and PHP contracts be required to provide that written notice be provided, within the time frames in paragraph (d), of decisions to ''deny, limit, reduce, delay, or terminate'' services, including specific reasons for the decision, along with information on the enrollees right to file a grievance or request a State Fair Hearing.

In paragraph (d), we proposed that contracts be required to specify that services will be provided as expeditiously as the enrollee's health condition requires, and within State-established time frames not to exceed 14 days in ordinary cases, and 72 hours if a further delay could ''seriously jeopardize the enrollee's life or health or ability to regain maximum function.

In paragraph (e) we required that each MCO and PHP contract must provide that, consistent with § 438.6(g) and § 422.208, compensation to individuals or entities that conduct utilization management activities is not to provide incentives to deny, limit or discontinue medically necessary services.

Comment: Numerous commenters expressed the view that proposed § 438.310(a)(1) would be difficult to implement. These commenters felt that while a general description of categories of core benefits and service limitations seemed reasonable, the requirement to include the amount, duration, and scope of each service in the contract was not reasonable, and would make the contract too extensive to manage; create unintended exclusions; not allow for consideration of patient specific needs; and require frequent contract amendments to keep current. They also urged that States have the flexibility to determine the level of detail to include in contracts, and believed that the requirements in proposed § 438.310 went beyond legislative intent. Commenters recommended that the contract identify, define, and specify each service that must be offered, but that the amount, duration, and scope be defined in a State Plan or other document. In contrast to the commenters who were opposed to the provision, several commenters supported the proposed provision, stating that it was essential that contracts make clear the services that an MCO must offer to ensure that the enrollee receives the services that they are entitled to under the State Plan. Commenters who supported the provision did not distinguish between the requirement to identify the services and the requirement to include the amount, duration, and scope of each service.

Response: The intent behind this provision was to ensure that enrollees receive the services that they are entitled to receive under the State plan, regardless of the MCO or PHP that they elect, with the recognition that some MCOs and PHPs may not directly provide some services, in which case the State must arrange for these services. While we acknowledge the difficulties that were raised concerning implementing this provision as proposed, we also agree with commenters who stated that it was essential that the contract make clear the services an MCO or PHP is to offer. Any limitations in amount, duration and scope are important features of benefit coverage. Failure to address them in a contract creates the potential for confusion between the State and MCO or PHP and thereby the possibility that an enrollee may not have timely access to service to which he or she is entitled. Because of these concerns, the final rule with comment period at § 438.210 still requires that the amount, duration, and scope of services be specified, now on the basis of what is contained in the State Plan. It further requires that the amount, duration, and scope be such as can reasonably be expected to achieve the purposes for which the services are furnished. However, we also note that if an MCO or PHP does not cover a particular service, the State must make arrangements to ensure that enrollees are able to receive all services covered under the State plan.

Comment: One commenter believed that proposed § 438.310(a)(1) gives the impression that States and MCOs may negotiate away existing Federal requirements governing coverage determinations in the Medicaid program. Specifically, the commenter pointed out that existing regulations for fee-for-service at § 440.230 require that services be provided in sufficient amount, duration, and scope ''to reasonably achieve its purpose.'' It further prohibits States from arbitrarily denying or reducing the amount, duration, or scope of such services solely on the basis of diagnosis, type of illness, or condition. Although State agencies may place limits on a service, limitations much be based on appropriate criteria such as ''medical necessity'' or on utilization control procedures. The commenter was concerned that § 438.310(a)(1) could be read to undermine these requirements by implying discretion to define amount, duration, and scope in contracts in a manner negotiated between the State and MCO or PHP.

Response: We agree with the commenter that the provisions at § 440.230 should also apply to a managed care arrangement, and we accordingly have included them in § 438.210 of the final rule with comment period in response to this comment. In addition, we have clarified that services limited for the purpose of utilization control must still be provided in sufficient amount, duration, and scope to reasonably achieve the purpose for which they are furnished.

Comment: One commenter suggested that benefits and services referenced in § 438.310(a)(1) include all Federally mandated benefits and services, including nurse-midwifery services.

Response: Federal law allows States to ''carve-out'' specific Medicaid services from contracts with MCOs and PHPs, and offer them on a fee-for-service basis or through a separate managed care contractor. For this reason, proposed § 438.310(a)(1) was not intended to govern what services are to be included in or covered by an MCO or PHP contract, but to require that, for those services that are included in or covered by the contract, that the contract identify, define and specify those services. Therefore, we are not requiring in the final rule with comment period that each MCO and PHP contract include all Federally mandated benefits and services, including nurse-midwifery services.

Comment: Many commenters suggested the regulation mandate a definition of medical necessity for States to use in their managed care contracts, or more specific guidance regarding the definition. Commenters presented a range of reasons for including a standard definition, including the need for consumers and providers to understand the scope and limits of health care benefits, ensuring enrollees are not denied services to which they are entitled, avoiding disputes between States and MCOs or PHPs and providers, eliminating State variances in the definition, curbing future lawsuits, and improving the incentive for managed care plans to compete based on innovative quality improvements, rather than restrictive authorizations.

Several different definitions were suggested by different commenters. Some of the recommendations suggested that the definition reflect maintenance of functioning, prevention of deterioration, optimum participation in community living, consideration of the differences between children and adults (especially age-appropriate services and the developmental, rather than rehabilitative, nature of some services for children), and should specifically address mental health needs.

Other commenters found the provision regarding medical necessity too prescriptive and believed that medical issues should not be resolved through a regulation or contracting process.

Response: We disagree that the provision is too prescriptive. States have existing medical necessity specifications in Medicaid fee-for-service programs and individuals enrolled in managed care are entitled to the same services as all other Medicaid eligible persons in the State. Clear specifications of medical necessity in the contract are critical in determining what a State is paying MCOs and PHPs to provide and, in some cases, what the State is providing outside the managed care setting for all parties in the program. The application of State specifications in individual situations allows for medical judgement.

However, we also do not agree that a definition of medical necessity should be included in the regulations. There currently exists no widely-accepted national definition, and at present States currently are allowed under § 440.230(d) to ''place appropriate limits on a service based on such criteria as medical necessity or on utilization control procedures,'' and have great flexibility in defining that criteria. Therefore, we do not believe it is appropriate to promulgate a national definition at this time. However, we believe that more specific guidance regarding State contract specifications is needed. In particular we believe that medical necessity criteria used by Medicaid MCOs and PHPs should not be more restrictive than the State Medicaid medical necessity criteria used in the State's Medicaid program overall, and that this be evident to all parties, thus decreasing the potential for disputes.

Therefore, we have revised the regulation to require that the specifications of medical necessity in the contract must be no more restrictive than any such specifications in the State Medicaid fee-for-service program, described in State statute, regulations, State plan, or other policy or procedures. This addition of ''State statute, regulations or other policy or procedures'' provides greater specificity than the sole reference to ''State plan.'' found in the proposed rule. We further agree that the contract should be clear about what the State's specifications are with respect to medical necessity criteria. Therefore, we have added provisions requiring that the contract address the extent to which the MCO or PHP is responsible for covering medically necessary services to: (1) prevent, diagnose, and treat health impairments; (2) enable the enrollee to achieve age-appropriate growth and development; and (3) attain, maintain or regain functional capacity. While we are not mandating that services must be covered to meet these goals, the contract must clearly address the extent of each MCO's and PHP's responsibility to provide such services. This provision will promote greater consistency of medical necessity specifications across MCOs and PHPs within a State. We believe that services to meet mental health needs are understood to be under the purview of these specifications without specific mention.

We believe this revised regulatory provision, in conjunction with other provisions in this regulation, will meet commenters' concerns regarding beneficiary understanding as well. Section 438.10 requires that information regarding the kinds of benefits, and amount, duration and scope of benefits available under the contract must be provided to enrollees or potential enrollees upon request. This provision should improve the understanding of beneficiaries so they are not denied services to which they are entitled. This section also requires the provision of information regarding grievance, appeal and fair hearing procedures to assure that beneficiaries understand their ability to dispute decisions made by MCOs and PHPs.

We anticipate that greater specificity in MCO and PHP contracts will reduce the potential for MCOs and PHPs to

develop specifications of medical necessity inconsistent with those developed by the State Medicaid agency. However, it must be noted that medical necessity relates to determinations regarding specific care given to a specific patient with specific medical condition under certain circumstances and is thus more focused on individual situations. Some potential for dispute is inherent in such decisions.

Comment: Many commenters indicated that the regulation should recognize the special status of Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) provisions, and provide specific reference to them under the medical necessity provision.

Response: This regulation does not affect any of the pre-existing EPSDT regulations. Further, some EPSDT services may be provided by the State outside of the managed care contract. We believe it is redundant and unnecessary to repeat all existing requirements in this regulation, which focuses on managed care programs. For this reason, we have not included any specific reference to EPSDT in the provisions on medical necessity.

Comment: Some commenters found that the proposed regulation gave the impression that the States and MCOs may negotiate away the Federal legal requirements governing coverage determinations in the Medicaid program. Comments suggested that the regulations ensure that States include in managed care contracts a definition of medical necessity consistent with Federal law.

Response: The provision addressing medical necessity in no way affects any other Federal requirements governing coverage determination in the Medicaid program. All parties must adhere to all other Federal statutes and regulations. However, we believe it would be redundant to repeat all such requirements in this regulation.

Comment: Commenters urged that we review and approve definitions of medical necessity before approving managed care contracts.

Response: Section 438.6 of this final rule with comment period requires us to review and approve MCO and PHP contracts. As part of that review, we will assure that regulatory requirements at § 438.210 pertaining to MCO and PHP contract provisions on medical necessity are met. While these provisions are not a definition of medical necessity, they will promote greater shared understanding by MCOs, and PHPs and beneficiaries about how medical necessity is determined.

Comment: One commenter asserted that ongoing monitoring by us is essential to ensure that States or MCOs do not define medical necessity so narrowly that they deprive beneficiaries of services to which they are entitled under Medicaid.

Response: We agree that ongoing monitoring of managed care programs is important. We utilize a variety of mechanisms to monitor State contracts and State Medicaid managed care initiatives. These mechanisms include: data reviews, State and MCO on-site reviews, and input from beneficiaries, advocates and providers. Furthermore, other provisions in this regulation, such as § 438.204(d) (which requires external reviews of the timeliness of and access to services covered under each MCO and PHP contract), provide significant additional information to assist us and States in monitoring.

Comment: One commenter believed that each State operating a Medicaid managed health care plan that includes children should be required to consult with the State agency that is responsible for overseeing the delivery of early childhood intervention services (under Paragraph B and C of Individuals with Disabilities Education Act) to ensure that the plan includes adequate provisions for coordination of health and early intervention services to such youngsters.

Response: We strongly support coordination between appropriate State agencies. In § 438.202, we require States to provide for the input of recipients and other stakeholders in the development of the State strategy for quality assessment and performance improvement. We consider other State agencies such as State Mental Health and Substance Abuse agencies, Title V Maternal and Child Health agencies, and IDEA agencies as stakeholders who should have input into the development of the strategy.

Comment: We received comments urging that there be no gaps in Medicaid services. A major problem, in the view of these commenters, is that States often are unaware of their responsibility to fill gaps left in the case of services not provided through an MCO or PHP.

Response: We agree that all needed Medicaid covered services must be furnished. In the final rule with comment period—

Section 438.210 requires that the contract identify, define, and specify services that the MCO or PHP is required to offer; and

Section 438.206 specifies if an MCO or PHP contract does not cover all of the services in the State plan, the State must make those services available from other sources and give enrollees information on how and where to obtain them, including how transportation is provided.

In determining whether services should be provided in individual cases, fair hearing officers are bound by their interpretation of the State's overall Medicaid program coverage criteria, and must apply these criteria rather than specific coverage criteria in the contract if the hearing officer determines that the contract criteria are inconsistent with State criteria. The State retains overall responsibility for covering all services in accordance with the Medicaid State plan and implementing policies and procedures, regardless of whether some or all of these services may have been contracted to an MCO or PHP.

Comment: Commenters expressed divergent views on the basis for medical necessity determinations, including preferences for evidence-based standards, professional standards, generally accepted standards of medicine, or deference to the recommendation by the treating professional. Some voiced concern that the evidence-based standard for determining which services are medically necessary would limit obligations to services deemed effective based on quantitative or scientific studies. Quantitative evidence of efficacy does not always exist with respect to persons with developmental disabilities or other special populations who have not been involved in studies. On the other hand, some commenters felt the professional standard of review was inappropriate because of disputes among professionals.

Response: Because of the variable evidence base for the efficacy of the multitude of therapeutic interventions possible for any population, and the lack of consensus regarding the best approach to medical necessity determinations (as evidenced by the comments received) we do not mandate a single approach for determining medical necessity. States have great flexibility in establishing this standard, which is applicable in both fee-for-service and managed care.

Comment: Commenters indicated that MCO subcontracts should be required to include the same ''medical necessity'' definition, as well as EPSDT requirements and access standards, and the clear description of benefits that are contained in contracts between the State and MCOs.

Response: MCOs and PHPs are responsible for assuring that services are provided in accordance with their contract with the State, regardless of any subcontracts in place. MCOs and PHPs

may delegate activities, but not responsibility, for contract provisions. Section 438.230(a)(1) requires the State to ensure that each MCO or PHP oversees and is accountable for functions delegated to subcontractors. States must monitor this process on an ongoing basis and insure the development of corrective action plans, where necessary.

Comment: A commenter believed that all coverage decisions made by the MCO should be consistent with current standards of medical practice.

Response: Section 438.210(b)(1) of the final rule with comment period, requires that the MCO or PHP and its subcontractors follow written policies and procedures that reflect current standards of medical practice in processing requests for initial and continuing authorization of services.

Comment: A commenter was concerned that proposed § 438.310(b)(1) could be interpreted to require a written authorization for every authorization decision. The commenter felt that while this may be possible for many courses of treatment, it was not universally possible.

Response: Section 438.210(b)(1) of the final rule with comment period requires MCOs and PHPs to follow written policies and procedures that reflect current standards of medical practice. The provision applies to the authorization process in general, not each determination. The intent is to ensure that actual determinations are consistent and made in accordance with policies and procedures that reflect current standards of medical practice.

Comment: Some commenters noted that a stated intent of the service request processing requirements in proposed § 438.310(b) was to ensure that the authorization process was not unduly burdensome for providers. These commenters believed that this objective would be better achieved by a more general requirement that the MCO's process be reasonable, rather than by asking States and MCOs to establish specific requirements in their contracts. They felt the requirements were too detailed for a contract, and that the level of specificity was not called for under the BBA. Commenters were most opposed to the requirement that each contract specify the information required for authorization decisions. In contrast, one commenter believed that there should be more specificity than we proposed, especially in the area of routine authorization decisions.

Response: The reason for proposed § 438.310(b) was that there is concern that the authorization process itself could be one of the reasons enrollees do not receive services to which they are entitled under the State plan. We want to ensure that the authorization procedure itself does not prevent enrollees from receiving services that they are entitled to receive under the State plan, and that the MCO's or PHP's information requirements do not place undue burden on the provider or the enrollee. To make explicit our intent that the authorization process not be unduly burdensome for providers or enrollees, in response to the above comments, we have expressly stated this in § 438.210(b)(2)(i) of this final rule with comment period.

Comment: One commenter believed that the requirement for consistent application of review criteria should be eliminated because in this commenter's view it would require health plans to establish another complicated audit process. The commenter felt that the inconsistencies that this provision addresses would be picked up by existing audit procedures.

Response: We believe that consistent application of review criteria is essential in assuring beneficiaries' access to care. Therefore, at § 438.210(b)(2) we retain the requirement that MCOs and PHPs have mechanisms in effect to ensure consistent application of review criteria for authorization decisions. Whether a mechanism is acceptable, as well as how a mechanism is defined, is not dictated in the regulations, but left up to the discretion of the State and the MCO or PHP.

Comment: One commenter felt that it was important to establish a structure that would assure that MCOs' authorization procedures are evaluated on a periodic basis, with the input of practice managers.

Response: Since the requirements of § 438.210 are part of MCO and PHP contract requirements for access to care, States are responsible for ensuring compliance with service authorization requirements as part of their overall quality strategy, as set forth in § 438.202 (State Responsibilities) and § 438.204 (Elements of State Quality Strategies). MCOs and PHPs are also required by § 438.240 to have an ongoing quality assessment and performance improvement program that has in effect mechanisms to detect both underutilization and overutilization of services. In light of the above requirements, we do not believe it is additionally necessary to require in this rule that authorization procedures separately be evaluated on a periodic basis with the input of practice managers.

Comment: One commenter recommended that the regulation require that initial coverage decisions that alter the request of the provider in any way be made, and certified, by a licensed medical doctor. The commenter also urged that initial coverage decisions mirror the requirement in the grievance process (proposed § 438.406(d)) that the review of a denial based on medical necessity be conducted by a ''provider with appropriate expertise in the field of medicine that encompasses the enrollee's condition or disease.''

Response: We agree, in part, with these comments. While we agree that individuals who make initial coverage decisions should be health professionals who have appropriate clinical expertise, we note that relevant expertise may be possessed by health care professionals who are not always physicians. Dentists, psychologists and certified addiction therapists are examples of health professional who are not physicians, but who may have appropriate clinical expertise. Therefore, in response to the above comments, we have provided in § 438.210(b)(3) of the final rule with comment, that any decision to deny or limit a service must be made by a health care professional who has appropriate clinical expertise in treating the enrollee's condition or disease.

Comment: Commenters contended that the requirement in proposed § 438.310(c) that a written notice be sent to the provider for all authorization decisions not fully approved as requested is not current practice for commercial MCO contracts.

Response: We believe that the provider should be notified of all MCO and PHP service authorization decisions that are not fully approved as requested. In § 438.210(c) of the final rule with comment period, we have removed the requirement that this notice be in writing to ease the burden on MCOs and PHPs.

Comment: Numerous commenters had difficulty distinguishing between the requirements at §§ 438.310(c) and (d) pertaining to a notice of adverse action and the time frames for such action, and those in § 438.404 requiring an MCO to give notice of intended action when an MCO intends to deny, limit, reduce, delay or terminate a service or deny payment for a service. There were other comments on these provisions.

Response: We agree that, in the proposed rule, the distinction between proposed §§ 438.310(c) and (d) and proposed § 438.404 was not clear. In the final rule with comment period, § 438.210(c) requires only that the notice of adverse action meet the requirements of § 438.404, and paragraphs (d) and (e) set forth only the

time frames for standard and for expedited authorization decisions, respectively. For further clarity, we note that the distinction between proposed § 438.310 and § 438.404 is drawn at the point the authorization decision is made. If the decision is authorized outright, there is no link to § 438.404; however, if the decision is made to deny or limit a service, notice must be given in accordance with § 438.404, as these decisions are subject to the grievance and appeal process.

Comment: Some commenters were opposed to proposed § 438.310(d) which specified the time frames for providing services. They did not believe it was reasonable to expect services to be provided within the specified time frames. Several commenters suggested that the time frames be consistent for both the Medicaid and the Medicare programs, since providers participate in both programs.

Response: There was an unintended ambiguity in proposed § 438.310(d). The time frames were intended to apply to authorization of services, not furnishing of services. The final rule with comment period, at § 438.210(d) and (e), makes clear that the time frames are applicable to standard and expedited authorizations. The time frames are necessary to ensure that the appeal time frames can be met when an authorization is not approved. In general, the time frames are consistent with those in Medicare.

Comment: In addition to comments interpreting the time frames in proposed § 438.310(d) to apply to the furnishing, rather than the authorization of services, there were comments that understood § 438.310(d) to apply to authorizations, but found 14 calendar days insufficient for a routine authorization if all of the supporting documentation was not present. The commenters recommended that the 14 days should begin after all of the supporting information is received.

Response: The time frame in proposed § 438.310(d) and § 438.210(d) of this final rule with comment period, allows for an extension of up to an additional 14 days if the enrollee or the provider requests extension, or the MCO or PHP justifies to the State agency that additional information is needed and that the extension is in the enrollee's interest.

Comment: Numerous commenters questioned whether enrollees were adequately protected by the provision in § 438.310(d)(2) requiring authorization to be made no later than 3 working days after receipt of the request for service (with a possible extension of up to 14 additional calendar days) if the ordinary 14 day time frame could seriously jeopardize the enrollees' life or health or ability to regain maximum function. The commenters felt that each case is unique, and that in some cases, immediate authorization is necessary, and in others, 24 hours, etc. A standing minimum of 3 working days, with an extension of 14 days possible, was not acceptable to these commenters. One commenter believed that 14 days was excessive for an ordinary authorization that could be completed in a much shorter time.

Response: We recognize that there may be situations in which 72 hours, or the additional 14 days, would be detrimental to the enrollee's health. Under § 438.210(e) of the final rule with comment period, the time frame for an expedited authorization decision is ''as expeditiously as the enrollee's health condition requires'' and in the case of a decision that denies or limits services, early enough to permit the MCO or PHP to process an appeal within 72 hours after receipt of the request for service. The time frames are provided as minimum requirements, but we expect States, MCOs and PHPs to consider the enrollee's health concern as the foremost deciding factor.

Comment: A commenter suggested that we revise § 438.310(d) to allow the provider, rather than just the enrollee, to request extensions in service authorization time frames. As justification, the commenter said that the time required for the provider to arrange for the enrollee to request an extension may force an MCO to deny services that would otherwise be approved, if the provider had time to submit additional documentation.

Response: We agree with the commenter, and in the final rule with comment period, have provided that the provider, acting on behalf of the enrollee, as well as the enrollee may request extension for a standard authorization decision, but only the enrollee may request extension for an expedited decision.

Comment: A commenter indicated that in § 438.310(d), as well as others in the subsection, the reference to ''physician'' should be deleted and ''attending provider'' should be inserted. The rationale for this recommendation was that the language should more accurately reflect the full range of qualified health professionals.

Response: We agree and have replaced the term ''physician'' with ''provider.''

Comment: Two commenters offered their support for the requirement in proposed § 438.310(e) that compensation to utilization review entities not be structured so as to provide incentives to deny, limit, or discontinue medically necessary services.

Response: We have retained this provision as § 438.210(f) of this final rule with comment period.

Comment: Several commenters encouraged us to avoid duplication in the regulation.

Response: We agree, and have attempted to avoid unnecessary duplication in this final rule with comment period. For example, we have eliminated duplication of information requirements that in the NPRM appeared both in proposed § 438.10 and proposed § 438.318.

7. Establishment of Provider Networks (Proposed § 438.314)

Proposed § 438.314 placed requirements on State Medicaid agencies to ensure that contracted MCOs and PHPs have written policies and procedures for the selection and retention of providers. This proposed section required States to ensure that such policies include requirements for initial provider credentialing and recredentialing in accordance with time frames set by the State, but not less frequently than what the State requires for private HMOs.

Comment: Many commenters believed that proposed § 438.314 was too prescriptive. Some commenters interpreted the proposed rule as extending credentialing requirements to providers who perform services under the supervision of physicians, and argued that these requirements generally should only apply to physicians. These commenters expressed the view that requiring credentialing of a broader range of providers adds no value. There were a number of recommended credentialing approaches ranging from adoption of the NCQA credentialing criteria, the American Medical Association's credentialing process, and Medicare policy.

Response: We reexamined the proposed rule in light of these comments and in response to these comments, have made several clarifications to the final rule with comment period. We believe these changes will address most of the commenters' overriding concerns about ambiguity as to who will be subject to credentialing requirements. The final rule with comment period at § 438.214(b) now includes provisions on credentialing that were intended, but not explicit in the proposed rule. Specifically, in § 438.214(b) we now clarify which providers are subject to credentialling and recredentialling

requirements, distinguishing in § 438.214(b)(1) requirements that must be met by physicians and other licensed, independent providers from requirements in § 438.214(b)(2) that must be met by other providers. Exceptions to these requirements are described in § 438.214(b)(3). These exceptions apply to providers who are permitted to furnish services only under the direct supervision of a physician or other provider, and for hospital-based health care professionals (such as emergency room physicians, anesthesiologists, and certified registered nurse anesthetists) who provide services only incidental to hospital services. The latter exception does not apply if the provider contracts independently with the MCO or PHP or is promoted by the MCO or PHP as part of the provider network.

We did not adopt the NCQA standards as suggested by commenters. While our requirements are not identical to the NCQA standards, they have much in common. For example, the exceptions to credentialing outlined above are the same as the exceptions under the NCQA standards. The AMA credentialling process no longer exists.

Comment: One commenter recommended that board certification be dropped as a credentialing criterion.

Response: No change was required in response to this comment, since board certification was not a requirement in the proposed rule, and is not in this final rule with comment period.

Comment: One commenter believed that credentialing criteria should be appropriate to the nature of the services provided.

Response: We believe the credentialing criteria are sufficiently flexible to recognize the characteristics of each MCO and PHP, and the providers within its network.

Comment: One commenter believed that provider selection should be based on objective quality standards.

Response: We believe that the final rule with comment period, as structured, provides for objective quality standards.

Comment: One commenter recommended that we require ''economic profiling'' to be adjusted to reflect varying practice characteristics.

Response: We cannot respond to this comment because we do not understand what the commenter means by ''economic profiling,'' or what its relationship is to credentialing. The intent of this rule was to ensure that MCOs and PHPs implement a formal selection process and, at a minimum, that the process address provider qualifications, provider discrimination, the exclusion of certain providers and additional requirements States may want to impose.

Comment: One commenter recommended that there be written policies and procedures for selection and retention of physicians.

Response: We agree, and in response to this comment, the final rule with comment period at § 438.214(a) now specifies that States must ensure that MCOs' and PHPs' selection and retention policies and procedures must be in writing.

Comment: One commenter recommended that the final rule with comment period, prohibit MCOs from removing providers from their networks without good cause.

Response: While States would be permitted under § 438.214(e) to adopt such a rule if they believe it would be appropriate based on conditions in the State, we do not believe that such a requirement should be imposed nationally in this final rule with comment period. This is because we believe that it may be reasonable, in some cases, for an MCO or PHP to remove providers from its network without cause. For example, there may be a need for an MCO to reduce the size of its provider network if its enrollment declines, and its payments to providers are based on a certain volume. In addition, evaluating the quality of care of providers may be facilitated by having fewer providers serve greater numbers of enrollees. We wish to note that under § 438.12(a)(1), if an MCO or PHP declines to include a provider in its network, it must give the provider written notice of the reason for this decision.

Comment: A number of commenters believed that there was a need to specifically assure that there be no discrimination against providers who traditionally serve more vulnerable populations, such as those who serve limited English proficient populations, high risk populations, and those requiring high-cost treatments. One commenter suggested that such providers be given priority in network selection and referrals. The same commenter believed that MCO gatekeepers frequently do not have professional credentials, and therefore should not control access to care.

Response: It is not clear why the commenters believe there is a need for assurance that there be no discrimination against providers who traditionally serve vulnerable populations, since proposed § 438.314(b)(3) expressly provided that selection and retention criteria could not ''discriminate against * * * those who serve high risk populations.'' This provision has been retained in the final rule with comment period at § 438.214(c). We believe the commenters' concerns are also addressed in a number of other sections. For example, as discussed above, § 438.10(b) requires that information be available in languages spoken in the service area, and that interpreters be available to meet the needs of all enrollees, and § 438.206(e)(2) requires that MCOs and PHPs provide services in a culturally competent manner. Both of these provisions would encourage the use of providers who ''serve limited English proficient populations.''

Under § 438.206(d), in establishing a provider network, MCOs and PHPs are required to consider persons with special health care needs and include the numbers and types of providers ''in terms of training and experience'' required to serve the population. Again, this favors the use of providers with experience with vulnerable populations. Finally, under § 438.50(f)(2), in the case of a default enrollment process under a mandatory program under section 1932(a)(1) of the Act, an attempt must be made to preserve existing provider-beneficiary relationships, and relationships with providers that have traditionally served the Medicaid populations. Again, this favors giving priority to providers serving the vulnerable populations cited by the commenter.

With respect to the concern that gatekeepers do not have necessary professional credentials, § 438.210(b)(3) requires that any denials of an authorization for services be made by ''a health care professional who has appropriate clinical expertise in treating the enrollee's condition or disease.'' We believe that all of the foregoing provisions adequately address the commenter's concerns.

Comment: Several commenters were unclear on the meaning of ''high-risk populations'' as used in proposed § 438.314(b)(3), and sought clearer standards under this provision. Commenters suggested specific examples of high risk patients, including adults and children with special health care needs, such as those with mental illness, substance abuse problems, developmental disabilities, functional disabilities, or complex problems involving multiple medical and social needs like HIV/AIDS, and the homeless. Other commenters felt that the provision governing providers who serve ''high-risk'' populations should be dropped from the rule as too vague to implement, and questioned the wisdom of employing such standards, which

they believed would lead to unresolvable disputes.

Response: We disagree with the commenters who believe that we should delete the requirement in proposed § 438.314(b)(3), because we believe that many Medicaid beneficiaries are best served by providers who are experienced in caring for individuals with the health or social conditions that make an enrollee ''high risk;'' (for example, poverty, homelessness, disrupted family situations). We agree that the specific examples of high risk populations cited by the commenters are examples of high risk populations. We do not believe, however, that we should include regulations text specifically citing such categories, since this may be seen as limiting the scope of this provision. We instead believe that States should be free to interpret ''high risk populations'' based on their knowledge of the high risk populations in their State.

Comment: One commenter discussed the very valuable role nonprofit social service agencies play in the care delivery system for Medicaid beneficiaries, and expressed the view that these provider agencies would gain more credibility if they were accredited by the Medicaid program. There are now standards for such agencies that are recognized by many States. The commenter recommended that such agencies be accredited, and that they have the option of accreditation from the Council of Accreditation (COA), a body more representative of the social service model, as well as by a medical accrediting body such as the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) or a JCAHO-type accrediting body.

Response: We do not believe it would be appropriate at this time to provide for accreditation of these agencies because (1) accreditation standards and procedures for such entities are in their formative stage, and (2) to the extent these agencies provide specific Medicaid State plan services, they would already be subject to any accreditation requirements applicable to the service in question. We note, however, that there is no Federal prohibition preventing States from adopting such quality standards if they choose.

Comment: One commenter took exception to the requirement at proposed § 438.314(b)(1) that provider selection criterion would be based in part on eligibility for payment under Medicaid. The commenter believed that there would be times when an MCO may wish to provide services through a provider in good standing who is not an eligible provider type under fee-for-service.

Response: We have clarified the final rule with comment period at § 438.214(d) to better reflect our intent to preclude only providers who have been barred from participation in the Medicaid program (for example, providers convicted of fraud). We did not intend to preclude States from allowing MCOs or PHPs to provide services through providers in good standing who do not participate in the traditional part of the Medicaid program (for example, alternative providers or providers who have not otherwise chosen to participate in the Medicaid fee-for-service program).

Comment: A commenter recommended that MCOs not be permitted to have separate panels of providers for Medicaid and for their other lines of business.

Response: Our experience has demonstrated that such a requirement is not practical. We have considered imposing such a requirement in the past, and have determined that it would not be in the best interests of Medicaid beneficiaries to do so. Some of the most successful managed care programs have employed providers with particular experience in treating the Medicaid population. Permitting these providers to exclusively serve Medicaid beneficiaries allows more Medicaid beneficiaries to access these experienced providers. It is also the case that some managed care organizations include physicians in their networks who would not agree to accept Medicaid patients. In such a case, if these MCOs or PHPs were not permitted to limit Medicaid patients to a subset of physicians who agree to treat Medicaid beneficiaries, they would not be available as a Medicaid option. We therefore are not including this requirement.

8. Enrollee Rights (Proposed § 438.320) (Redesignated as § 438.100)

As part of these standards, in proposed § 438.320(a), we required that each contract with an MCO or PHP have written policies with respect to enrollee rights, and the MCO or PHP ensure compliance with Federal and State laws affecting the rights of enrollees, and ensure that its staff and affiliate providers take these rights into account when furnishing services. Under proposed § 438.320(b), States must ensure that each enrollee has a right to: Receive information regarding their health care; have access to health care; be treated with respect and consideration for enrollee dignity and privacy; participate in decision making regarding his or her health care; receive information on available treatment options or alternative courses of care, and have access to his or her medical records. Proposed § 438.310(c) required that States ensure compliance with various civil rights laws.

Comment: Several commenters felt that the rights in proposed § 438.320 should be extended to individuals enrolled in PCCMs, as well as those in MCOs and PHPs.

Response: As discussed above, to the extent requirements in proposed subpart E are grounded in section 1932(c)(1) of the Act, we determined that it would be inconsistent with the Congressional intent to apply them to PCCMs, since the Congress made a conscious decision not to do so even when other provisions in section 1932 of the Act did so apply. We believe that the rights in § 438.100(a)(2), (b)(1), (b)(4), (b)(5), (b)(6), (b)(8), (c), and (d), however, are supported by our authority under section 1902(a)(4) of the Act to specify methods necessary for proper and efficient administration, and the requirement in 1902(a)(19) of the Act that States provide ''safeguards as may be necessary to assure that * * * care and services will be provided * * * in the best interests of the recipients.'' Therefore, in response to this comment, we are revising § 438.100(a)(2), (b)(1), (b)(4), (b)(5), (b)(6), (b)(8), (c), and (d) to make these paragraphs and subparagraphs applicable to PCCMs.

Comment: Several commenters suggested that without proper enforcement, the ''rights'' that were contained in proposed § 438.320 were just ''paper rights.''

Response: We agree that to be effective, enrollees'' rights must be enforced, and believe that the final regulation with comment period include provision for enforcement. First, under subpart F, discussed in section II. E. below, enrollees have the right to file a grievance with their MCO or PHP if they believe any of their rights have been violated. In addition, (1) § 438.66 mandates that States actively monitor MCOs' and PHPs' operations, (2) § 438.202(d) requires that States ensure compliance by MCOs and PHPs with the quality standards established by the State, and (3) § 438.204(b)(2) requires that State quality strategies include continuous monitoring and evaluation of MCO and PHP compliance with standards. We believe that these provisions do provide for enforcement of enrollee rights.

Comment: Several commenters were concerned that the enrollee rights outlined in proposed § 438.320 contained too much subjective language

that could be construed in any way that an MCO chooses.

Response: We believe that the provisions for Enrollee Rights now set forth in § 438.100 are specific enough to ensure specified rights for enrollees of MCOs, PHPs, and PCCMs, while still affording States the flexibility to determine how to guarantee that these rights are upheld.

Comment: Several commenters found the rights outlined in proposed § 438.320 too sparse, and believed that they did not fully implement the recommendations in the Consumer Bill of Rights and Responsibilities (CBRR).

Response: Proposed § 438.320 was intended to articulate a broad set of fundamental enrollee rights, and was not intended to encompass all aspects of the CBRR, which are reflected in detail in numerous provisions throughout virtually every subpart in part 438. For example, important enrollee rights are reflected in the information requirements in § 438.10 in subpart A, the continuity of care requirements in § 438.62 in subpart B, the rights related to provider enrollee-communication and emergency services in §§ 438.102 and 438.114 in subpart C, the right to access to a woman's health care specialist in § 438.206(d)(2) in subpart D, and the grievance and appeal rights throughout subpart F. See our discussion of these and other provisions for further discussion of how this final rule with comment period implements the CBRR.

Comment: One commenter objected to the provision in § 438.320(c) requiring that MCOs and PHPs must ''comply with any other Federal and State laws that pertain to enrollee rights,'' because the commenter believed it was not appropriate for the Federal government to regulate compliance with State laws.

Response: The language in the proposed rule was intended to acknowledge that there are a number of States with their own requirements pertaining to enrollee rights. We do not believe that it is inappropriate to require that the State ensure that the MCOs, PHPs and PCCMs also comply with these regulations. However, we are not expecting States to take over the enforcement of State and Federal laws that are not within their jurisdiction. In order to more narrowly define the Federal and State laws that are being referenced, we have added the term ''applicable'' to the final regulation.

Comment: One commenter suggested that in addition to providing services in accordance with proposed §§ 438.306 through 438.310, proposed § 438.320(b)(2) should also include the right to ''receive all services provided under the State plan.''

Response: The requirement that a beneficiary receive all services provided under the State plan is set forth in § 438.206(c), which is incorporated in § 438.100(b)(2), so that this right is included in § 438.100.

Comment: One commenter requested that we explicitly state that enrollees have a right to a second opinion.

Response: We agree, and in response to this comment, have added a reference at § 438.100(b)(3) to the right to a second opinion provided for under § 438.206(d)(3).

Comment: Several commenters offered their support for proposed § 438.320(b)(3) which required that enrollees be treated with respect and due consideration for their dignity and privacy. It was the commenter's belief that populations with special needs have not always been treated in this manner. However, one commenter, while supporting the provision, felt that the standard was not appropriate for a Federal regulation, and would be difficult for States to measure or enforce.

Response: We believe that there are ways to monitor compliance with this provision retrospectively through such means as enrollee surveys, site visits, hot lines, and grievance procedures. In addition, including respect, dignity and privacy as explicit enrollee rights attempts to address this issue proactively. As commenters indicated, we believe this is a fundamental and important enrollee right and, as such, should be included in the regulation.

Comment: Several commenters suggested that we revise the language in proposed § 438.320(b)(4) to state that the information must be presented in a language appropriate to the consumer's condition and ability to understand.

Response: Section 438.100 provides that enrollees receive information in accordance with § 438.10, which requires that all information furnished to enrollees and potential enrollees meet specified language and format requirements. We believe these provisions address the commenter's concern. We therefore do not believe that a revision to the language at § 438.100 is necessary.

Comment: While offering support for the provision that requires information to be provided to enrollees, some commenters suggested that we revise the proposed regulation to require ''full and complete'' information on ''all'' available treatment options and ''alternatives,'' including alternatives as to the ''site of care.'' These commenters felt that these revisions are essential in ensuring that enrollees receive information on family planning services that are not covered by the MCO.

Response: We consider the commenters' suggestions already addressed in the regulations. For example, § 438.102(b)(1)(ii) and (iii) give enrollees a right to all ''information the enrollee needs in order to decide among all relevant treatment options.'' and ''the risks, benefits and consequences of treatment or non-treatment.'' With respect to information on family planning services, § 438.10(e)(2)(vi) expressly requires that information be provided on how enrollees may obtain family planning services from out-of-network providers. In the case of services not covered through the MCO or PHP, under § 438.10(e)(2)(xii), information must be provided on how and where the enrollee must obtain the benefits. In the case of benefits not covered on moral or religious grounds, information must be provided on how or where to obtain information about the service.

Comment: Several commenters offered their support for proposed § 438.320(b)(5), requiring that enrollees be permitted to participate in decisions on their health care, but requested that this provision be revised to clarify that enrollees not only have the right to participate in decisions, but that they also had the right to refuse treatment. Additionally, commenters wanted this provision to explicitly state that enrollees had the right to participate in ''all'' treatment decisions and to make ''informed decisions.''

Response: We agree with the commenters that it may not be clear that the right to participate in decisions also includes the right to refuse care, although this was our original intent. Consequently, we have revised § 438.100 (b)(6) to expressly include the right to refuse treatment. However, we believe that the suggested changes to include the qualifiers ''all'' and ''informed'' are not necessary, as these concepts are already contained in the provision as written.

Comment: A number of commenters believed that enrollee ''access'' to records was not sufficient, and that they also needed to be able to receive ''copies'' of their medical records, and all relevant documents, at no cost. They also requested that we revise proposed § 438.320(b)(6) to include the right to correct inaccuracies, and to append the record if there was a disagreement.

Response: We agree with the commenters that enrollees should also have the right to receive copies of medical records, and have addressed the commenters concerns in § 438.224 (Confidentiality and accuracy of

enrollee records), discussed in section II. D. 8. below. In response to this comment, we have provided in § 438.100(b)(7) for the right to receive a copy of records, and request that they be amended or corrected, and have referenced § 438.224. We have not, however, required that enrollees be able to receive a copy of his or her medical record at no cost, because we believe that providers may incur some costs in responding to numerous requests to photocopy medical records and related documents.

Comment: Some commenters suggested that we provide additional detail on the specific relevant sections of the laws cited in proposed § 438.320(c) and citations for the regulations implementing these provisions.

Response: In response to this comment, we have included additional detail, including citations to implementing regulations in some cases, in § 438.100(d) of the final rule with comment period.

Comment: A commenter recommended that the text of proposed § 438.320(c), and not just the preamble, make clear the point that State Medicaid Agencies are not expected to take over the enforcement of State and Federal laws not within their jurisdiction.

Response: We believe that it is clear from the preamble to the proposed rule and to this final rule with comment period, that we are not expecting States to take over the enforcement activities that are not within their jurisdiction. However, as noted above, in order to more narrowly define the Federal and State laws that are being referenced, we have added ''applicable'' to the regulation.

Comment: A number of commenters believed that enrollees should be free to exercise their rights without fear from reprisal from the MCO or PHP in which they are enrolled, including the right to refuse services, without the loss of other desired services or disenrollment.

Response: We agree with commenters, and in response to this comment have added language at § 438.100(c) to ensure that an enrollee's free exercise of his or her rights does not adversely affect the way the MCO, PHP, PCCM, their providers, or the State agency treats the enrollee.

Comment: Commenters requested that we include explicit statements of additional enrollee rights, including the right to: (1) Fully participate in the development of their plan of care and treatment decisions; (2) participate in research or experimentation only with informed, voluntary, written consent; (3) be free from physical, verbal, sexual, or psychological abuse, exploitation, coercion, or neglect; and (4) be treated in a humane environment that affords reasonable protection from harm and ensures privacy.

Response: Section 438.100(b)(6) provides enrollees with the right to participate in decisions regarding their health care, which we believe would include plans of care, treatment decisions, or participation in any research or experimentation. With respect to the right to be free from abuse, exploitation, or neglect, or to be treated in a humane environment that affords protection from harm and ensures privacy, we believe that these rights are inherent in the right under § 438.100(b)(4) to be treated with respect and dignity and the confidentiality rights in § 438.224, discussed in section II.D.9. below. Further, we have revised proposed § 438.306(e)(3)(iii)(now § 438.208(f)(5) to require that treatment plans, developed for individuals who are pregnant or who have special health care needs, are to be developed ''with enrollee participation''.

Comment: Commenters suggested that we add as a right that beneficiaries have the right to be free from seclusion, physical or chemical restraints, used by staff as a means of coercion, discipline, convenience or retaliation.

Response: We agree that this is a fundamental right, and in response to this comment, have added it to the requirements of § 438.100 in the final rule with comment period.

Comment: Commenters proposed the inclusion in proposed § 438.320 of a number of additional rights in the following areas: information standards, complaint and grievance procedures, quality assurance, service authorization, choice, disenrollment, emergency services, access and capacity, and benefits and coverage.

Response: As discussed previously, § 438.100 was intended to put forth a basic and general fundamental set of rights. More detailed and specific enrollee rights are articulated in greater detail in other sections of the regulation. The suggested changes in the areas of information standards, complaint and grievance procedures, quality assurance, service authorization, choice, disenrollment, emergency services, access and capacity, and benefits and coverage are more fully detailed in the corresponding provisions of the regulations which are dedicated to these respective topic areas. Therefore, the specific suggestions offered by the commenters were considered in the context of these other provisions. For example, the comment that the enrollee has the right to receive timely and adequate advance written notice of any decision to deny, delay, reduce, suspend, or terminate medical services is addressed in §§ 438.210(c) and 438.404.

9. Confidentiality (Proposed § 438.324)

Current regulations at 42 CFR part 431, subpart F govern the safeguarding of beneficiary information at the State level. The regulations in part 431, subpart F, specify for State Medicaid agencies, among other things, the types of information to be safeguarded, when such information may be released, and how such information is to be distributed.

In proposed § 438.324, consistent with the regulations at part 431 subpart F, we proposed that the State ensure, through its contracts with MCOs and PHPs, that each MCO and PHP (1) maintain records and information (in oral, written, or electronic format) in a timely and accurate manner, (2) safeguard the privacy of any information that identifies a particular enrollee by ensuring that original records are released only in accordance with Federal or State law, or court orders or subpoenas; copies of records and information are released only to authorized individuals; and unauthorized individuals do not gain access to, or alter, patient records, (3) protect the confidentiality and privacy of minors, subject to applicable State and Federal laws, (4) ensure that enrollees have timely access to records and information that pertain to them, and (5) abide by all Federal and State laws regarding confidentiality and disclosure of mental health records, medical records, other health information, and any information about an enrollee. The requirements we proposed in this section are consistent with the right to confidentiality of health information supported by the CBRR.

We received numerous comments in response to this section requesting that we include specific guidelines and address substantive issues in more detail. Prior to addressing these comments, we must first clarify our original intent in proposing this section. We included this section in order to ensure that MCOs and PHPs would be held responsible for safeguarding the confidentiality of enrollee information. We did not intend to impose specific guidelines for the use and disclosure of enrollee information. We recognized that there are many different State and Federal laws that specifically address confidentiality and it was not our intent to interfere with these laws. Several States have enacted strong privacy

protections that will continue to apply to MCOs and PHPs participating in the Medicaid program. In addition, the Secretary is currently developing a final regulation that will address confidentiality of health information at the Federal level in accordance with section 264 of the Health Insurance Portability and Accountability Act (HIPAA) (Public Law 104–191). In order to remain consistent with existing laws and regulations, as well as the forthcoming HIPAA regulation, we only included general requirements in this section.

Comment: We received two comments on proposed § 438.324(b)(1), which provided that original medical records must be released only in accordance with Federal or State law, or court orders or subpoenas. One commenter recommended that we revise the regulation to require that both the original and copies of patient medical records be released to Medicaid fraud control units and other law enforcement agencies. Another commenter suggested that this provision conflicts with requirements in § 431.306(f). That section requires that when a court issues a subpoena for a case record, the Medicaid agency must inform the court of the applicable statutory provisions, policies, and regulations restricting the disclosure of information. The commenter believed that in light of this existing requirement, the release of information should not be required through the use of subpoena power alone.

Response: The requirement proposed in § 438.324(b)(1) was intended to highlight the importance of ensuring the integrity and availability of original medical records. If an MCO or PHP receives a request for an enrollee's information, we would expect that the MCO or PHP would typically only release a copy of that information. However, as the commenters note, the proposed language could create confusion regarding the requirements for this subset of identifiable health information, and how it differs from the protections afforded to other such information. It was our intent that originals should only be released in accordance with applicable laws. Therefore, in order to more accurately reflect this intent, in § 438.224(c) of the final rule with comment period, we have deleted the specific reference to court orders and subpoenas, and eliminated the provision singling out original records from other health information. We rely on the State, the MCO, and the PHP to make appropriate decisions regarding disclosure of copies versus originals, based on the specific circumstances of each disclosure. Procedures to be followed in response to a subpoena are addressed by the requirement (in the parenthetical in the first line of § 438.224) that MCOs and PHPs must follow subpart F of part 431.

Comment: We received several comments in response to proposed § 438.324(b)(2), which requires that copies of records and information from MCOs be released only to authorized individuals. Several commenters believed that we did not define the term ''authorized individual'' or ''authorized representative'' in the proposed rule, and that it was thus unclear who may receive medical records from an MCO or PHP. Other commenters found that this provision did not include necessary language addressing inappropriate disclosures of information within an MCO or PHP. Specific recommendations made by commenters were that the definition of ''authorized individual'' include family members, guardians, and legally authorized representatives.

Response: We recognize that the use of the term ''authorized'' in this section has generated some confusion. It was our expectation that the MCO or PHP would establish and follow procedures to specify who would be ''authorized'' to received confidential enrollee information, and that these procedures would reflect applicable Federal and State law. We recognize that the term could be interpreted in other ways. Therefore, in § 438.224(b) and (c) of the final rule with comment period, we have revised the language to make more explicit our intent as to what would constitute an authorized disclosure, and in doing so, we removed the term ''authorized individual.''

Comment: Several commenters requested that the proposed rule be strengthened with regard to limiting the flow of identifiable data. Some commenters suggested that we require MCOs and PHPs to use non-identifiable data whenever identifiable data is not needed to complete a task. Some commenters stressed that the final rule with comment period should also include additional safeguards to protect a beneficiary's sensitive health information, so that the disclosure of identifiable data can be used only for activities which MCOs or PHPs and providers need for legitimate purposes. One commenter recommended that an MCO or PHP should be required to define when identifiable data is necessary for a particular activity. In addition, several commenters recommended that we include technical standards in the regulations to address electronic and paper records. Finally, other commenters suggested we include incentives in the regulation for MCOs and PHPs to use non-identifiable data, and include a requirement for MCOs and PHPs to justify the use of identifiable data needed for an activity.

Response: These comments describe many standard procedures that should be in place for protection of health information and ones which MCOs and PHPs will likely put in place to comply with the requirements of this section. However, consistent with the above discussion of our purpose in writing this section of the rule, our intent was not to create specific technical mechanisms (including standards regarding the use of identifiable and non-identifiable data) that MCOs and PHPs must have to safeguard data. As discussed previously, we proposed this section because we believe that MCOs and PHPs should have safeguards in place (including, as appropriate, the ones suggested by the commenters) to ensure that patient-identifying information is used for legitimate purposes. To underscore our intent not to create new technical standards, we have deleted sections of the proposed rule (§ 438.224(d) and (e)) that we believe are already covered by the requirements at Subpart F of part 431 and which may have inadvertently lead readers to believe that we were attempting to create new standards.

Therefore, we have not revised this section to include technical standards for securing electronic and paper records, or to impose specific requirements on MCOs and PHPs as to when they must use non-identifiable data. However, in response to the broad concern expressed by commenters about the different ways patient-identifying information might be used or disclosed to others, we have added a new requirement at § 438.224(e) that requires the State to ensure that each MCO and PHP establish and implement procedures to ensure that enrollees receive, upon request, information pertaining to how MCOs and PHPs use and disclose identifiable information.

Comment: We received several comments in support of proposed § 438.324(c), which requires MCOs and PHPs to have procedures to protect the confidentiality and privacy of minors, subject to applicable Federal and State law. Several commenters indicated that a major obstacle to minors obtaining needed health care is due to concerns about the lack of confidentiality. They suggested that we maintain the proposed regulation and preamble, which they believe is clear in that it refers to services and treatment which minors can obtain without parental consent and what information can be

released to a parent upon request. They also suggested that family planning, mental health, and substance abuse services be addressed by the MCO's or PHP's procedures.

In contrast, several commenters contended that all information about a minor should be released to parents barring a court order stating otherwise. One commenter focused on the developmentally disabled population, and believed that copies of medical records, treatment options, and confidential information relevant to the receipt of medical services must be communicated to a family member or guardian prior to proceeding with the proposed treatment. Other commenters suggested that the final regulation stress confidentiality of family planning services for adults as well as minors.

Response: Section 438.324, as a whole, was intended to ensure that MCOs and PHPs have procedures to protect the confidentiality of all enrollees. We proposed a specific provision addressing the confidentiality of minors in recognition of the large number of enrollees under age 18. It was not our intent to interfere with Federal and State laws that address the confidentiality of minors. Therefore, in the final rule with comment period, we have removed the reference to minors because we intend the term ''enrollee'' to encompass all enrollees.

Comment: Several commenters recommended that we revise proposed § 438.324(d) to clarify that, in addition to enrollees, authorized representatives of enrollees must have timely access to records and information. One commenter recommended that we revise this provision to require MCOs to provide enrollees with access to their records within 24 hours (excluding weekends and holidays); and to obtain photocopies. Another commenter pointed out that under their State law, the Medicaid agency is not required to provide timely access to records if the beneficiary is currently under civil or criminal investigation. Another commenter questioned this provision, and suggested that under patient/doctor confidentiality, the patient holds the privilege of confidentiality, not the provider. Further, the commenter contended that patients are the owners of their medical records and always have had the opportunity to review and correct errors. The commenter wondered what role an MCO or PHP should play in enforcing patient rights. Several commenters also suggested that enrollees be able to receive copies of their records. Commenters also recommended that enrollees be able to request amendments or corrections to their records.

Response: We proposed § 438.324(d) to ensure that MCOs and PHPs have orderly procedures to enable an enrollee to access his or her medical records in a timely manner. It was not our intent to interfere with Federal or State laws governing access to medical records or other information. While we have not included specific time lines, exceptions, and rules in this provision, we have, in § 438.224 of the final rule with comment period, clarified the language to more clearly reflect our intent. We have replaced the general term ''access'' with more specific language in § 438.224(f) that requires the State to ensure that each MCO and PHP has procedures to ensure that the enrollee can request and receive a copy of his or her records and information and that the enrollee may request amendments or corrections.

Comment: Several commenters questioned proposed § 438.324(e), which required MCOs and PHPs to abide by all Federal and State laws regarding confidentiality and disclosure of mental health records, medical records, other health information, and any information about an enrollee. One commenter believed that it was redundant for the Federal government to regulate compliance with State law. Another commenter contended that Federal requirements should preempt State and local confidentiality laws. This commenter suggested that requiring multi-state Medicaid MCOs to adopt different State confidentiality procedures in each State was unduly burdensome, and serves no legitimate purpose. This commenter recommended that confidentiality requirements be uniform and pre-empt State and local confidentiality laws.

Response: It was not our intent to preempt or supersede other Federal or State laws governing confidentiality. Rather, we intended to create a baseline of protections for Medicaid managed care enrollees that is consistent with other applicable laws. We continue to believe that it is important to highlight other applicable laws and to require that States ensure that MCOs and PHPs have procedures that comply with these laws; and therefore, we have retained this requirement. With respect to the commenter urging that Federal requirements be established that would pre-empt State law, we believe that this would be inconsistent with the structure of the Medicaid program, which is a State-run program under which States are granted discretion to establish their own approach. While a national MCO or PHP may have to follow different rules in different States under the Medicaid program, this would be equally true for their commercial lines of business in different States.

Comment: We received several comments supporting proposed § 438.324(e). Several commenters appreciated that we made a distinction between medical records, and the sharing of necessary information between physical health providers and mental health and substance abuse providers. While some commenters recommended that the language be maintained, other commenters recommended that we clarify the regulation to require compliance with Federal rules concerning confidentiality of substance abuse treatment and to emphasize the primacy of 42 CFR Part 2, Confidentiality of Alcohol and Drug Abuse Records.

Response: Under this provision, MCOs and PHPs must abide by all Federal and State laws regarding the confidentiality of health information, including laws pertaining to the confidentiality of substance abuse treatments. We have clarified our final rule with comment period to require that the State must ensure that, for medical records and any other health and enrollment information that identifies a particular enrollee, the MCO or PHP establishes and implements procedures to abide by all Federal and State laws regarding confidentiality and disclosure. We believe that this provision, as stated, includes existing laws that govern confidentiality and disclosure of medical records, mental health records, substance abuse records, and any other identifiable information.

Comment: A commenter expressed concern that § 438.324 does not address how confidentiality policies will affect the use of patient information in research. The commenter stressed that studies of disease, epidemiology, therapy, and health services depend on access to patient records, including records for Medicaid managed care enrollees. The commenter recommended that we address the issue of research in the final rule with comment period so that medical records are available through a process that meets confidentiality concerns but is not unduly burdensome.

Response: The use and disclosure of health information for research is an extremely complicated issue. We do not believe that this regulation is the appropriate vehicle to specify when such uses and disclosures are appropriate and what specific safeguards must be in place to protect that information. We do require the State to ensure that MCOs and PHPs safeguard the confidentiality of any

information that identifies a particular enrollee. In addition, we require the State to ensure that MCOs and PHPs have procedures in place that address how the information will be used and disclosed. We would expect that these procedures would specifically address when the MCO or PHP would use enrollee information for research and under what circumstances it would disclose the information to outside researchers. As noted above, the forthcoming HIPAA regulation will address this issue in more detail.

10. Enrollment and Disenrollment (Proposed § 438.326) and Grievance Systems (Proposed § 438.328)

These proposed sections required that a State agency include as part of its quality strategy ensuring compliance with the enrollment requirements in § 438.56, and, consistent with section 1932(c)(1)(A)(ii) of the Act, with the grievance requirements in subpart F. We received no comments on proposed § 438.326, and one comment relating to proposed § 438.328.

Comment: One commenter requested that we mandate that States conduct random reviews of service denial notifications, and other forms of non-coverage to ensure that MCOs and PHPs are notifying members in a timely manner.

Response: We agree with this comment. In § 438.228(b) of the final rule with comment period, we have added a requirement that States must conduct random reviews to ensure that each MCO and PHP and its providers and contractors are notifying enrollees in a timely manner. We have further added at § 438.228(c) a requirement that State must review, upon request of the enrollee, grievances not resolved by an MCO or PHP to the satisfaction of the enrollee.

11. Subcontractual Relationships and Delegation (Proposed § 438.330)

Proposed § 438.330 set forth requirements specifying that the State must ensure that an MCO or PHP entering into a contract with the State oversees and remains entirely accountable for the performance of any activity it delegates to a subcontractor. Under proposed § 438.330, it is the sole responsibility of the MCO or PHP to ensure that the delegated activity or function is performed in accordance with applicable contractual requirements. Specifically, under proposed § 438.330, the MCO or PHP should: (1) Evaluate the ability of the prospective contractor to perform the functions delegated; (2) enter into a written agreement that specifies the delegated activities and reporting requirements of the subcontractor, and provides for revocation of the delegation or imposition of other sanctions if the subcontractor's performance is inadequate; (3) monitor the subcontractor's performance on an ongoing basis, and subject the subcontractor to formal review at least once a year; and (4) if deficiencies or areas for improvement are identified, take corrective action. These provisions are consistent with the CBRR as they relate to consumer choice of provider networks that are adequate to serve the needs of consumers, and in particular, these provisions ensure that States hold MCOs and PHPs accountable for the availability and adequacy of all covered services.

Comment: One commenter recommended requiring certifications to the State that payments under a subcontract are sufficient for the services required. Commenters recommended that all subcontracts should be made available for public inspection, so that they are available to the State, enrollees, and advocates.

Response: While we are not requiring a direct certification to the State, it is the MCO's or PHP's responsibility under § 438.230(b)(1) to evaluate, before delegation occurs, the prospective subcontractor's ability to perform the activities that are to be delegated. This evaluation may include evaluation of the subcontractor's financial stability and financial ability to deliver services. Subsequently, the MCO or PHP is held accountable for any functions it delegates, and therefore, has ultimate responsibility for oversight of the subcontractor. In addition, there is nothing in this provision that would preclude a State from requiring such a certification if it so chooses.

Moreover, we do not review subcontracts and normally do not become involved in the relationship between MCOs and PHPs and their subcontractors, with the exception of physician incentive rule arrangements, which must be disclosed. The law imposes requirements on MCOs, not on their subcontractors. We do not believe that we should be involved because the MCO or PHP (with whom there is a direct relationship) is ultimately responsible that requirements are met. Therefore, we will not in this final rule with comment period require public access to subcontracts. However, public access to subcontracts is subject to State procedures and policies governing their disclosure.

Comment: Several commenters requested clarification on the definition of subcontractor. The commenters questioned whether we intended for this provision to apply to individual providers or solely to organizations. One commenter expressed the view that if an individual physician/provider is considered to be a subcontractor, the requirement for annual recredentialing would be unreasonable. Another commenter suggested that we give States the flexibility to define subcontractor as it applies to these provisions, while other commenters recommended that we define the term so that these provisions would apply solely to organizations.

Response: Any entity, whether an individual or organization, that is not an employee of the organization, but who assumes responsibility on behalf of the MCO or PHP, would be considered to be a subcontractor. While we are not specifically defining subcontractor, we do intend for it to include any non-employee individuals or organizations within the MCO's or PHP's network.

Comment: One commenter believes the requirement that the MCO subject each subcontractor's performance to formal review on an annual basis is unnecessarily prescriptive. The commenter notes that there is considerable overlap between this requirement and the provider credentialing requirements, and that States should have flexibility in this area.

Response: The intent of this provision was not to require recredentialing once a year. Proposed § 438.330 was designed to hold MCOs and PHPs accountable for the availability and adequacy of all covered services delivered through their subcontracts. As a result of this comment, we have revised § 438.230(b)(3) of the final rule with comment period to require that the MCO or PHP monitor the subcontractor's performance on an ongoing basis, and subject it to formal review according to a periodic schedule established by the State, consistent with industry standards or State laws and regulations.

Comment: One commenter expressed the view that the proposed rule did not go far enough in protecting an enrollee's rights when Medicaid services are delegated to subcontractors. The commenter believed that the enrollee has the right to know what to expect of a subcontractor, and that the State should be much more involved in making sure the subcontractor complies with the requirements of the contract and State and Federal law. The commenter recommended that, at a minimum, all subcontracts should be directly monitored by the State with the

monitoring procedures applicable to the MCO also applied to subcontractors.

Response: Section 438.230(a) of the final rule with comment period requires that the MCO or PHP oversee, and be held accountable for, any functions and responsibilities that it delegates to any subcontractor. Therefore, it is the MCO's or PHP's responsibility to ensure that its subcontractors are in compliance with all applicable laws, including those identified under § 438.100 (Enrollee Rights). It is the sole responsibility of the MCO or PHP to ensure that the delegated function is performed in accordance with applicable contractual requirements. However, there is nothing in this provision that precludes States from monitoring subcontracts if they so choose.

Comment: One commenter recommended that regulatory language be revised so that it is the same as that used in the Medicare+Choice regulations. The commenter believes that this will reduce the regulatory burden on managed care organizations that contract under both programs. The commenter recommends that the Medicaid final rule with comment period require that subcontractors comply with all applicable Medicaid laws, regulations, and our guidance.

Response: For the most part, the requirements contained in the Medicare regulations for subcontractors are reflected in the Medicaid regulatory language. However, in response to this comment, we have added a new provision at § 438.6(l) to require that all subcontracts fulfill the requirements of part 438 that are appropriate to the service or activity delegated under the subcontract.

Comment: One commenter suggested that the final rule with comment period address the obligation of States and MCOs to certain subcontractors, specifically Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs). They recommended that the rule reflect the statutory requirement that MCOs that enter into contracts with FQHCs and RHCs are required to provide payment that is not less than the level and amount of payment which would be made for services from a provider which is not an FQHC or RHC. These commenters also believed that the final rule with comment period should reflect the requirement that States directly compensate FQHCs and RHCs if they receive less compensation than that to which they are entitled. The commenters believe that an FQHC's or RHC's ability to provide high quality services, such as HIV services, in a managed care environment depends upon linkages with MCOs that include adequate compensation.

Response: The rules cited by the commenter are ''transitional'' in nature, as the payments provided for thereunder are to be phased out over the next several years. We do not believe it appropriate to promulgate regulations that will be obsolete in a relatively short period of time. Moreover, we do not believe regulations are necessary, as the statutory requirements are straightforward and self-implementing, and we have provided guidance to all States on FQHCs and RHCs, through State Medicaid Director Letters on April 21, 1998, October 23, 1998, and September 27, 2000. We will continue, as necessary, to clarify FQHC and RHC payment policies.

Comment: One commenter expressed the view that subcontractual relationships may not be advantageous between Indian Health Service (IHS) and tribally operated programs and MCOs, if they are only reimbursed at a capped rate that does not give them the ability to recoup the costs of providing services in reservation communities located in rural and isolated locations. However, the commenter believed that some contracts may be desirable in communities where a local relationship with an MCO provider provides a network of support services not available in the Indian health care system. Another commenter cited a Memorandum of Agreement between IHS and HCFA, and Federal legislation, which each provide that IHS is compensated at a special rate, and that tribally operated programs may also choose to be compensated at the IHS rate. Furthermore, services furnished by these entities are entitled to a 100 percent Federal matching rate. The first commenter requested that we require that IHS or tribal providers operating as subcontractors be allowed to bill States or their fiscal intermediaries directly for American Indian Medicaid beneficiaries. The second commenter recommended that IHS, tribal providers, and urban Indian clinics receive payment for services to IHS beneficiaries who are also Medicaid beneficiaries from States or their fiscal intermediaries directly and not be required to bill MCOs, regardless of whether the facility is a subcontractor or providing ''off-plan'' services.

Response: As also noted in section II. H. below, policies concerning IHS or tribal providers, the rates paid to such providers, or the Federal matching applicable to such providers, are unaffected by, and are outside the scope of, this rulemaking.

12. Practice Guidelines (Proposed § 438.336)

Proposed § 438.336 required that States ensure that each MCO and PHP develop or adopt and disseminate practice guidelines that met standards set forth in proposed § 438.336(a), which required that the guidelines: (1) Be based on reasonable medical evidence or a consensus of health care professionals; (2) consider the needs of MCO and PHP enrollees; (3) be developed in consultation with contracting health care professionals, and (4) be reviewed and updated periodically. MCOs and PHPs were required under proposed § 438.336(b) to disseminate the guidelines to providers and enrollees where appropriate, or when they request them. Proposed § 438.336(c) required that decisions with respect to utilization management, enrollee education, coverage of services, and other areas be consistent with the guidelines.

Comment: Several commenters requested clarification of the regulatory language requiring MCOs and PHPs to ''develop'' (or adopt) practice guidelines. One commenter assumed that § 438.336 did not require the development of ''new'' practice guidelines, but only that if practice guidelines currently exist, they should be disseminated according to the language in this section. Another commenter was unclear if the provision required MCOs to adopt guidelines, or required MCOs, if using practice guidelines, to use them in accordance with this section.

Other commenters requested that MCOs be allowed to ''develop'' their own practice guidelines instead of ''utilizing'' existing practice guidelines developed by governmental agencies. Some commenters believed that practice guidelines should not be required. These commenters believed a blanket requirement for practice guidelines in all disease management areas is unwise, as not all areas have developed guidelines. Also, the commenters noted that the Medicare+Choice regulations do not mandate the development of guidelines.

Response: We realize that the words ''develops'' and ''development'' were misleading in that they appeared to suggest that we were encouraging MCOs and PHPs to develop their own practice guidelines, instead of using those already established by expert panels. We have removed those words from § 438.236 of the final rule with comment period. Since a number of practice guidelines already exist for a variety of clinical areas, we do not specify how

many or which practice guidelines MCOs and PHPs must adopt. Rather, each MCO and each PHP will need to establish a process for identifying and reviewing guidelines that are relevant to the health conditions of its enrolled population and implement a process, in conjunction with its providers, for the adoption and implementation within the MCO or PHP. This is consistent with industry standards in the private sector. NCQA's 1999 accreditation standard QI8, ''Clinical Practice Guidelines,'' states, ''The MCO is accountable for adopting and disseminating practice guidelines for the provision of acute and chronic care services that are relevant to its enrolled membership.''

Comment: Multiple commenters recommended that the final rule with comment period specifically mention or require MCOs to use the following specified Federal Practice Guidelines: (1) Federal ''Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents,'' (2) Federal ''Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection,'' and (3) the ''USPHS/IDSA Guidelines for the Prevention of Opportunistic Infections in Persons with Human Immunodeficiency Virus,'' and update as appropriate.

Several commenters felt this section should be clearer and more specific to the unique health care needs of children, for example, specifically referencing the American Academy of Pediatrics (AAP) immunization guidelines.

One commenter believed that MCOs should be required to report on compliance with scientifically grounded clinical practice guidelines where they exist for persons with disabilities.

Response: Many evidence-based practice guidelines exist that would be beneficial for MCOs and PHPs to adopt as tools for improving the quality of health care provided to enrollees. Because of the growing number of such guidelines, the variation in the strength of the evidence base supporting these guidelines, and the need for ongoing review and updating of guidelines, we are reluctant to single out a subset of practice guidelines as superior to all others and preferentially require adherence to them in this regulation. We do, however, reference the Adult and Pediatric Guidelines for use of Antiretroviral Agents in Treatment of HIV Disease as examples of the type of guidelines that should be adopted. We did not specifically require that the guidelines be adopted due to the reasons stated above. However, we have referenced HIV guidelines in the text of § 438.236(b) as examples of guidelines that could be adopted consistent with this final rule with coment period, to reflect our strong belief that adherence to the HIV guidelines is essential to providing quality HIV care. We would continue to hold this position as long as the guidelines continue to meet the criteria in § 438.236(b). In addition to the guidelines referenced in the regulations text, we also strongly recommend that MCOs and PHPs adopt the following HIV guidelines if they continue to meet the criteria in § 438.336(b): USPHS/IDA Guidelines for Prevention of Opportunistic Infections in Persons Infected with HIV, Public Health Task Force Recommendations for the Use of Antiretroviral Drugs in Pregnant Women Infected with HIV–1 for Maternal Health and Reducing Perinatal HIV–1 Transmission in the United States, and US Public Health Service Recommendations for Human Immunodeficiency Virus Counseling and Voluntary Testing of Pregnant Women. We did not include references to any immunizations schedules, because current law requires State Medicaid agencies to provide all immunizations recommended by the Advisory Committee on Immunization Practices as part of the EPSDT program.

Comment: One commenter expressed the view that practice guidelines should take into consideration the needs of populations with special health care needs. One other commenter believed that a lack of medical evidence cannot be taken as a sign of a lack of efficacy. People with disabilities have limited access to clinical trials, and would suffer if practice guidelines based on clinical proof of efficacy were needed to ensure coverage. One commenter felt that guidelines should not be required to be based on ''reasonable medical evidence,'' because in some specialty areas, including mental health, there is not an established base of published clinical trial outcomes. The commenter also noted Federal case law, that requires the provision of appropriate treatment, even if the treatment is not supported by clinical studies.

Two commenters agreed that MCOs should use practice guidelines that are evidence-based and developed by clinicians with training and expertise in a field, but they believed that some guidelines are not developed in an empirical framework, and if implemented, could jeopardize both children's access to and types of treatments received.

One commenter agreed that practice guidelines can be helpful, but found that the area of mental health has not developed sufficient guidelines for all courses of treatment. The commenter believed that use of guidelines in the area of mental health may result in the denial of treatment as new treatment methods are developed.

Response: Some commenters have interpreted the regulation as requiring practice guidelines to be based on clinical trials, and were concerned about the potential lack of clinical trials including populations with special health care needs. In fact, this regulation does not require the use of practice guidelines for all conditions, or restrict the use of guidelines to those based on clinical trials. Section 438.236(b)(1) of the final rule with comment period requires that the guidelines be based on ''reasonable clinical evidence or a consensus of health care professionals in the particular field,'' which does not necessitate that a clinical trial have been conducted; for example, guidelines for Perinatal Care, developed by the American Academy of Pediatrics and the American College of Obstetricians and Gynecologists.

The commenters are also concerned over the lack of practice guidelines for some conditions, such as mental health, and fear that treatment may be denied. The regulation does not specify the number of practice guidelines that must be adopted, nor does it mandate for which conditions practice guidelines must be developed. The lack of practice guidelines for a particular condition does not provide a basis for an MCO or PHP to fail to treat conditions for which there is no guidance.

Comment: Two commenters suggested that we only permit practice guidelines developed by licensed health care providers in a particular field. Another commenter wanted to give greater weight to the requirements that guidelines based on ''reasonable medical evidence or a consensus of health care professionals in the particular field (§ 438.336(a)(1)),'' and that they ''consider the needs of the MCO's enrollees (§ 438.336(a)(2))'' than the requirement that they be developed ''in consultation with contracting health care professionals (§ 438.336(a)(3)).'' The commenter believed that guidelines developed in accordance with § 438.336(a)(3) could lead to ''garden variety'' practice guidelines. One commenter believed that professional specialty organizations have adopted many national standards and practice guidelines that should be used.

Response: Because there is variation in the evidence base that supports all medical interventions, we believe we must be flexible and accept the use of guidelines developed both by clinical evidence or a consensus of health care professionals in the particular field. We

have replaced the word ''reasonable'' with the words ''valid and reliable'' to better describe the type of clinical evidence that should serve as a basis for practice guidelines that MCOs and PHPs are to adopt. The language we have used in the proposed rule and final rule with comment period at § 438.236 is consistent with industry standards.

Comment: One commenter suggested that practice guidelines be based on reasonable ''clinical'' evidence instead of reasonable ''medical'' evidence. Two commenters believe that if medical evidence does not exist, it may be due to the rarity of the disease, inadequate research infrastructure, or the fact that people with disabilities do not have as much access to clinical trials.

Response: We agree with the commenters. The term ''medical'' typically refers to actions and treatments related to physician practices, while ''clinical'' extends to health care researchers, as well as other health care providers, such as dentists, pharmacists, and nurses. Because of this, in response to this comment, we have substituted ''clinical'' for ''medical'' in § 438.236(b)(1). By replacing ''medical'' with the broader term, ''clinical,'' we are also being more consistent with the following examples. The Institute of Medicine (IOM) discusses practice guidelines in the context of ''clinical practice.'' For example, ''Practice guidelines must include statements about when they should be reviewed to determine whether revisions are warranted, given new clinical evidence or professional consensus (or the lack of it).'' The IOM also points out that two of the key attributes of practice guidelines include ''clinical applicability'' and ''clinical flexibility.''

One source of clinical practice guidelines on a variety of topics and that can help interested parties compare different practice guidelines on the same topic is the Agency for Healthcare Research and Quality's (AHRQ) National Guideline Clearinghouse, available at www.AHRQ.gov.

Comment: One commenter believed that MCOs should be required to report on compliance with scientifically grounded clinical practice guidelines where they exist for persons with disabilities. The same commenter also believed that the regulation should require that the amount, duration, and scope of coverage for covered benefits be reasonably sufficient to achieve the purpose of the service.

Response: We have decided not to require reporting on, or State monitoring of, compliance with the guidelines adopted by each MCO and PHP due to excessive cost and administrative burdens. Instead we have chosen to emphasize the adoption and dissemination of evidence-based and widely accepted practice guidelines by MCOs and PHPs to their providers. We also believe that compliance with those practice guidelines adopted by States and MCOs and PHPs can be monitored through the quality assessment and performance improvement project requirements in § 438.240.

The commenter's second concern about the amount, duration, and scope of coverage for covered benefits was addressed in the response to comments on § 438.310.

Comment: One commenter believed that MCOs need to require their providers to use practice guidelines through a MOA or linkage agreements.

Response: We do not believe it is appropriate for the regulation to specify how MCOs and PHPs are to promote adherence to the guidelines by their contracted providers. We note that the state-of-the-art of information dissemination, technology transfer, and changing provider practice patterns is complex and continues to be the subject of much study.

Comment: One commenter believed that decisions about medical care should be based on medical necessity and medical judgement, and that these may not in individual cases, be consistent with the guidelines. Several commenters stated that practice guidelines are guidelines only, and should not restrict access and should be consistent with individual needs.

Many commenters expressed a concern that no requirement exists requiring individual coverage decisions to conform to government practice and care guidelines, especially in the area of HIV/AIDS treatment.

One commenter expressed a concern regarding how MCOs contracting with Medicaid will apply EPSDT standards and guidelines to children being served, and specifically to children with special health care needs.

Response: Our intent is not to substitute practice guidelines for professional judgement in the care of individuals. Practice guidelines are guidelines, not mandates, and should be applied consistent with the needs of the individual.

Comment: One commenter expressed a concern that MCOs will not reimburse subcontractors for services that are not recognized as medically necessary, or not consistent with nationally recognized practice guidelines.

Response: As noted above, there are many evidence-based practice guidelines that would be helpful to MCOs and PHPs in undertaking efforts to improve the quality of health care provided to enrollees. However, we are not prescribing a uniform set of guidelines that must be used, or specifying that guidelines must be used whenever they are available. Rather, we are requiring that MCOs and PHPs consider relevant guidelines and choose those they find appropriate. Because it is not practical for an MCO or PHP to focus its quality assessment and improvement efforts simultaneously on all areas for which there are practice guidelines, it is not our expectation that MCOs and PHPs will adopt practice guidelines for all areas of treatment.

For those clinical areas for which an MCO or PHP has adopted a clinical practice guideline, if an enrollee requests services that contradict the practice guideline, the MCO or PHP may have grounds for withholding the services or refusing to pay for the service. Similarly, if an MCO or PHP found a requested service not to be medically necessary, the MCO or PHP would have grounds for withholding the service or refusing to pay for the service. However, there are two means of recourse for beneficiaries who believe that they have been inappropriately denied a service based on a practice guideline. First, the enrollee may appeal the denial of services on an individual basis. Second, the enrollee may request that the Medicaid agency review the guideline to see that it meets the regulation requirements that guidelines be evidence-based and up-to-date. We believe this will protect enrollees from the misuse of practice guidelines.

Comment: One commenter believed that guidelines should also be disseminated to enrollee representative, advocates, and the general public. Several commenters agree that enrollees, as well as the public, should have a right to obtain a copy of the practice guidelines.

In contrast, many other commenters voiced concern over the dissemination of guidelines to anyone other than appropriate providers. Some stated that the dissemination of guidelines intrudes on the practice of medicine and exceeds BBA requirements. One commenter believed that the administrative effort and expense would be too high if guidelines were to be disseminated ''as appropriate.'' Two commenters were unclear about the meaning of ''as appropriate.'' One commenter stated that disclosure of practice guidelines to enrollees may present problems around inclusion of proprietary information directly related to the conduct of business between providers and the MCO. Two commenters question the

value/usefulness of guidelines being disseminated to individual enrollees, as the information may be too confusing for them to comprehend. Finally, several commenters agree that guidelines should be disseminated to practitioners, but not to enrollees. These commenters believed the provider could give the guidelines to the enrollee as part of a treatment plan.

One commenter feared that the requirement to disseminate guidelines to all providers may result in MCOs collecting or creating guidelines in cases where medical outcomes are uncertain, expert preferences are mixed, or no justification is needed when following a treatment option. Another commenter believed that guidelines should only be disseminated to providers affected by the guidelines.

Response: Concerns over the dissemination of practice guidelines fell into two opposing views. Some commenters believed that guidelines should be available not only to enrollees, but also to enrollee representatives, advocates, and the general public. Other commenters believed that the current dissemination language is too broad, and that it would create a burden on MCOs to have to disseminate guidelines to all providers and all enrollees. Others were simply unclear as to what the words disseminate ''as appropriate'' entailed. We believe that guidelines should be disseminated to all providers who are likely to deliver the type of care that is the subject of the guideline (e.g. an MCO need not disseminate guidelines on childhood immunizations to its adult specialty surgeons). We also believe that enrollees with particular health concerns; e.g., asthma, may reasonably want to know if an MCO or PHP has adopted any particular guidelines on asthma care (such as those promulgated by the National Institutes of Health), and if so, would want to receive a copy of the guidelines. To clarify this section, and the intentions of the regulatory language regarding dissemination, we are revising the regulation at § 438.236(c)to read as follows: ''Each MCO and PHP disseminates the guidelines to all affected providers, and upon request to enrollees and potential enrollees.''

13. Quality Assessment and Performance Improvement Program (Proposed § 438.340)

Proposed § 438.340 required each MCO and PHP that contracts with a State Medicaid agency to have an ongoing quality assessment and performance improvement program, and specified the basic elements of such a MCO and PHP program. Under proposed § 438.340(b), MCOs and PHPs were required to: (1) Achieve minimum performance levels on standardized quality measures, using standard measures required by the State; (2) conduct performance improvement projects; and (3) have in effect mechanisms to detect both underutilization and overutilization of services. Proposed § 438.340(c) provides for minimum MCO and PHP performance levels to be established by the State. Proposed § 438.340(d) established criteria for performance improvement projects, requiring, among other things: (1) the State to establish contractual obligations for the number and distribution of projects among specified clinical and non clinical areas; and to specify certain non clinical focus areas to be addressed by performance improvement projects; (2) that each MCO and each PHP assess its performance for each project based on systematic, ongoing collection, and analysis off valid and reliable data on one or more quality indicators; (3) that each MCO's and each PHP's interventions result in improvement that is significant and sustained over time; and (4) that each MCO and each PHP report the status and results of each project to the State agency as requested. Proposed § 438.340(e) required the State to review, at least annually, the impact and effectiveness of each MCO's and each PHP's quality assessment and performance improvement program; and authorized the State agency to require each MCO and each PHP to have in effect a process for its own evaluation of the impact and effectiveness of its quality assessment and performance improvement program.

Comment: Several commenters believed that States could be faced with the loss of FFP when MCOs fail to achieve minimum performance levels, since meeting these levels is a requirement under proposed § 438.340(b)(1), and section 1903(m) of the Act requires that requirements under section 1932 of the Act be met as a condition for FFP. These commenters believed that this would give States an incentive to set performance levels that are low enough to be easily achieved. The commenters felt that the States needed the flexibility to make exceptions for MCOs and providers with high-risk patient caseloads.

Response: We would not expect to deny FFP to any State that establishes a Quality Assessment and Performance Improvement Program that meets the requirements in the regulations, even if an individual MCO or PHP might not achieve required performance levels in a single instance. Therefore, we do not agree that States will establish low minimum performance levels because of fear of loss of FFP. States are responsible for judging MCO and PHP performance in meeting the levels. We intend that the minimum performance levels be set at levels that can realistically be achieved. We require States to consider data and trends in managed care and fee-for-service in setting the levels. This is key to the process of quality improvement that we establish in this regulation.

Comment: One commenter believed that phase-in of full compliance with the imposed standards, and ongoing improvement over time should be allowed.

Response: As stated above, we believe that these regulations allow for flexibility. We believe that all MCOs and PHPs should be responsible for measuring their performance using standard measures set by the State, meet State-established minimum performance levels and conduct performance improvement projects. These are basic elements of a quality improvement program.

Comment: Several commenters were concerned that the proposed rule did not expressly require States to study care across the spectrum of enrolled populations, or to establish minimum quality measures relevant to all enrollees.

Response: For performance improvement projects, the regulation specifies four clinical areas that must be addressed over time. We intend that these areas (that is, prevention and care of acute and chronic conditions, high-volume services, high-risk services, and continuity and coordination of care) to apply to all enrolled populations. We do not specify that States must use measures of performance that address all conditions affecting all enrollees, because the state-of-the-art and limitations on resources do not allow this. However, in response to this comment, and other comments discussed in section II. C. above, we have added a provision at § 438.240(c)(2)(ii)(A) that permits us to specify standardized quality measures to be used by MCOs and PHPs. This provides us with the opportunity to specify measures for subpopulations of Medicaid enrollees and we could use this authority if a State failed to address certain subpopulations of enrollees. In addition, also in response to this and other comments, we have added at § 438.240(b)(4) a requirement that MCOs and PHPs must have in effect mechanisms to assess the quality and

appropriateness of care furnished to enrollees with special health care needs.

Comment: Several commenters believed that minimum performance levels should not be set below established compliance levels, for example in EPSDT, even if the State/MCOs are well below these standards at present.

Response: While we permit States to set minimum performance levels for their MCOs and PHPs, this authority does not diminish the responsibility of States to meet performance levels established by law, such as conducting EPSDT screening and providing EPSDT services.

Comment: Several commenters believed that the Federal government should develop over time performance measures, and set minimum performance levels, based on an aggregation of data submitted by the MCOs.

Response: We agree with this comment. In the final rule with comment period, in response to this comment and other comments discussed in section II. C. above, we have added a provision (§ 438.204(c)) that requires States to include among their strategies, performance measures and levels prescribed by us. This does not reduce the State's authority to set minimum levels for MCOs and PHPs. We expect that States will pass on to MCOs and PHPs responsibility to meet Federally-established performance levels in order for the States to meet their own targets.

Comment: One commenter read proposed § 438.340(c)(2)(i) to imply that States cannot impose standards on MCOs in addition to those specifically allowed by this regulation. The commenter also believed that proposed § 438.340(c)(6), which allows States to require the MCO to undertake performance projects specific to the MCO, and to participate annually in statewide performance improvement projects, could be read to prevent the State from being able to go further. The commenter suggested deleting §§ 438.340(c)(2)(i) and (c)(6).

Response: Section 438.240(c)(2)(i) of the final rule with comment period permits States to choose how many performance measures and performance measurement projects to require from their MCOs and PHPs. It sets as a minimum requirement that MCOs and PHPs measure, report to the State, and conduct performance improvement projects (PIPs). This regulation does not prohibit a State from imposing standards in addition to those specifically provided for in the regulation. Neither does it prohibit the State from imposing a greater number or diversity of performance improvement projects specific to a given MCO or PHP or on a statewide basis.

Comment: One commenter believed that the level of detail for quality assessment and performance improvement left little flexibility for States to accommodate the special needs of newly formed MCOs that may have limited resources and experience with such activities required during their initial contract period.

Response: States have considerable flexibility in determining how many projects an MCO or PHP must conduct, the areas to be addressed by the projects, the scope of the projects, and the amount of improvement expected. We believe this latitude is sufficient for States to address the circumstances of new MCOs or PHPs and those with fewer resources than others.

Comment: Several commenters were concerned that prospectively determined, quantifiable quality improvement goals could be difficult for MCOs and PHPs to achieve, as they do not control all factors impacting such improvement. They believed that circumstances outside the control of the MCO could make it difficult or impossible to complete a study and collect clean data. These commenters felt that States needed flexibility to accommodate these problems appropriately, without facing sanctions, when noncompliance occurs as a result of factors beyond the control of the MCO.

Response: As stated in the responses to several comments above, we believe these regulations provide States with considerable flexibility to set requirements for their MCOs and PHPs. States also have flexibility in deciding when sanctions should be imposed on MCOs and PHPs. Also, while we agree that some factors that affect quality improvement may be outside of the MCO's or PHP's control, we believe that many factors are within the control of MCOs or PHPs, and that MCOs and PHPs should be held accountable for quality improvement.

Comment: Several commenters believed that we should require States to allow MCOs sufficient time to implement programs and systems. They were concerned about the total administrative burden being imposed by the proposed rule (for example, the requirement that MCOs maintain health information systems that collect, analyze, integrate, and report necessary data).

Response: We do not agree that States should be able to postpone the Quality Assessment and Performance Improvement (QAPI) provisions to give MCOs or PHPs the time to develop programs and systems. MCOs and PHPs now have the responsibility to monitor care, and to do this requires that they have programs and data that can be used to measure their performance.

Comment: One commenter did not believe new requirements on MCOs should be imposed unless specific additional funding covering the costs of such requirements is made available.

Response: In this final rule with comment period we are replacing the upper payment limit on payments to MCOs and PHPs with a different mechanism to contain managed care costs. This new method will allow for additional costs to be considered in setting capitation rates including the costs of complying with QAPI requirements.

Comment: Another commenter wanted us to review existing QI projects that MCOs are conducting as part of HEDIS reporting and NCQA accreditation, so as not to duplicate measures and increase administrative costs.

Response: The relationship in Medicaid is between the State and the MCO or PHP, not between us and the MCO or PHP. In establishing these requirements, nothing in the regulation prohibits States from considering other QI projects their MCOs are conducting, and we would encourage States to do so.

Comment: Several commenters believed that State agencies should consider historical MCO and FFS Medicaid performance data and trends to determine the appropriateness of quality measures. They also believed that performance levels adopted by States should be reasonably attainable. They asked that the following preamble language be inserted into the regulation text, ''In establishing minimum performance levels, the State agency should ensure that the targets are achievable, meaningful, and equitable. The State agency must consider historical plan and FFS Medicaid performance data and trends.''

Response: Section 438.240(c)(2)(ii)(B) of the final rule with comment period provides that States should ''consider data and trends for both the MCOs and PHPs and fee-for-service Medicaid in that State,'' in setting minimum performance levels. This addresses the issues of achievability and equity.

Comment: Several commenters believed that a predefined percentage, like QISMC's standard of a 10 percent reduction in deficient care, would stifle creative approaches to QI. They also object to the 10 percent standard because it is inconsistent with NCQA's

''meaningful'' standard for improvement, based on effort. The same commenters also believed that the 10 percent standard could cause MCO not to pursue QI projects for which a 10 percent reduction was difficult to predict. The commenters would like to see the defined percentages removed from the preamble, and in its place have NCQA's ''meaningful'' improvement standard inserted.

Response: The 10 percent reduction rule from QISMC is in the preamble as an example only and is not a requirement. However, we believe that the true test of quality improvement is measurable improvement. This requires that a numeric benchmark or percentage improvement goal be in place. Therefore, we do not agree that a standard of ''meaningful'' improvement is sufficient. The regulation does not require the use of the 10 percent reduction standard. States have the discretion to establish specific numeric, objective improvement levels themselves.

Comments: Many commenters believed that without specific instructions from us, stating that MCOs must identify and monitor care delivered to populations with special health care needs enrolled in an MCO, it is unlikely that results from QAPI will reflect the experiences of these groups. They also believed that HEDIS for Medicaid does not include many measures specific to children or adults with special health care needs. The commenters would like to see specific quality assurance activities and outcome measures, focusing on the various populations with special health care needs, to be developed in conjunction with advocates and experienced providers in these areas.

Response: We agree that populations with special health care needs should not be left out of MCO and PHP quality assessment and performance improvement activities. Section 438.240(d)(2) of the final rule with comment period requires that performance measurement and quality improvement projects address the entire Medicaid enrolled population in an MCO or PHP to whom the measure is relevant. The regulation also requires that all enrolled populations be measured over time. As discussed above, we have added provisions permitting the Secretary to specify annual quality measures and performance improvement project topics for MCOs and PHPs. Through this mechanism, we have the authority to direct States, MCOs, and PHPs to address subgroups of enrollees should the States fail to do so. To make explicit the requirement that populations with special health care be included in MCO and PHP quality assessment and performance improvement activities, we have added a new item at § 438.240(b)(4) requiring that MCOs and PHPs have in effect mechanisms to assess the quality and appropriateness of care furnished to enrollees with special health care needs. We note however that more effective and plentiful quality indicators to measure the quality of care delivered to individuals with special health care needs are still needed.

Comment: One commenter believed that in addition to reporting performance measures, States or medical auditors should also target and access medical records to study overall treatment of specified conditions and adherence with treatment protocols.

Response: We do not agree that we should require States (in addition to using performance measures and quality assessment and performance improvement projects) to separately review medical records to study overall treatment of specific conditions and monitor the use of treatment protocols. While States are free to undertake this activity, we believe that the elements of State quality assessment and performance improvement strategy will be sufficient to monitor health care quality (including adherence to treatment protocols).

Comment: One commenter favored outcomes measured through both process indicators and ''quality of life'' indicators.

Response: The term performance measure, as we are using it, provides the option for States to use process and outcome measures, including quality of life indicators.

Comment: A commenter recommended a requirement that HEDIS be the standardized tool for QAPI, instead of leaving this up to States.

Response: We believe that the choice of performance measures and measurement tools should be left to the discretion of individual States. Many States now use a number of HEDIS measures; however, we note that HEDIS as a measurement set has limitations and may not serve the complete needs of States or fully address the Medicaid population.

Comment: A commenter believed that the statement, ''projects are representative of the entire spectrum of clinical and non-clinical areas,'' should be qualified so that projects are not required to cover the entire spectrum every year, but should focus on one area each year, as long as the subject varies over time.

Response: The proposed rule did not, and the final rule with comment period does not, require that all areas be addressed each year. States may specify the number of projects its MCOs and PHPs must conduct, and the requirement would be met if the State requires only one project. We have clarified the final rule with comment period to state at § 438.240(d)(3) that States must require each MCO and each PHP or more to initiate one or more performance improvement projects per year.

Comment: One commenter asked if a successful NCQA review would be acceptable in lieu of the required yearly audit, since this would save administrative efforts and expense.

Response: As discussed above in section II. C., while section 1932(c)(2) of the Act provides for external quality review (EQR) requirements to be met based on other accreditations, there is no such authority for the requirements under section 1932(c)(1) of the Act (as is the case with respect to similar requirements under the Medicare+Choice program).

Comment: A commenter was concerned about the fact that many subpopulations served by an MCO were small in number, and believed it may be difficult to produce any meaningful results for quality assurance and performance measurement. The commenter asked if aggregate results of a performance project across several MCOs of a national company would be acceptable.

Response: States are accountable for the quality of care for their Medicaid beneficiaries, and must be permitted to set the requirements for the MCOs and PHPs with which they contract. Therefore, we will not modify the regulation to permit MCOs or PHPs to aggregate data across States.

Comment: Several commenters wanted States to publish performance measurement tools and results of assessments. The commenters were concerned that no requirement exists that requires MCOs to provide information about quality assurance programs to enrollees and potential enrollees in Medicaid.

Response: While we have not provided in this final rule with comment period for the provision of information on MCO or PHP quality measures, this will be provided for in the final EQR regulation, as it is required under section 1932(c)(2)(A)(iv) of the Act.

Comment: Several commenters believed that self-reported quality measures should be subject to external validation by the State, and that State-

defined measures and performance improvement projects should be required to use audited data.

Response: This type of external review is provided for in section 1932(c)(2) of the Act, which is being implemented in a separate rulemaking.

Comment: Some commenters did not believe that the use of the word benchmark in the preamble discussion of proposed § 438.340(d)(9) was clear. Yet they believed that benchmarking is one of the key terms for QI, and needs to be expanded in the final rule with comment period.

Response: We agree that the term ''benchmarks'' can have many connotations, and have deleted it from the final rule with comment period.

Comment: A commenter requested that we include a definition of ''high-volume'' or ''high-risk'' services. The commenter believed this should be defined to require the review of mental health services, and did not believe that mental health services would be considered high-volume or high-risk without these services being expressly included in the definition.

Response: We have chosen not to define ''high-volume'' or ''high-risk'' services, as they differ relative to individual MCOs or PHPs and the populations they serve. For example a PHP behavioral health carve-out would only include mental health services. We believe States are in the best position to define this for their MCOs and PHPs.

Comment: One commenter urged that cultural competence be included as a nonclinical area of performance measurement in the regulation.

Response: We agree that cultural competence is a nonclinical area that may be a topic of a performance improvement project. In response to this comment, in § 438.240(d)(5)(iii) of the final rule with comment period, we have added ''cultural competence'' as a non-clinical area.

Comment: Several commenters asked that we establish a process for detailed discussions with MCOs to better understand the operational issues associated with implementing the proposed standards of the regulation. Two of the commenters desired discussions with us to define short- and long-term goals for Medicaid managed care quality oversight and to arrive at a focused strategy. For example, they believed that HEDIS was undermined by the ability of States to establish an independent system of quality improvement strategies.

Response: We are working to provide technical assistance tools to the States. In turn, the States will be able to work with MCOs and PHPs, and MCOs and PHPs will have an opportunity to provide public input to the quality strategy in their respective State.

Comment: A commenter believed that more ''horizontal'' lines of communication regarding performance improvement and measurement needed to occur, in addition to the current ''vertical'' lines of communication between the States, MCOs, and HCFA. For example, they would like to see communication take place across MCOs and across State agencies.

Response: We agree that communication across organizational components is of considerable value, and this function is currently addressed through membership organizations, such as the American Public Human Services Association (APHSA). These organizations can assist with the exchange and gathering of information through conferences and publications.

14. Health Information Systems (Proposed § 438.342)

Section 1932(c)(1)(iii) of the Act requires States that contract with Medicaid managed care organizations to develop a State quality assessment and improvement strategy that includes procedures for monitoring and evaluating the quality and appropriateness of care and services to enrollees that reflect the full spectrum of the population enrolled under the contract, and that includes requirements for provision of quality assurance data to the State, by MCOs using the data and information set that the Secretary has specified for use under the Medicare+Choice program, or such alternative data as the Secretary approves, in consultation with the State.

In proposed § 438.342, we provided that the State ensure that each MCO and PHP maintain a health information system that collects, analyzes, integrates, and reports data that can achieve the objectives of this part. Under the proposed rule, we specified that the system should provide information on areas including, but not limited to, utilization, grievances, disenrollments and solvency. Furthermore, we proposed that the State ensure through its contracts with MCOs and PHPs that each MCO and PHP be required to: (1) Collect data on enrollee and provider characteristics, as specified by the State, and on services furnished to enrollees; (2) ensure that the data received from providers are accurate and complete by verifying the accuracy and timeliness of reported data, screening the data for completeness, logic and consistency, and by collecting service information in standardized formats to the extent feasible and appropriate; and (3) make available all collected data to the State and HCFA. An MCO or PHP was permitted to use any method or procedure for data collection, so long as it could demonstrate that its system achieves the objectives of this standard.

Comment: Several commenters believed that the regulation should specifically require appropriate acquisition of data by MCOs concerning race, ethnicity, sex, age, disability, and primary language. These commenters believed that without the collection of such data, compliance and enforcement with civil rights laws including Title VI and the ADA would be difficult.

Response: All of the above, with the exception of age and sex, are explicitly addressed in this final rule with comment period. Information on disability will be captured through the initial and ongoing assessment provisions of § 438.208. Primary language spoken is addressed in the language requirement of § 438.10(b). As discussed previously, race and ethnicity are addressed in § 438.204(b)(1)(iii). However, sex and age are fundamental pieces of demographic information that are essential if MCOs and PHPS are to be able to comply with the information system requirements in § 438.242. Age and sex are such routinely collected demographic information, that we do not believe it necessary to expressly mandate their collection in the regulation.

Comment: Several commenters urged that the timing and costs associated with implementing the regulations be evaluated. These commenters suggested that we allow more time to comply with the regulation, because of millennium activities that are utilizing the majority of State and MCO resources. Several other commenters questioned how funding for this activity would occur, as they did not believe they had the resources to meet the requirements.

Response: Given the passage of time since January 1, 2000, ''Y2K'' activities should no longer be utilizing State systems resources. We will work with States to assist them in implementation of this final rule with comment period. As for the funding for implementing the requirements, new Medicaid State agency system development design and implementation is funded at 90 percent and maintenance to existing systems is matched at 50 percent.

Comment: Several commenters questioned the logic of including solvency information in the same system as enrollee-specific data such as utilization, grievances and disenrollments. These commenters did not believe solvency information should

be included as a mandatory element of a health information system. The commenters believed that a State's current standards for reporting and format should be sufficient.

Response: We agree that this is not the appropriate place to capture solvency information. In response to this comment, we have removed the reference to solvency from § 438.342(a).

Comment: Several commenters found the requirement that MCOs make all collected data available to both the State and HCFA excessive and redundant since the State must also submit data to us. The commenters noted that it is the MCO's business to manage their population and to report required data to the State. Duplicative reporting requirements could increase the administrative expenses of MCOs, and make contracts with State Medicaid programs less attractive to commercial HMOs.

Response: We agree that it is burdensome to request all information to be sent to both the State and to HCFA. In response to this comment we have provided in § 438.242(b)(3) of this final rule with comment period that MCOs and PHPs make all collected data available to the State as required in subpart D, and to us upon request.

Comment: Several commenters recommended that we establish national data collection standards for States to use for the collection of encounter data, EPSDT, and network information. These commenters specified that these standards should be based on current data elements that could be systematically produced by providers, and captured by MCOs and PHPs.

Response: We desire to have consistency of information, and to have national standards in those cases where it makes sense to do so. However, we must also balance that desire with providing States with the necessary flexibility to implement their individual Medicaid programs. We are working on several initiatives to standardize data collection on a national level. The Health Insurance Portability and Accountability Act (HIPAA) requires us to work toward the goals recommended by several of the commenters.

E. Grievance Systems (Subpart F)

Background

Proposed subpart F was based on section 1902(a)(3) of the Act (requires a State plan to provide an opportunity for a fair hearing to any person whose request for assistance is denied or not acted upon promptly), section 1902(a)(4) of the Act (authorizes the Secretary to specify methods of administration that are ''necessary'' for ''proper and efficient administration''), and section 1932(b)(4) of the Act (requires that MCOs have an internal grievance procedure under that a Medicaid enrollee, or a provider on behalf of an enrollee, may challenge the denial of coverage of or payment by the MCO).

In this subpart, we proposed regulations that lay out the required elements of the grievance system required under section 1932(b)(4) of the Act, and how it interfaces with the State fair hearing requirements in section 1902(a)(3) of the Act; describing what constitutes a notice (that is, the first step in the grievance system); addressing complaints and grievances, including timeframes for taking action; the process for actions; how grievances are to be handled; and how enrollees are to be notified of the resolution of grievances. In addition, the proposed rule provided for expedited resolution of grievances and appeals in specific circumstances; addressed the requirement for continuation of benefits; included the requirement that MCOs and PHPs clearly and fully inform enrollees of the entire system so that they are aware of it and how to use it; specified what materials must be provided when notifying an enrollee, and the requirements for those materials; and lay out the requirements relating to record keeping, monitoring, and the consequences of noncompliance.

1. Statutory Basis and Definitions (Proposed § 438.400)

Definitions of terms that would apply for purposes of proposed subpart F are found in § 438.400 of the proposed rule, in that the following terms have the indicated meanings:

Complaint was defined as any oral or written communication made by or on behalf of an enrollee to any employee of either the MCO, PHP, its providers, or to the State, expressing dissatisfaction with any aspect of the MCO's, PHP's, or provider's operations, activities, or behavior, regardless of whether the communication requests any remedial action.

Enrollee was defined for purposes of subpart F, as an enrollee or their authorized representative.

Governing body was defined as the MCO's or PHP's Board of Directors, or a designated committee of its senior management.

Grievance was defined as a written communication, submitted by or on behalf of a Medicaid enrollee expressing dissatisfaction with any aspect of the MCO's, PHP's, or providers's operations, activities, or behavior that pertains to the following: (1) The availability, delivery, or quality of health care services, including utilization review decisions that are adverse to the enrollee; (2) payment, treatment, or reimbursement of claims for health care services; or (3) issues unresolved through the complaint process provided for under the proposed rule.

Comment: Some commenters questioned HCFA's statutory authority to promulgate the detailed requirements in proposed subpart F, given the limited amount of text in section 1932(b)(4) of the Act.

Response: As noted above, these rules are based only in part on section 1932(b)(4) of the Act. We believe that those portions of subpart F that address an MCO's internal grievance system constitute a reasonable implementation of authority under section 1932(b)(4) of the Act. This rule is also based on our general authority under section 1902(a)(4) of the Act, and on the State fair hearing requirements in section 1902(a)(3) of the Act, that prior to this final rule with comment period have not been implemented in regulations that apply to managed care enrollees. We believe that the requirements in subpart F of this final rule with comment period are warranted in order to ensure that MCOs have an effective and useful internal grievance process, as required under section 1932(b)(4) of the Act, and in order to ensure that MCO and PHP enrollees have access to the same State fair hearing process that fee-for-service enrollees have under subpart E of part 431. This final rule with comment period applies the general rights in section 1902(a)(3) of the Act to managed care enrollees both in MCOs and PHPs. In the case of PHPs, the requirements in subpart F are based both on section 1902(a)(3)of the Act and, in the case of longstanding PHP regulations, they are generally on our broad authority under section 1902(a)(4) of the Act to specify methods necessary for proper and efficient administration. In the case of MCOs, we are also implementing the requirements in section 1932(a)(4) of the Act, and setting forth what we believe is necessary to adequately meet these requirements as we have interpreted them. The analysis of key court decisions has also guided the development of these final regulations, just as the Supreme Court's *Goldberg* v. *Kelly* decision was incorporated in the State fair hearing regulations under part 431, subpart E to which the MCO and PHP grievance system is linked.

Comment: Some commenters believed that while we took case law into account in proposed subpart F, HCFA did not go far enough to protect

Medicaid managed care enrollees' rights in the following three areas: (1) Continuation of benefits; (2) direct access to State fair hearings; and (3) time frames for action.

Response: We have carefully considered all comments on these three issues and address each issue below in the context of our discussion of regulation language that pertains to the issue. In general, we recognize that we have a responsibility to protect Medicaid enrollees and ensure their rights. To meet this responsibility, we have established a set of Federal protections that apply to Medicaid enrollees regardless of their State of residence. This will ensure a minimum degree of consistency with the level of protection afforded Medicare beneficiaries. States may choose to add to these protections by exceeding the minimum levels required by this regulation.

In developing these regulations, we relied heavily on the Consumer Bill of Rights and Responsibility (CBRR). We also examined the grievance procedures of many States, and considered all comments on these issues. We have carefully documented, tracked, and analyzed each decision we have made with respect to our consideration of commenters' suggestions in light of the guiding principles in the CBRR.

Comment: We received comments that suggested that we specify a different grievance process for enrollees with addiction or mental health issues or, at a minimum, make specific mention of these concerns in the regulation, and adopt the principles of the Model Managed Care Consumer Protection Act proposed by the President's Commission on Model State Drug Laws. Under this Act, the patient, family, or program must be permitted to appeal directly outside the MCO or PHP. These commenters also suggested that there be a separate office responsible for the addiction and mental health grievance process and to advocate for patients and families.

Response: We do not agree that there should be separate grievance processes, procedural requirements, or offices based on diagnosis-specific or population-specific criteria. The grievance system set forth in this regulation is designed to address the needs of all Medicaid enrollees, including those with special health care needs. PHPs providing mental health or substance abuse services are also subject to these provisions, that we believe adequately protect individuals with these conditions.

Comment: Many commenters strongly recommended that we eliminate the ''complaint'' category set forth in the proposed rule, while others supported the broad definition of ''complaint'' as separate from ''grievances'' subject to a State fair hearing, but recommended changes to better distinguish these categories. The comments advocating the elimination of a separate complaint category are first presented below followed by the comments supporting retention of the two categories but recommending changes related to these categories.

In support of eliminating separate categories, one commenter contended that it has been well documented that Medicare+Choice organizations misidentify what should be appeals under the Medicare+Choice appeals system as ''grievances,'' are not subject to external administrative and judicial review under that system. The commenter believed that HCFA should eliminate the ''complaint'' level, because the commenter saw it as the equivalent of ''grievances'' under Medicare+Choice, and in order to avoid confusion and prevent the potential mishandling of appeals. One commenter noted that under the proposed rule, an MCO or PHP could fail to acknowledge an appeal and provide the required notice to enrollees simply because the enrollees failed to ''use the magic words'' when filing their dispute.

Another commenter believed that because the NPRM does not require that complaints be monitored and tracked as closely as grievances, MCOs and PHPs have an incentive to categorize a dispute as a complaint. The commenter stated that this could benefit the MCO or PHP because complaints would not be reflected in the MCO's or PHP's performance ratings, and MCOs and PHPs should not be given the authority to decide whether an issue is a complaint or grievance.

Another commenter expressed the view that a complaint process does not protect the enrollee and, therefore, should be deleted from the regulation. This commenter believed that MCOs and PHPs would be able to resolve complaints on a more informal basis through the customer service department, while enrollees' rights to a formal appealable grievance would remain.

One commenter noted that many States have a single definition for a ''grievance'' in order to avoid confusion for MCOs, PHPs and enrollees. The commenter felt that this simplifies reporting and facilitates the resolution of a complaint. One commenter said that all issues should be tracked as grievances whether submitted orally or in writing. Another said that enrollees should be able to address any problem that they have with the MCO, PHP, or a provider without getting trapped or confused by a labeling and tracking process. Several commenters said the documentation of all complaints as well as grievances should be required.

A commenter felt that allowing both an informal complaint and a formal grievance process has led to confusion of enrollees, MCOs and PHPs, as well as to inappropriate transfers and unnecessary delays. This commenter believed that there have been many instances of MCOs and PHPs re-classifying grievances as ''complaints'' in order to evade review or to slow the dispute resolution process, and that an enrollee's rights may hinge on this classification process.

One commenter believed that enrollees should be given the right to request expedited resolution of complaints and these should be treated in the same manner as grievances were under the proposed rule, for when expedited resolution is requested by the enrollee or the provider.

One commenter noted that under existing fee-for-service regulations, all disputes are dealt with in a uniform manner and all that is required to obtain a hearing is a ''clear expression by the applicant or recipient, or his authorized representative, that he wants the opportunity to present his case to a reviewing authority.'' According to this commenter, this [42 CFR 431.201] definition allows for differences in presentation of disputes and does not require beneficiaries to refer to rules and definitions when presenting them. In the commenter's opinion, many beneficiaries do not have the capacity to distinguish between a ''complaint'' and a ''grievance.''

Other commenters agreed that there should be distinct categories for complaints and grievances subject to appeal, but suggested changes to how these categories are defined and the provisions applying to each. These comments follow.

One commenter believed that complaints that are not resolved to the beneficiary's satisfaction within 30 days after filing should automatically become appealable grievances.

Another commenter stated that if the complaint process is not eliminated, it should be regulated to the same extent as the grievance process was under the proposed rule. The commenter suggested that the regulation should provide more guidance on how complaints are to be handled. The regulation should also specify who distinguishes a complaint from a grievance and the qualifications of this

decision-maker. The distinction between a complaint and grievance, as used in the proposed rule, needed to be clarified with examples, in the commenter's view. Matters do not always squarely fit within one category.

One commenter said that the terms ''complaint'' and ''grievance'' should be clarified in the regulation, and that the complaint process would address those communications that were not grievances under the proposed rule. The commenter provided examples of topics that would likely be addressed as complaints in this process for example, waiting times, operating hours, demeanor of health care personnel, and the adequacy of facilities.

A commenter noted that the preamble's characterization of complaints differs from the regulatory definition. The commenter stated that the regulation defines complaints but includes no guidance on how they are to be handled. One commenter noted that the preamble says that complaints include problems involving waiting times and operating hours. However, the commenter noted, if a beneficiary must wait three weeks for an appointment during limited afternoon hours, this clearly is an availability and quality problem which should be defined as an appealable grievance.

One commenter believed that the distinction made in the proposed rule between complaints and grievances was subjective and suggested that the proposed rule's requirement that grievances be in writing would greatly reduce the number of disputes handled through the grievance process, because of the difficulty enrollees may have in filing a written appeal. The commenter further noted that some problems require immediate response, which a telephone communication allows.

One commenter thought that grievances which result from unresolved complaints should apply only to unresolved complaints that are related to service delivery or treatment. This commenter believes that appeals should be available only for ''actions'' (that is, the denial, reduction, or termination of services), and that frivolous complaints not resolved to the enrollee's satisfaction should not be entitled to a State fair hearing. This commenter was concerned that the proposed regulation opens up the State fair hearing process to virtually any expression of dissatisfaction with the operation of the MCO or PHP.

A final commenter recommended that we use the terms used in the Medicare+Choice regulations to simplify MCO and PHP documentation, and MCO and PHP enrollee education. According to the commenter, consistent use of terms would also make life easier for providers and for enrollees who participate in both the Medicare and Medicaid programs.

Response: We agree with the commenters who were confused by the way the term ''grievance'' was used in the proposed rule, particularly in light of Medicare+Choice's use of the term ''grievance'' as a complaint that is not subject to external review or a State fair hearing. Our use of the term ''grievance'' in the proposed rule was based on the fact that the Congress, in section 1932(b)(4) of the Act, referred to an internal ''grievance procedure under that an enrollee could challenge a denial of payment or coverage.'' The Congress used the term ''grievance'' to refer to a type of appeal that under the Medicare+Choice program was subject to appeal and was under that program's terminology not a grievance. It was for this reason that we used the term ''complaint'' to refer to the type of problem labeled a ''grievance'' in the Medicare+Choice program. In order to adopt an approach more consistent with Medicare's (to avoid confusion for organizations that participate in both programs). In this final rule with comment period, we are deleting the use of the word ''complaint,'' and using the term ''grievance'' to refer to the same types of enrollee problems. Also, in this final rule with comment period, like in the Medicare+Choice program, we establish two mutually exclusive categories: (1) a ''grievance,'' that is not subject to the State fair hearing process (called a ''complaint'' in the proposed rule), and (2) an ''appeal,'' that is subject to a State fair hearing (encompassed in the term ''grievance'' in the proposed rule). Because the Congress employed the term ''grievance procedure'' in section 1932(c)(4) of the Act, we continue to use the term ''grievance system'' to refer to the overall grievance and appeal system provided for in subpart F.

Specifically, in response to the above comments, we have in this final rule with comment period: (1) dropped the definition of ''complaint;'' (2) changed the definition of ''grievance'' to roughly track the definition of ''complaint'' used in the proposed rule; and (3) added a new definition of ''appeal'' to § 438.400 so that grievance and appeal are two mutually exclusive categories. We agree with the commenters favoring the employment of two distinct categories because we believe that certain disagreements between the MCO or PHP and its enrollees should have a higher standard of review, and should be subject to a State fair hearing if the MCO or PHP decision is adverse to the enrollee. The term ''appeal'' also is used by most States for State fair hearing requests. In this final regulation, the term ''appeal'' is used to refer to requests for an MCO or PHP hearing, as well as, for a State fair hearing. As just noted, it is also the term used in Medicare and will reduce the burden on MCOs and PHPs for educating providers and dually-eligible enrollees.

To clearly distinguish between a grievance and an appeal, in this final rule with comment period, we have added a definition of ''action'' as the event that entitles an enrollee to file an appeal and defined a grievance as involving a matter other than an action. An action includes the following: (1) the denial or limited authorization of a requested service; (2) the reduction, suspension, or termination of previously authorized services; (3) the denial of payment, in whole or in part for a service, for a resident of a rural area with only one MCO or PHP; (4) the denial of a Medicaid enrollee's request to exercise their right to obtain services out of network; (5) the failure to either furnish, arrange or provide for payment of services in a timely manner; and (6) the failure of an MCO or PHP to resolve an appeal within the timeframes provided in the regulation. In addition, for a State agency, the denial of a Medicaid enrollee's request to disenroll is an action.

In response to comments that we should set out additional requirements for MCOs and PHPs when they are addressing complaints (now called grievances), we have added several requirements. In this final rule with comment period, we require that MCOs and PHPs ensure correct classification of grievances. We also provide examples of grievance issues in the regulation text (in a parenthetical in the revised definition of grievance). We specify maximum timeframes for MCOs and PHPs to dispose of grievances. We provide in § 438.406(a)(7)(ii) that grievances involving clinical issues and those regarding denials to expedite resolution of appeal be decided by a health care professional with appropriate clinical expertise. We also provide that while grievances are not subject to review at the State fair hearing level, they are subject to further review by the State at the request of the enrollee. We also provide that MCOs and PHPs must work with the State to dispose of grievances if the State considers the MCO or PHP response to be insufficient. In addition, the State must monitor these processes and incorporate that monitoring into its overall quality improvement strategy.

Overall, we believe that this new approach will streamline the grievance and appeal process, eliminate confusion on the part of enrollees and providers, be more consistent with Medicare, and provide protection for enrollees.

Comment: Some commenters believed that the grievance and appeals provisions should apply to PCCMs, as well as, to MCOs and PHPs.

Response: We do not agree with the commenter's suggestion that the grievance and appeal provisions should apply to PCCMs. PCCMs are often individual physicians or small group practices and can not be expected to have the administrative structure to support a grievance process. Because PCCMs that are not capitated (capitated PCCMs would be subject to subpart F as PHPs) are reimbursed through the fee-for-service system, they are subject to the State fair hearing process described in 42 CFR 431 Subpart E. Moreover, as noted above in section II. D. with respect to the quality requirements in section 1932(c)(1) of the Act, the Congress made a conscious decision in section 1932(b)(4) of the Act to apply the grievance requirements only to MCOs in that section, notwithstanding the fact that other requirements in section 1932 of the Act apply to PCCMs. We believe it would be inconsistent with Congressional intent to apply grievance requirements to PCCMs. In the case of PHPs, the Congress was silent in section 1932 of the Act. We believe that because PHPs are paid on a risk basis like MCOs and have a financial incentive to deny care like MCOs, grievance and appeal protections are as important for PHP enrollees as they are for MCO enrollees.

Comment: One commenter urged that grievances and appeals be classified according to the type of denial (for example, a clinical determination should be subject to appeal). The commenter stated that this differentiation is important because denials of service may have a critical impact on the patient's health, unlike denials of payment and general grievances.

Response: In this final rule with comment period (§ 438.400(b)) the definition of ''action'' distinguishes what is subject to appeal from what is addressed as a grievance. In addition, we also distinguish between grievances involving quality of care issues and other grievances. Section 438.406(a)(7)(ii) of this final rule with comment period provides that grievances involving a clinical issue or a grievance of a denial of a request for expedited appeal must be decided by a health care professional who has appropriate clinical expertise in treating the enrollee's condition or disease.

2. General Requirements (Proposed § 438.402)

Proposed § 438.402 stated the general requirements of the MCO and PHP grievance system, and required MCOs and PHPs to have a grievance system that includes a complaint (now referred to as grievance) process, a grievance (now called appeal) process, and a link to the State's fair hearing system. Proposed § 438.402 required the MCO and PHP to—

- Base its complaint (now grievance) and grievance (now appeal) process on written policies and procedures that, at a minimum, meets the conditions set forth in this subpart.
- Obtain the State's written approval of the grievance (now appeal) policies and procedures before implementing them.
- Provide for its governing body to approve and be responsible for the effective operation of the system;
- Provide for the governing body to review and resolve complaints (now grievances) and grievances (now appeals) unless it delegates this responsibility to a grievance committee.
- Provide through its grievance (now appeal) process clearly explained steps that permit the enrollee to appeal to the MCO, PHP, and to the State.
- Allow the enrollee a reasonable time to file an appeal, include for each step timeframes that take into consideration the enrollee's health condition and provide for expedited resolution of grievances (now appeals) in accordance with § 438.410, not substitute for the State's fair hearing system.
- Permit enrollees to appear before the MCO and PHP personnel responsible for resolving the grievance (now appeal), and provide that, if the grievance (now appeal) resolution decision is wholly or partly adverse to the enrollee, the MCO or PHP submits the decision and all supporting documentation to the State as expeditiously as the enrollee's health condition requires but no later than the following for—

++A standard resolution, no later than 30 days after receipt of the grievance (now appeal) or the expiration of any extension; and

++An expedited resolution, no later than 24 hours after reaching the decision.

Additionally, the State must either permit the enrollee to request a State fair hearing on a grievance (now appeal) at any time, or provide for a State fair hearing following and MCO or PHP adverse decision on the matter that gave rise to the grievance (now appeal).

Comment: Given the provision in proposed § 438.402(a) requiring a link between the grievance system under section 1932(b)(4) of the Act and the State fair hearing system, the right under proposed § 438.402(d) to a fair hearing (either directly, or following an adverse MCO or PHP decision), and language in the preamble to the proposed rule requesting comments on whether fair hearing timeframes should be revised, several commenters were prompted to comment generally on the State fair hearing process. Many of these commenters recommended substantial revisions to HCFA's State fair hearing regulations, and requested that HCFA convene a meeting to discuss proposed changes to those recommendations. The commenters agreed that the State fair hearing process needs to be revised, but there was no consensus on how it should be revised. Several commenters wanted Medicaid to adopt the same standards for the State fair hearing process that were proposed for the MCO and PHP internal grievance process. Other commenters wanted an expedited State fair hearing. Commenters suggested various timeframes which ranged from 24 hours to 15 days. Finally, one commenter wanted HCFA to eliminate extensions for State fair hearings provided for in the Medicaid manual.

Response: We have decided to postpone consideration of major modifications to the State fair hearing regulations generally and to develop an NPRM to propose changes to the State fair hearing rules. At that time we will also review the provisions in the Medicaid Manual related to fair hearings. We will consider using the negotiated rule-making process in developing this NPRM.

In response to these and other comments, however, this final rule with comment period does require, under §§ 438.408(j)(3)(ii) and 431.244(f)(2), expedited State fair hearings when a service has been denied and a delay in receipt of that service could jeopardize the enrollee's health. States must conduct a State fair hearing and issue a final decision on these cases as expeditiously as the enrollee's health condition requires, but no later than 72 hours from receipt of the appeal.

Comment: Several commenters requested modifications to the State fair hearing regulations to allow MCOs and PHPs to become a party to the hearing. The commenters believed that the MCO or PHP should have an opportunity to present its position on the dispute at the hearing. Other commenters noted that

several States have not recognized MCOs and PHPs as parties to State fair hearing.

Response: We agree that MCOs and PHPs should be parties to the State fair hearing and in response to this comment, have provided for this in the final rule with comment period at § 438.408(j)(2). As parties to the hearing, we believe it is clear that MCOs and PHPs are subject to the hearing decision. As parties to the hearing it will also be clear that an MCO or PHP can present its position at a State fair hearing which we think is appropriate because the MCO or PHP will be liable for providing and paying for a service if the State fair hearing officer overturns the decision.

Comment: Several commenters noted that some State fair hearing officers do not believe that they have jurisdiction over MCOs and PHPs and believe they lack authority to order MCOs and PHPs to take a particular action. These commenters believed it would be very helpful for the regulations to provide that both the agency and the State fair hearing officer have authority to order the MCO or PHP to provide a required service or perform a corrective action, including reimbursing for services.

Response: We agree with commenters that State fair hearing officers should have jurisdiction over Medicaid MCOs and PHPs. As just noted, we have provided at § 438.408(j)(2) that MCOs and PHPs are parties to a State fair hearing appealing their decisions. With this addition, we think it will be clear that the presiding officer of the proceeding has jurisdiction over a party to the hearing.

Comment: One commenter recommended that an expedited State fair hearing be available to Medicaid beneficiaries who are not enrolled in managed care. The commenter noted that increasingly, fee-for-service arrangements use prior authorization processes, and as in managed care, the care under review may be urgently needed.

Response: While we believe there is merit in the commenter's suggestion from a policy perspective, we are not amending the State fair hearing regulations to provide an expedited hearing in fee-for-service situations, because the proposed regulation addressed Medicaid managed care, not the fee-for-service delivery system. We plan to develop an NPRM to revise the State fair hearing regulations as they pertain to fee-for-service and managed care. When this NPRM is published, the public will be invited to comment on these proposed rules. In this final rule with comment period we revise the State fair hearing regulation only to provide an expedited timeframe for resolution of appeals involving MCO or PHP denials of services in situations that require expedited resolution. This matter was put before the public in our proposed rule.

Comment: Several commenters recommended that HCFA establish more specific standards for the State fair hearing processes, including specific standards regarding the qualifications of hearings officers. Commenters were concerned with State use of hearing officers who lack adequate understanding of clinical issues when a hearing involves a denial based on lack of medical necessity.

Response: We have not addressed this concern in this final rule, comment period. As with judicial review, the presiding officer is usually not medically trained. It is the responsibility of both parties to explain the matter in a way that can be understood by the adjudicator. Parties may retain experts to present technical issues. In addition, as provided in section 431.420, provides that if the hearing officer finds it necessary, they may order an independent medical assessment to be performed at State expense.

Comment: Several commenters recommended that we require States to consult with beneficiaries, advocates, and the State MCAC when developing State grievance requirements.

Response: In § 438.202(c) we require that States provide for the input of beneficiaries and stakeholders in the development of their quality strategies. Grievance and appeal procedures must be addressed as part of State quality strategies. This provides an opportunity for beneficiary and stakeholder input. We are not specifying the mechanisms States must use to receive input. Therefore, States may, but are not required to, consult with their MCAC on grievance requirements.

Comment: Several commenters supported the requirement in proposed § 438.402(b)(3) that the MCO and PHP grievance process must be approved by the MCO's or PHP's governing body. Other commenters were concerned that requiring the governing body to approve and be responsible for the operation of the process was unnecessary and inefficient. They believed that the State should determine whether MCOs and PHPs have appropriate staff to handle the grievance process.

Response: Our intent is to ensure the involvement of individuals with authority to direct corrective action should systemic changes be required. The regulations at § 434.32, that this regulation replaces, required that the MCO ensure the participation of individuals with authority to require corrective action. We retain this requirement in this final rule with comment period. The actual processing of grievances and appeals can be delegated to a grievance committee of less senior employees.

Comment: Several commenters thought that the 90-day period for filing appeals following the notice of action was burdensome to MCOs and PHPs, because MCOs and PHPs need more timely filing by enrollees in order to assess their potential payment liabilities. Another commenter noted that § 431.221 of the current regulation, that is cited in proposed § 438.402(c)(1)(ii) provides that the State must allow for a reasonable time, not to exceed 90 days for beneficiaries to file an appeal. One commenter implied that the proposed rule states that the State must allow a minimum of 90 days for filing of appeals is inconsistent with the current regulation and that application of the proposed rule would result in different standards for managed care and fee-for-service appeals.

Response: Our intent in the NPRM was to mirror the filing timeframes for the State fair hearing, that is, a reasonable amount of time up to 90 days. This is reflected in the parenthetical in proposed § 438.402(c)(1)(ii) stating ''as provided under the fair hearing process at proposed § 431.221.'' Our reference to 90 days was incorrect because it did not reflect the fact that the regulation we intended to incorporate provided for ''up to'' 90 days. We therefore have revised this final rule with comment period to mirror § 431.221. In addition, we have incorporated in the regulation the longstanding policy at § 2901.3 of the Medicaid Manual that beneficiaries be given a minimum of 20 days to file an appeal. We believe that this policy more specifically defines the requirement in the current regulation that beneficiaries be given ''a reasonable amount of time'' to file an appeal. We believe that placing this requirement in this final rule with comment period will increase public awareness of this standard.

In the notice of action, MCOs and PHPs must include information on the deadline for filing an appeal. Further, in States that do not require that enrollees appeal first through the MCO or PHP grievance system, the notice of action must also state that the enrollee may appeal directly to the State for a fair hearing.

Comment: We received several comments concerning the manner in

which grievances and appeals may be filed.

One commenter recommended that an enrollee be permitted to submit a grievance or appeal either orally or in writing. If the decision is made to require that grievances and appeals be submitted in writing, the commenter urged that MCOs and PHPs be required to provide assistance in the process. The commenter believed that requiring Medicaid enrollees to submit grievances and appeals in writing may deprive some beneficiaries of their rights if they are not proficient in English, have little formal education or a low level of literacy, or have disabilities that prevent or make writing difficult.

Another commenter suggested that staff designated to receive and resolve grievances or appeals (proposed § 438.406(a)) be charged with reducing to writing any oral request for official review or remedial action. The commenter felt that the regulations should require MCOs and PHPs to record oral grievance and appeal requests.

One commenter suggested that we clarify whether the enrollee or the MCO or the PHP must put in writing the request for expedited resolution. Another commenter noted that the requirement for written confirmation of an oral request for expedited resolution can be a barrier to an enrollee who has severe and persistent mental illness, and who is in a period of cognitive deficit. This commenter recommended that an oral request should be allowed to suffice in this circumstance.

One commenter stated that we should delete all reference to oral requests because information received orally may be misconstrued. Another commenter stated that the regulation should include language requiring MCOs and PHPs to record oral grievances.

Response: For standard appeals, as is the case for State fair hearing requests, in this final rule with comment period, we are providing in § 438.402(c)(2) that enrollees may start the appeal clock with an oral request but must follow it with a written request. A written appeal best documents the issue being appealed. This requirement cannot be used to limit enrollees' rights. MCOs and PHPs are required in § 438.406(a)(3) to provide reasonable assistance to enrollees who file grievances or appeals, including assistance with the completion of forms. Our requirement should not preclude Medicaid enrollees with legitimate claims from pursuing those claims because of language or physical barriers. In expedited situations, this final rule with comment period provides that the enrollee is not required to place the appeal in writing. In § 438.410(c)(3) we require that MCOs and PHPs record all expedited oral appeals in writing.

Comment: Some commenters interpreted the NPRM to require that all denials of service authorization be automatically transferred to the MCO and PHP grievance system for processing as an appeal. They believed that a requirement would be too burdensome.

Response: We did not intend that all service authorization denials automatically become appeals. Proposed § 438.402(c)(1)(i) provides for the ''enrollee to appeal'' to the MCO and to the State. Even the expedited appeal process under proposed § 438.410 provided in paragraph (a)(1) apply only when ''an enrollee makes the request''. In this final rule with comment period, we continue to provide that the enrollee must appeal service authorizations denial.

Comment: We received many and varied comments on proposed § 438.402(c)(4), that required MCOs and PHPs to forward information to the State on appeal decisions that were adverse to the beneficiary (in whole or part).

Several commenters believed that the regulation should not only require the transfer of information to the State, but that this should automatically start the process for a State fair hearing.

Similarly, several commenters thought that HCFA should provide that a denial of a request for expedited appeal be automatically appealed to the State agency for a fair hearing. Several commenters noted that the 90-day limit for completion of the State fair hearing would be difficult to meet unless the State starts the fair hearing process upon receipt of the information from the MCO or PHP. Other commenters felt that this requirement would create an overwhelming amount of paperwork and that States would prefer to receive the information at the time a State fair hearing is requested. Several commenters thought that the 24-hour turnaround timeframe for an MCO or PHP to forward the paperwork for an expedited hearing decision is too short and unrealistic given holidays. Several commenters believed that a complex system would be costly and prone to error. One commenter supported the practice of one State that requires MCOs to report only those grievances that are unresolved after 30 days, noting that the State reviews other grievances as part of the annual MCO audit process. One commenter thought that beneficiaries should have to affirmatively request a State fair hearing and that this is sufficient to guarantee the appeal rights of enrollees. One commenter noted that the States are already able to get this type of information through the audit process.

Response: We have revised the requirement for MCOs and PHPs to automatically forward information to the State on appeal decision adverse to the beneficiary to require this only in the case of decisions that are expedited. For these cases, we believe that it is necessary for the State to receive the file and supporting documentation so that it can begin the State fair hearing process as soon as an appeal is filed. Because we have included a requirement for States to expedite the fair hearing process in these cases and decide the appeal within 72 hours of receiving the request, it is essential that they not lose time by needing to request the appeal file from the MCO or PHP. Also, because of the requirement for an expedited fair hearing, we continue to require that the file be forwarded within 24 hours.

For standard appeals, we have removed the requirement that the file be forwarded automatically. We are persuaded by the comment that this requirement would be burdensome on MCOs, PHPs, and States, and is not necessary to protect beneficiaries. In this final rule with comment period, we require MCOs and PHPs to forward within 72 hours files requested by the State. States will request these files upon receipt of a request for a fair hearing or for a standard appeal.

Comment: Several commenters expressed the view that in proposed § 438.402(c), HCFA has taken an important step by recognizing the need for uniform timeframes across managed care programs, and that setting timeframes recognizes the need for MCOs and PHPs to conclude their reviews promptly. However, these commenters recommended that the final rule with comment period should explicitly provide that MCOs and PHPs must resolve appeals within a timeframe that would allow the State agency to proceed with a State fair hearing, if applicable, and ensure a final decision within 90 days of the initial appeal. The commenter believes that this is needed so that beneficiaries, States, and MCOs and PHPs will clearly understand that the timeframe for final administrative action is not affected by the appeal process at the MCO and PHP level. One commenter expressed the opposite view and requested that the regulations clarify that the time allowed for State fair hearing decisions under 42 CFR 431.244(f) does not begin until a Medicaid beneficiary requests a State fair hearing following the conclusion of the MCO and PHP appeal process. This

commenter expressed the opinion that if both the MCO and PHP appeal process and the State fair hearing process are to have sufficient time to meet all the requirements imposed on each of them, then both should not have to be completed in the time allowed for one.

Response: We believe that it is important to maintain a total maximum time period for appeals to be resolved at the MCO and PHP level and by the State at the fair hearing level. However, we recognized that the 90-day timeframe for the completion of both reviews discussed in the preamble of the proposed rule is not workable because the time allowed the MCO or PHP to complete action (30 days with a possible 14 day extension), together with the time allowed by the State for a beneficiary to file a fair hearing request (up to 90 days), may exceed 90 days. Therefore, in this final rule with comment period, we have retained a total of 90 days for consideration of an appeal, but we are providing that this period be interrupted between the time the MCO issues its notice of decision and the beneficiary files for a State fair hearing. We provide that the State has 90 days to complete the State fair hearing process minus the number of days taken by the MCO or PHP to resolve the initial appeal. In addition, in order to ensure that MCO and PHP review does not unduly delay the appeal process, we have provided that if an MCO or PHP does not complete its review within the required timeframes that this becomes an adverse action.

Comment: Several commenters agreed with our statement that the MCO and PHP grievance process is not a substitute for the State fair hearing process.

Response: We agree with the commenter that it is critical that all beneficiaries, including those enrolled in MCOs or PHPs, have access to the State fair hearing process rights provided for under section 1902(a)(3) of the Act.

Comment: Several commenters wanted specific mention of members' right to a second opinion, and would like that right mentioned in adverse action notices. The commenters believed that members should have a right to out-of-plan, unbiased second opinions.

Response: In response to this and other comments, we explicitly provide in § 438.206(d)(3) of this final rule with comment period for the right to a second opinion in the network, or outside the network if an appropriate provider is not available within the network, and this right is referenced in § 438.100(b)(3). We do not provide the right to a second opinion out of network if there is another provider within the network qualified to provide a second opinion. We believe that this is consistent with the concept of holding the MCO or PHP accountable for services to their enrollees. This final rule with comment period provides that enrolles must be informed of the right to a second opinion as part of enrollment information and we therefore, do not believe it is necessary to require that it be included in the notice of action.

Comment: Several commenters supported allowing the State to choose whether to require that enrollees exhaust MCO and PHP grievance procedures prior to appealing to the State for a fair hearing. Other commenters believed that the regulations should not permit States to require the exhaustion of the internal MCO and PHP grievance process prior to permitting access to the State fair hearing process. These commenters felt that requiring the exhaustion of an MCO's and PHP's internal grievance process would inevitably lead to delays, confusion about timing, and a denial to the right to a timely State fair hearing. Commenters also believed that the internal MCO and PHP process was not impartial because the MCO or PHP has a financial interest in the outcome. Finally, one commenter argued that forcing individuals with disabilities to navigate the administrative procedures of the grievance process would be inconsistent with the provisions of the Americans with Disabilities Act (ADA), because in this commenter's view, the ADA prohibits requiring qualified individuals with disabilities to complete administrative processes that cannot be directly linked to the provision of the services offered.

Response: We continue to believe that a State should be permitted to require Medicaid managed care enrollees to exhaust MCO and PHP appeal remedies prior to accessing the State fair hearing process. This not only gives the MCO or PHP an opportunity to reconsider its decision, if the decision is reversed, it reduces the burden on the fair hearing system. We do not understand the commenter's contention that requiring exhaustion in the case of people who have disabilities necessarily would violate the ADA. While we would agree that exhaustion would not be required in the case of a claim under the ADA itself, the exhaustion requirement at issue here involves an appeal of an ''action'' (for example, a denial of payment or coverage). It is true that the ADA requires that reasonable accommodations be made for people who have disabilities in the conduct of the MCO or PHP level grievance process, and the extent of an obligation is based on the facts and circumstances of the individual case. It is not clear, however, why it would be any more of a burden for an individual who has a disability to file an appeal with their MCO or PHP than it would be to file a request for a State fair hearing. If anything, it might be easier, because the enrollee would have an existing relationship with the MCO or PHP. MCOs and PHPs should be aware of their obligations under the ADA to accommodate people who have disabilities in the grievance process. We do not believe that requiring enrollees who have disabilities to use the same process as other enrollees violates the ADA.

Comment: One commenter questioned HCFA's statutory authority for the requirement that the State fair hearing process be available to review MCO and PHP determinations. This commenter noted that the BBA does not mention the State fair hearing process and infers that the Congress intended that the MCO and PHP appeal process alone address enrollee appeals. Another commenter believed that open access to State fair hearings essentially would negate the grievance procedures within an MCO or PHP.

Several commenters applauded HCFA for providing detailed guidance to MCOs and PHPs on establishing grievance processes. One commenter felt that there also is currently little, if any, link between the MCO and PHP appeal process and the State fair hearing process. Beneficiaries are informed of both options, but are not advised as to whether they must exercise these options in a particular order or whether one ''trumps'' the other. One commenter believed that allowing the State to choose to provide a fair hearing only after running the course of the MCO's and PHP's grievance system could be the equivalent of denying a fair hearing, which is a beneficiary right. This commenter stated that better mechanisms to coordinate simultaneous participation in both the MCO and PHP and State systems should be devised.

Response: As discussed above, the requirements in subpart F are based only in part on the internal grievance requirements in section 1932(b)(4) of the Act. To the extent these regulations apply to the MCO internal grievance process, they are grounded on section 1932(b)(4) of the Act. To the extent these regulations involve the State fair hearing process, however, including the requirement that MCO and PHP internal grievance processes interface with the

State fair hearing process, they are based on the fair hearing requirements in section 1902(a)(3) of the Act. The State fair hearing process guarantees all Medicaid beneficiaries an independent hearing. At the time the original fair hearings regulations were promulgated, beneficiaries were not enrolled in managed care arrangements as they are today. Even if the BBA had never been enacted, there would have been a need to promulgate regulations applying the fair hearing rights that all beneficiaries have in the managed care context. We took the opportunity to do so in the proposed rule implementing the grievance requirements in section 1932(b)(4) of the Act. We believe that these regulations are clearly authorized. With respect to the commenter's argument that allowing States to require exhaustion could be ''the equivalent'' of denying a fair hearing, which is a beneficiary right, this is clearly not the case. As noted above, in cases that exhaustion is required, if the MCO or PHP does not favorably resolve the case by the timeframe provided, the case is automatically forwarded to the State for a fair hearing, and a decision must be made within the same 90-day timeframe that would apply if the fair hearing was requested directly. States should work with MCOs, PHPs, and enrollees to ensure that enrollees understand the linkage between the MCO and PHP grievance processes and the State fair hearing process.

Comment: Several commenters thought that the proposed regulations should preserve beneficiaries' State fair hearing rights, not expand them to include appeals from unresolved complaints, that these commenters saw as a burden on State fair hearing systems. They requested that proposed § 438.402(d) be amended to restrict the right to a State fair hearing to enrollees appealing MCO and PHP decisions denying, reducing, or terminating medical care for an enrollee. Other commenters requested that HCFA confirm that the State fair hearing process applies only to issues that involve claims for services or denials of coverage. These commenters noted that current regulations at § 431.200 provide that the hearing right arises when the ''Medicaid agency takes action to suspend, terminate, or reduce services.'' In the commenter's view, quality or access grievances that do not also involve the denial of services should not be appealed through the State fair hearing process and should be pursued through the MCO's and PHP's internal grievance process or with the External Quality Review Organization with which the State contracts. These commenters also stated that medical treatment decisions made by providers should not be subject to the State fair hearing process.

Response: We agree that the scope of issues subject to the State fair hearing process should not be as broadly defined as in the NPRM. This final rule with comment period specifies that actions, as defined in the regulation, are subject to appeal at the MCO or PHP, and to the State for a fair hearing. This includes a denial of a service, a limitation on receipt of a service, or the reduction, suspension, or termination of a service. We recognize that a provider may deny a requested service for a variety of reasons, including that the provider does not believe the service is medically appropriate for the enrollee. However, because of the financial arrangement that provides a capitated payment to an MCO or PHP for services provided to an enrollee, we believe that the enrollee needs to have recourse through an appeal if a requested service is not provided.

Comment: One commenter contended that the option for the State to require exhaustion at the MCO and PHP level or allow for direct appeal to a State fair hearing could be interpreted to allow an enrollee to file an appeal after the conclusion of the 90-day timeframe for filing.

Response: As discussed above, this final rule with comment period clearly provides that the enrollee has a reasonable time period specified by the State, not less than 20 days and not to exceed 90 days, to file an appeal with the MCO or PHP, or with the State following an unsuccessful appeal to the MCO or PHP, or initially with the State if the State does not provide for exhaustion. If an enrollee does not file an appeal with the MCO, PHP or State, the enrollee would have waived their right to an appeal.

Comment: Several commenters asked for clarification on how Medicare-Medicaid dual eligible enrollees would access the Medicare and Medicaid external hearing processes.

Response: As in the fee-for-service system, dually eligible Medicare-Medicaid beneficiaries have the appeal rights provided for under both programs, to the extent the particular program has paid for the service in question. If a dually-eligible enrollee is enrolled in a Medicare+Choice plan, then the Medicare+Choice appeals process would apply to benefits covered under that program, including otherwise non-Medicare benefits covered under the Medicare+Choice plan. When a dually eligible beneficiary is enrolled in a Medicaid MCO or PHP, and is denied a service covered by Medicare, the beneficiary similarly has Medicare appeal rights, as well as Medicaid rights to the extent that Medicare applies a different standard from Medicaid. In the case of an MCO or PHP denial of a Medicaid service not covered by Medicare, the appeal rights in subpart F apply. In all cases, the notice of action will inform the beneficiary of how to file an appeal.

Comment: Commenters requested that HCFA amend the language in the regulation to say that the MCO and PHP must ''have,'' rather than ''provide for,'' a link to the State fair hearing process.

Response: In this final rule with comment period at § 438.402(a) we define ''grievance system'' as including the MCO and PHP grievance and appeal processes, and access to the State's fair hearing system. We believe this change clearly establishes the link from the MCO and PHP processes to the State fair hearing process.

Comment: Several commenters asked that HCFA require States to allow providers the right to challenge MCO and PHP decisions on behalf of enrollees.

Response: Section 1932(b)(4) of the Act expressly requires that MCOs have a grievance procedure in place under that an enrollee ''or a provider on behalf of an enrollee'' can ''challenge the denial of coverage or payment'' by an MCO. We agree with the commenters that States are required to allow providers the right to do so, on behalf of an enrollee. In response to this comment, we have added at § 438.402(c)(1) a provision to permit the provider to file a grievance or appeal or request a State fair hearing on behalf of an enrollee with the enrollee's written consent. This condition that the enrollee provide written consent for the provider to act on their behalf reflects policy communicated in a letter to the State Medicaid Directors dated February 20, 1998 that stated, the enrollees' consent is needed if a provider submits an appeal on their behalf. We note that enrollees may be financially liable for the costs of services when provided as a continued benefit during appeal. Therefore, it is important that enrollees understand the possible implications of an appeal and consent to the appeal.

Comment: Commentators urged that HCFA require States to establish a system for administrative appeals that providers could appeal adverse network selections, payments, or other administrative actions that directly affect providers but that only indirectly affect beneficiaries.

Response: The Congress spoke to issues involving MCO relationships with subcontracting providers in provisions: (1) regulating physician incentive arrangements in section 1903(m)(2)(A)(x) of the Act, (2) prohibiting discrimination based on licensure in section 1932(b)(7) of the Act, prohibiting restrictions of provider-enrollee communications in section 1932(b)(3) of the Act, and in section 1932(b)(4) of the Act providing for a provider to file a grievance on behalf of an enrollee. We believe that if the Congress had intended that providers have specific appeal rights under Federal law, these would have been provided for in section 1903(m) or section 1932 of the Act. We believe that this is best left for providers and MCOs or PHPs to negotiate. However, this regulation does not prohibit a State from granting providers the right to challenge MCO and PHP decisions affecting them.

Comment: One commenter suggested that if a decision to deny an item or service is reversed, the MCO or PHP should be required to review all similarly situated beneficiaries and make the item or service available to them as well, regardless of whether the beneficiaries have filed appeals.

Response: We believe that decisions on appeals are so fact-specific that it would not be practical to apply an across the board rule. However, where a State requires MCOs and PHPs to extend the benefit of a hearing decision or court order to individuals in the same situation as those directly affected by the decision or order. Under § 431.250(d), FFP may be claimed for such expenditures.

3. Notice of Intended Action (Proposed § 438.404)

Under proposed § 438.404, MCOs and PHPs were required to provide enrollees timely written notice of a decision to deny, limit, reduce, delay or terminate a service, within timeframes specified in § 438.310, and in the notice explain the action the MCO or PHP intends to take, the reasons for the action, any laws and rules that support the action, the enrollee's right to file a grievance with the MCO or PHP, the enrollee's right to request a State fair hearing, the circumstances under which expedited grievance review is available and how to request it, how to file grievances (called complaints in proposed § 438.404), appeals (called grievances in proposed § 438.404), and State fair hearing requests; that if an appeal is filed, the enrollee has a right to appear in person before the MCO or PHP personnel assigned to resolve the appeal; the circumstances under which benefits will continue pending resolution, how to contact the designated office described in § 438.406(a), and how to obtain copies of enrollee's complete records.

Comment: We received many comments regarding notice to enrollees. Several commenters believed that a strict application of this principle would be burdensome, especially if applied to the following: (1) Prescription drugs; (2) decisions of primary care physicians (PCPs) made without involvement of the MCO or PHP utilization control unit; (3) MCO and PHP decisions to authorize a limited number of visits; and (4) denials of payment to a specialist when the visit was without a referral by a PCP. One commenter pointed out that denials are typically the result of provider administrative issues involving coding practices, contractual fee schedules, and timely filing. The commenter recommended that the regulation not require that notice be sent to members as a result of provider administrative issues.

One commenter found this provision fairly consistent with current Medicaid fee-for-service requirements, except for the requirement to give notice of a ''delay of service.'' This commenter expressed concern that a notice would be required when a utilization management representative asks for additional information or tests prior to approving a service, as this would confuse the member and create an administrative burden for the MCO or PHP. Several commenters strongly agreed that notice should be provided in all instances when an enrollee's authorization is denied or limited or a service already provided to the enrollee is reduced, terminated, suspended, or delayed.

Several commenters wanted the definition of grievance in the proposed rule (containing grounds for a grievance now included in the definition of ''action'' in this final rule with comment period) to be expanded to include a determination by the MCO or PHP to deny a service because the MCO or PHP believes that the service is not included in its contract. Similarly, the commenters wanted a State's denial of a service included if the State's reason for denial is because the service is to be provided by the MCO or PHP.

Response: In this final rule with comment period, we define ''action,'' and specify that notice must be sent to enrollees any time an action occurs. We believe that it is an essential enrollee protection that they be sent a notice of all actions, including those that the commenter believes to be burdensome to the MCO and PCP. We define ''action'' as a denial or limitation of a service authorization request; a reduction, suspension, or termination of a service previously authorized; a denial of payment for a service by an MCO, PHP, or its providers; the failure to furnish, arrange, or provide for payment in a timely manner; or a decision by the State not to grant an enrollee's request to disenroll from the MCO or PHP. In addition, an action includes, for residents of rural areas with only one MCO or PHP, the denial of an enrollee's request to go out of plan. Actions may be taken by the MCO, PHP, or its providers.

The terms ''deny or limit'' apply when the service requested by the enrollee or provider on behalf of the enrollee is not yet authorized or referred by either the MCO's or PHP's primary care physician, or otherwise authorized by the MCO or PHP in whole or in part. Under this final rule with comment period, a notice of service denial must be sent to the enrollee even if the MCO or PHP believes that its contract does not require that it provide the service. Without this requirement, the enrollee would have no recourse if the MCO or PHP denied the service in error. In this final rule with comment period, we have deleted the reference to a ''delay'' in service. We provide in § 438.210 that requested services must be approved or denied within 14 days. A request not acted on within this timeframe is considered a denial and a notice of denial must be sent to the enrollee. Extensions to the 14-day time period to act on a service authorization can be requested by the enrollee or by the MCO or PHP when taking additional time is in the best interest of the enrollee. The terms ''reduction, suspension, or termination of services or denial of payment'' are the same as the traditional fee-for-service definitions of those terms, that is, when a service has been authorized or is being provided and the MCO, PHP, or its provider reduces the number or frequency of the service, stops providing the service prior to the end of the time that was originally authorized, stops providing the service for a period of time, or refuses to pay for a covered or authorized service. The final two criteria in the definition of an action give managed care enrollees a remedy when the State denies a request for disenrollment or the State, MCO or PHP denies the request of an enrollee who is enrolled in a single rural MCO or PHP to go out-of-plan.

Comment: Some commenters contended that MCOs and PHPs do not always know when their providers deny

services, making it difficult for them to comply with the notice requirements.

Response: MCOs and PHPs must have a system in place to identify these situations, and to ensure that notice is provided. In this final rule with comment period, we allow providers of MCOs and PHPs to provide only general information in the notices they give to enrolles. When this option is chosen, the MCO or PHP must send the enrollee another notice that provides information specific to the enrollee's situation. (See § 438.404(d)(2)). To meet this requirement, MCOs and PHPs will need to have systems in place to find out from their providers when an enrollee has been denied a service or had a service reduced, suspended, or terminated.

Comment: Several commenters believed that Medicaid beneficiaries do not file grievances and appeals very often because of the complex requirements imposed by States, MCOs and PHPs. These commenters further stated that a system established to facilitate resolution of grievances or appeals should ensure that beneficiaries are encouraged to voice their dissatisfaction without fear of reprisal or consequences of any kind.

Response: To ensure beneficiary rights to appeal, in response to this comment, in this final rule with comment period at § 438.404(b), we specify what must be included in the notice of action. This includes information about the right to appeal, how to file an appeal, how to obtain assistance with filing, and that filing an appeal will not negatively affect the way enrollees are treated by MCOs, PHPs, their providers, or the State.

Comment: Several commenters were concerned that enrollees' rights to notice may be violated if HCFA did not prohibit States from delegating responsibility for State fair hearing notices to MCOs and PHPs. They believed that until States, MCOs, and PHPs can better ensure timeliness in processing appeals as well as full constitutional protections, there should be no delegation of the State's responsibility for providing a due process notice to beneficiaries.

Response: We have not accepted this recommendation because we believe that States may find MCO or PHP issuance of State fair hearing notices the most efficient and timely way to get the information about State fair hearing rights to enrollees when an action is taken by the MCO or PHP.

Comment: Several commenters requested that § 438.404 be amended to specifically address situations in which an MCO or PHP intends to deny, limit, reduce, delay, or terminate a service, or deny payment for a service in whole or in part.

Response: The current appeal notice requirements require a notice any time there is an ''action'', that can include the reduction of services for a Medicaid-eligible individual. Similarly, the notice requirements in this regulation apply when MCOs or PHPs intend to deny, limit, reduce, suspend, or terminate a service, or deny payment for a service in whole or in part. The terms ''reduce'' and ''limit'' were included in the notice requirements to cover instances in which already authorized services or requested services, respectively, were decreased or diminished in part.

Comment: Several commenters noted that they do not believe that the expiration of an approved number of visits should be considered a termination. They noted that the enrollee is free to request that the service be continued, but that this request should be treated as a new request for a service. Other commenters expressed the opposite view, and noted that they believe that re-authorization of a service at a lower level than previously received, or a denial of re-authorization is a termination or reduction of the service and should require notice and the continuation of benefits pending appeal. Several commenters requested that the regulation clarify how continuation of benefits applies to prescription medications.

Response: We believe that the expiration of an approved number of visits does not constitute a termination for purposes of notice and continuation of benefits. When a prescription (including refills) runs out and the enrollee requests another prescription, this is a new request not a termination of benefits. In these circumstances, the MCO or PHP would not need to send a notice or continue benefits pending the outcome of an appeal or State fair hearing. If the enrollee requests a re-authorization that the MCO or PHP denies, the MCO or PHP must treat this request as a new request for service authorization and provide notice of the denial or limitation. However, in this situation, if the enrollee appeals the action, benefits would not be continued.

Comment: Several commenters pointed out that HCFA exclusively relies on a written notice to meet the enrollees' needs. They found this policy insufficient, given language, literacy, and disability barriers. Other commenters noted that some States require MCOs and PHPs to send notices by certified mail, and believed that this was very costly, and often unsuccessful in reaching enrollees.

Response: We recognize that Medicaid beneficiaries often face language, literacy, and disability barriers. To address this issue, we have applied the information requirements found at § 438.10, including the language requirements in § 438.410(b) to the notice requirements. We also require that MCOs and PHPs mail notices to an authorized representative designated by the enrollee. We are not requiring States to provide notice in formats other than in writing, except in the case of notices about expedited hearings, that must be provided orally due to time considerations. In this final rule with comment period, we do not prohibit States from setting additional requirements for MCOs and PHPs concerning notices.

Comment: One commenter believed that HCFA has underestimated the true burden associated with MCO and PHP notices.

Response: We address this issue under the Collection of Information Requirements section of this preamble.

Comment: One commenter requested that we adopt the notice timeframes in part 431, subpart E for the situations covered by those sections, and allow States to set other notice timeframes. Several commenters disagreed with the use of a 10-day notice period prior to the date of action. They found that period to be too long because the medical condition of the enrollee may require quicker action. They also suggested that HCFA disregarded the exceptions to the 10-day rule set forth in § 431.213(h). That regulation allows for notice to be sent on the date of the action when a change in the level of medical care is prescribed by the beneficiary's physician. This exception should be interpreted to give MCO's and PHP's the flexibility to give notices, in specified cases, immediately prior to the action being taken.

Response: This final rule with comment period does not change the current regulation at § 431.213 and is consistent. Under § 438.404(c)(1) of this final rule with comment period, timeframes for notices for the reduction, suspension, or termination of previously authorized services are governed by the State fair hearing regulations found in 42 CFR 431 subpart E. While some MCOs and PHPs may find the advance notice requirement inappropriate, there are exceptions to advance notice, that allow notice to be given on the date of the action (see § 431.213). These exceptions would cover situations that a provider believes an immediate change in care is appropriate for the health

condition of the enrollee, for example, the reduction in dosage of a prescription drug.

Comment: We received several comments regarding the elements of a notice. Several commenters suggested that the written notice requirements of proposed § 434.404 be modified to mirror the existing State fair hearing regulations. Other commenters pointed out that HCFA is requiring a great deal of information in the notices required under proposed § 434.404. They suggested deleting some of the requirements. One commenter believed that information on continuation of benefits should be provided if a service is terminated or reduced. Commenters requested that information be provided in the notice about how to contact the MCO or PHP to receive help in filing an appeal. One commenter requested that the rule require MCOs and PHPs to notify the enrollee of their right to expedited review.

Several commenters wanted the content and time line requirements clarified in the notice and a full explanation to be provided of the laws and rules that support the action, rather than a citation to a particular statute or regulation. These commenters requested clarification that the enrollee has a right to obtain other relevant information germane to the resolution of the enrollee's issue. These commenters further requested a clarification that notices must specify the reasons or criteria used in determining that the request was not medically necessary.

Response: We agree that notices given by MCOs and PHPs should, at a minimum, contain the information required by the State fair hearing notices. We have provided for this in this final rule with comment period. However, we have retained the requirements specified in the NPRM concerning the content of the notice, including information about the circumstances under which an enrollee may receive expedited review, and the reason for the action. We believe that requiring the inclusion of the reason for the action will provide the enrollee with information to understand why it occurred, and help the enrollee to decide whether to appeal. We made one change to the NPRM requirements to remove the requirement that the notice specify that the enrollee may appear before the person assigned by the MCO or PHP to resolve the appeal, as we have deleted this requirement for MCOs and PHPs in this final rule with comment period.

In response to the commenter who favored inclusion of information in the notice about continuation of benefits when benefits are being terminated or reduced, we have added a requirement that the notice state that an enrollee may be held liable for payment for services if the enrollee requests continuation of benefits during appeal. This provides the enrollees with a more complete picture of what the continuation of benefits provision means to them. We also agree with the commenter favoring a requirement that the notice contain information on how to obtain assistance from the MCO or PHP in filing an appeal, and have provided for this in § 438.404(b)(8) of this final rule with comment period.

Comment: Several commenters believed that we should require MCOs and PHPs to provide enrollees with copies of their records within 24 hours of the request and, if the member (or authorized representative) is unable to pick up the copies, that they be mailed the next business day.

Response: In § 438.224 we provide that MCOs and PHPs must ensure that enrollees may request and receive a copy of their medical records and information. MCOs and PHPs should allow members to obtain copies of their medical records in a timely manner to allow the enrollee to submit information in support of their appeal. However, we have not accepted the commenter's suggested deadline, as we believe that this would be impractical and create too great a burden for MCOs and PHPs. We believe that States should have the flexibility to decide whether to establish deadlines in this area.

Comment: Several commenters believed that the notice should explain that the enrollee may be represented by counsel or a legal representative during the grievance process and include the address and phone number for free legal assistance. They noted that the right to be represented by counsel is required under the *Goldberg* v. *Kelly* ruling and that this right is given to fee-for-service Medicaid beneficiaries in the State fair hearing process.

Other commenters believed that it is sufficient to provide enrollees information regarding free legal services in a Medicaid brochure or other enrollee notification materials. Another stated that providing this information on a routine basis would be burdensome and that it may not be accurate because assistance is not available in all areas.

Response: In response to these comments at § 438.404(b)(1) of this final rule with comment period, we provide that the notice must inform the enrollee of the right to represent themselves or to use legal counsel, a relative, a friend, or other spokesperson. We do not believe it is necessary to require that the notice itself include information about free legal assistance, and we leave it to States to decide how this information is to be made available to beneficiaries.

Comment: Several commenters urged us to require each State to develop a uniform notice to be used by MCOs and PHPs. They contended that requiring use of a State-developed uniform notice is a simple, common sense way to assure consistency in the grievance and State fair hearing process across MCOs and PHPs, and would best protect the constitutional rights of the beneficiary.

Response: We believe that due process and notice requirements can be observed without requiring each State to develop a uniform notice for MCO and PHP use. States are expected to review MCO and PHP notices to ensure that all required elements, including those listed in § 431.200 et seq., are included. Nothing in our regulations prohibits States from developing a uniform notice for use by their MCOs and PHPs if they choose.

Comment: Several commenters suggested that the notice should explicitly inform the beneficiary that filing an appeal or State fair hearing request would not affect the way the member is treated by the provider, MCO, PHP, or the State.

Response: In response to this comment, we have provided under § 438.404(b)(11) of this final rule with comment period that the notice must inform the enrollee that filing an appeal or requesting a State fair hearing (where an enrollee is permitted to do so directly) will not negatively affect or impact the way the MCO or the PHP and their providers, or the State agency, treat the enrollee.

Comment: Several commenters believed that providing for an in-person hearing before the MCO or PHP would significantly increase the time and expense involved, without substantially improving the quality of the system. They also questioned if this requirement is realistic for appeals that are expedited. Finally, commenters noted that the appearance of disgruntled enrollees before MCO and PHP personnel may pose a security risk to MCO and PHP staff.

Response: We agree that due process does not require an in-person hearing at the MCO and PHP. However, we believe that enrollees should have an opportunity to present evidence and allegations of fact or law related to the issue in dispute, in person as well as in writing. In this final rule with comment period (§ 438.406(b)(4)), we provide enrollees the opportunity to present their cases in person but do not require a formal hearings process. We have also

removed the requirement that the in-person presentation must be before the decision maker for the MCO or PHP. We do this because of the burden this would place on MCOs and PHPs. Appeals requiring expedited resolution, MCOs and PHPs must notify enrollees of the limited time available for them to appear in person.

4. Handling of Complaints (Grievances) (Proposed § 438.406)

Proposed § 438.406 set forth how grievances or appeals (called complaints and grievances in the proposed rule) must be handled. The general requirement for handling grievances and appeals required MCOs and PHPs to have an adequately staffed office, acknowledge receipt of each grievance and appeal, give enrollees any assistance with completing forms or taking other steps necessary to obtaining resolution at the PHP level, and conduct appeals using impartial individuals who were not involved in any previous level of review. Proposed § 438.406(d) required that in the case of a denial based on lack of medical necessity, the individual must be a physician with appropriate expertise in the field the encompasses the enrollees condition.

Comment: One commenter advocated deleting proposed § 438.406 altogether. Other commenters believed that requirements should be added to those in § 438.406. Among the suggested additions, one commenter wanted the regulation to prohibit MCOs and PHPs from using internal appeal timeframes and procedures to avoid the medical decision process, or to discourage or prevent members from receiving medically necessary care in a timely manner. Another commenter asked that we include a clear explanation of the role of personnel provided by the MCO or PHP to advocate for the enrollee, provide customer service, or assist in resolving grievances. Another suggested that we require MCOs and PHPs to give consumers written notice of a hearing and a description of the hearing procedures, at least fifteen days in advance. One suggested that we require MCOs and PHPs to hold internal hearings at mutually convenient times. Another said we should require MCOs and PHPs to postpone hearings at the request (for just cause) of the enrollee. When enrollees have cause, one commenter wanted us to provide that enrollees need not appear at a hearing and that the hearing be conducted in the same manner regardless of the consumer's presence. Another asked that we forbid all ex parte discussions. One commenter wanted us to require MCO and PHP staff to attempt, whenever possible, to resolve grievances informally pending a decision, but that resolution should not permit the MCO or PHP to consider the grievance ''withdrawn'' in order to evade State review. Another asked that formal rules of evidence not be used, but rather that enrollees be allowed to submit written information in support of their claims, arrange for a physician or other expert to testify on the enrollee's behalf, and compel the appearance of MCO or PHP staff to answer questions concerning the dispute. Commenters believed that if the MCO or PHP has an attorney present at the hearing, the role of the attorney should be to ensure that a fundamentally State fair hearing takes place and all issues in dispute are adequately addressed. The attorney should not, in these commenters' view, be permitted to argue the MCO or PHP position in the dispute. These commenters believed that consumer representatives should be trained and certified by the State on a periodic basis, that MCOs and PHP should be required to document how they select the consumer representatives on the internal hearing committee, and that this selection process should be approved by the State on a yearly basis.

Response: The proposed rule did not propose to require a formal hearing at the MCO and PHP level. We believe that commenters misconstrued the provision in the proposed regulation concerning the in-person appearance of the enrollee to be a requirement for a formal hearing. This was not our intent. The proposed rule only addressed the presentation of evidence by the enrollee in person to the MCO or PHP. We do not believe a hearing is necessary at the MCO and PHP level and therefore, do not require it in this final rule with comment period. Because we did not propose a hearing and are not providing for a hearing before the MCO or PHP in this final rule with comment period, we are not addressing the comments relating to the nature of a hearing. We believe that the provisions remaining in this section strike an appropriate balance between proscribing sufficient provisions to protect beneficiaries and retaining some flexibility for MCOs and PHPs to design, with State approval, the procedures for their appeal processes.

Comment: One commenter was concerned that proposed § 438.406(b) did not specify a time period within that the MCO or PHP must transmit its acknowledgment of receipt of a grievance or appeal. The commenter believed that an enrollee who files a grievance or appeal needs to know in a timely manner whether the MCO or PHP has received it. Consequently, the commenter suggested that § 438.406(b) indicate that the MCO or PHP must acknowledge receipt within a specified time period, perhaps 24 hours after receiving a grievance or appeal. One commenter believed that the regulation was intended to require the MCO or PHP to acknowledge receipt of grievances or appeals in writing.

Response: We require MCOs and PHPs to acknowledge the receipt of grievances and appeals, but we do not specify that the acknowledgments be in writing, nor do we specify the timeframes in which they must be provided. We believe that requirements would be burdensome for MCOs and PHPs. States, at their option, may consider adding these requirements.

Section 438.416(b) of this final rule with comment period requires that MCOs and PHPs track the date of acknowledgment and report it to the State as part of the annual disclosure report under § 438.416(d). State monitoring should include tracking this activity.

Finally, if the appeal was oral and is not expedited, the acknowledgment must tell the enrollee that although the timeframe for resolution has begun, the appeal must be submitted in writing. The MCO or PHP must assist the enrollee with the written request, if asked.

Comment: Several commenters requested that HCFA modify the language in proposed § 438.406(c) to change the requirement that MCOs and PHPs must provide enrollees ''any assistance'' to ''reasonable assistance'' with the completion of forms or other procedural steps in the grievance process. These commenters were concerned that the phrase ''taking other steps necessary to obtain resolution of the grievance'' may require the MCO or PHP to pay for a second opinion on the disputed service in order to ''obtain resolution.'' Other commenters wanted this provision clarified so that MCOs and PHPs would not be required to pay for attorney representation or other unreasonable assistance.

Other commenters urged that the following be required elements of MCO and PHP assistance to beneficiaries during the grievance process: (1) A toll-free number with adequate interpreter capability including TTY; (2) outreach to beneficiaries with limited English proficiency, in accordance with Title VI of the Civil Rights Act of 1964; (3) an ombudsman program; and (4) a State established consumer assistance program to assist enrollees (especially homeless persons) to navigate the grievance process.

Response: In response to the above comment, we have revised the language to require MCOs and PHPs to provide ''any reasonable assistance'' for the completion of forms or other procedural steps in the grievance and appeal process. Also in response to the above comments, we have deleted the phrase ''to obtain resolution of the complaint or grievance at the MCO level,'' as we do not intend for this provision to require MCOs and PHPs to do more than assist enrollees during the grievance process.

In response to the above suggestions to specify required elements of assistance, in § 438.406(a)(3) of this final rule with comment period, we require MCOs and PHPs to make interpreter services available to enrollees, as well as, toll-free numbers that have adequate TTY/TTD and interpreter capability. By including these as examples of types of assistance required to meet certain needs, we do not intend that other reasonable assistance need not be given. We believe, for example, that MCOs and PHPs are required by this provision to provide reasonable assistance to meet other needs of enrollees, and assisting enrollees who have low-literacy abilities.

In this section, we do not address outreach to beneficiaries with limited English proficiency, but we note that the information requirements in § 438.10(b) and (c), in the section on Notice of Action (§ 438.404), and in the section on Information about the Grievance System (§ 438.414) require that information and assistance be provided to these enrollees.

The remaining comments relate to State responsibilities. This section addresses MCO and PHP requirements. We have not revised § 438.404 to address these points.

Comment: One commenter urged HCFA to create an affirmative duty of the provider to assist the enrollee in registering an appeal.

Response: We do not agree that the provider should be required to assist the beneficiary in filing a grievance or an appeal. We believe that this is appropriately the responsibility of the MCO and PHP, and we are requiring in this regulation that they provide this assistance. They are free, however, to use their contracting providers to provide this assistance on their behalf.

Comment: Several commenters commended HCFA for specifying that individuals making decisions on appeals must not have been involved previously in the claim, but requested that § 438.406 omit the word ''impartial'' when referring to individuals employed by a MCO or PHP who serve as decision makers. These commenters believed that MCO and PHP employees involved in appeal decisions can never be impartial.

Response: The requirement is that the MCO and PHP decision makers not have played a role in the original decision. Therefore, the term ''impartial'' is unnecessary and in response to this comment, we have removed it in § 438.406(a)(7) of this final rule with comment period.

Comment: Several commenters requested that enrollees receive access to hearings presided over by independent panels of clinical peer professionals. One commenter believed that enrollees should be able to seek review by an external panel and receive a de novo determination if the decision denies or limits a covered benefit, denies payment of services deemed not medically necessary or experimental, involves services that exceed a significant threshold, or puts the patient's life or health in jeopardy.

Response: The regulations provide for external review through the State fair hearing process that is available to all beneficiaries as required under section 1902(a)(3) of the Act. These regulations link the internal grievance procedures required under section 1932(b)(4) of the Act with the existing State fair hearing process that implements section 1902(a)(3) of the Act. Under the State fair hearing process, Medicaid beneficiaries are guaranteed due process through an independent hearing meeting the standards set forth in the Supreme Court's *Goldberg* v. *Kelly* decision. While the hearing officer is not required to be a health professional, we would expect medical evidence to be presented by clinicians to support an enrollee's appeal.

While the State fair hearing provides beneficiaries with an independent review of their appeals and is a beneficiary right that cannot be denied, we are aware that some States have established independent panels to review MCO and PHP decisions unfavorable to enrollees, and have made these available to Medicaid managed care enrollees. This regulation does not prohibit use of this review process by Medicaid enrollees. However, any process cannot be substituted for the grievance process and fair hearing process that is required under this final rule with comment period and the regulations at 42 CFR part 431, subpart E. If an enrollee chooses to appeal through the grievance and State fair hearing process, the decisions under this process would be controlling over any inconsistent determination made by another State body.

Comment: We received several comments concerning our decision, stated in the preamble, not to require the establishment of ombudsman programs. One commenter suggested that an enrollment broker may effectively serve as an initial unbiased contact for grievances and appeals and assist beneficiaries through the grievance process or refer them for appropriate assistance from an ombudsman or other outside source. One commenter suggested that States should establish centralized advocacy and customer service programs available to all citizens enrolled in MCOs (not just Medicaid enrollees).

Several commenters requested that ombudsman programs be established and have sign language, interpreters, and TTYs. The commenters stated that the need for an external agency, as an ombudsman program, is well proven and should be required by the regulation.

Commenters noted that the Medicaid population includes individuals with limited education, linguistic and cultural barriers to care, and frequent negative experiences in accessing entitlements and challenging bureaucratic institutions. They stated that enrollees should have designated points of contact to receive counseling on grievances or appeals if managed care is to be successful as a quality health delivery system for the Medicaid program.

Response: We encourage States to establish consumer assistance programs to assist enrollees in navigating the grievance and appeal system. After careful consideration, we have decided not to include a requirement that MCOs, PHPs, or State agencies establish ombudsman programs to assist beneficiaries. We believe that each State agency should establish its own approach to how enrollees obtain assistance during the grievance process, including the State fair hearing process. We require that MCOs and PHPs assist enrollees in completing forms and taking other procedural steps. Other assistance could be provided through a more comprehensive ombudsman program. We encourage States, MCOs, and PHPs to work with the ombudsman programs currently operating through State Medicaid Agencies, Departments on Aging, and Insurance Commissioners. In many instances, States may be able to expand existing State ombudsman programs with few additional resources. As noted in 42 CFR 431.250, FFP is available for transportation costs and other expenses of Medicaid enrollees during the appeals process.

Comment: One commenter pointed out that the word ''contracts'' in the first paragraph of the preamble to proposed § 438.406 should be ''contacts''.

Response: This commenter is correct. However, because this language did not appear in proposed regulations text, and the preamble to this final rule with comment period controls the meaning of the final regulations, no action was required in response to this comment.

Comment: Several commenters suggested that all appeals be filed by enrollees on a form developed by the State. They further suggested that MCOs and PHPs submit these to the State Medicaid agency, and that the Medicaid agency log in the appeals and return them to the MCO and PHP within 72 hours.

Response: We do not agree with this suggestion. We are not requiring use of a State-developed form for filing appeals, as this would require that enrollees obtain these forms, possibly delaying the process, and may be an impediment to enrollees wishing to file appeals. We note that States may wish to develop forms to guide and assist enrollees in filing appeals. However, their use must be at the option of the enrollee. As for filing appeals with the State, we are aware that a similar process is required by the State of Tennessee. We are concerned that the central log-in system used by that State agency would not work well in other States. A log-in procedure would require a well-developed infrastructure that could be costly and burdensome to many States, and that would add another layer (and, even under the commenter's proposal add 72 hours) to the appeals process. Furthermore, we believe that other parts of this rule will result in many of the same benefits noted by advocates of the approach used by Tennessee. For example, under § 438.416, we require that MCOs and PHPs keep a log of grievances and appeals and that its contents be reported to the State. This will provide the State the same information obtained through the commenters' suggested approach. Additionally, State on-site reviews can monitor appeal processes to determine if MCOs and PHPs are meeting required timeframes.

Comment: Several commenters requested that the person investigating the grievance should receive training on the Medicaid statute, regulations, and contractual provisions; on confidentiality and patient protections; and on the grievance process.

Response: We agree that MCOs and PHPs should provide this training to their personnel. States should consider making this a requirement of their MCOs and PHPs. However, we do not think it necessary to require specific MCO and PHP training programs in Federal regulations.

Comment: Several commenters urged that this final rule with comment period require that grievances and appeals involving application of medical standards should be reviewed by an appropriately trained physician.

Response: This final rule with comment period at § 438.406(a)(7)(ii) provides that the individual making a decision must be a health professional; with appropriate clinical expertise in treating the enrollee's condition or disease for—(1) an appeal of a denial that is based on lack of medical necessity, (2) a grievance regarding denial of expedited resolution of an appeal, and (3) a grievance or appeal that involves clinical issues.

Comment: Several commenters pointed out that the NPRM referred to ''physicians'' when describing individuals with appropriate medical expertise to make decisions on grievances and appeals concerning clinical issues. They noted that other health care professionals, not just physicians, are competent to make decisions and commonly perform these services in the private market. They stated that Medicaid beneficiaries are best served by having service denials reviewed by qualified health care professionals with appropriate expertise.

Response: We agree that health providers, other than physicians, may be appropriate to make decisions when the area of expertise required is other than a physician (for example, a dentist). In § 438.406(a)(7)(ii) of this final rule with comment period we have removed the term ''physician'' and replaced this with ''health care professionals who have the appropriate clinical expertise in treating the enrollee's condition or disease.''

5. Grievance (Appeal): Resolution and Notification (Proposed § 438.408)

Proposed § 438.408 required MCOs and PHPs to investigate each appeal (called grievance in the proposed rule) to base the decision on the record of the case, including any MCO or PHP hearing provided under § 438.402(c)(3), and relevant program laws, regulation and policies; and to resolve each as expeditiously as the enrollee's health condition requires, within State established time-frames, but no later than 30 days after it receives the appeal. The MCO or PHP would be permitted to extend the 30 day timeframe by up to 14 days if the enrollee requests the extension, or if the MCO or PHP justifies a need for additional information on how the delay is in the interest of the enrollee. For an appeal that requires an expedited resolution under § 438.10, proposed § 438.408(a)(3) required that it be resolved as expeditiously as the enrollee's health condition requires, within timeframes established by the State, but no later than 72 hours after it receives the appeal. The MCO or PHP again would be permitted to extend the timeframe by up to 14 days if the enrollee requests the extension, or if the MCO or PHP justified a need for additional information or how the delay is in the best interest of the enrollee. Proposed § 438.408 also set forth requirements for notification if the decision is adverse or partially adverse to the enrollee. For a standard resolution the timeframe was no later than 30 days after it received the appeal, and for an expedited resolution, no later than 24 hours after it reaches the decision. The content of the notice must include the name of the MCO or PHP contact, the results of the appeal and the date competed, a summary of the steps taken on behalf of the enrollee to resolve the issue, a clear explanation of the right to a State fair hearing, circumstances under which benefits would continue if a State fair hearing request was filed, and the potential for enrollee liability for services furnished during the pending appeal if an adverse decision is reached.

Comment: One commenter believed that HCFA underestimated the burden associated with the grievance system timeframes.

Response: We address the burden imposed by this provision elsewhere in this preamble, in the section titled Collection of Information Requirements.

Comment: Several commenters believed that extensions to the appeals timeframes benefit the MCOs and PHPs more than the enrollee, and recommended that we eliminate them.

Response: We believe that extensions may be necessary to provide additional time to decide appeals when information necessary to the decision cannot be obtained in time to meet the timeframes, and that extensions may be in the enrollee's interest In expedited cases, however, we agree with the commenter that giving MCOs and PHPs the discretion to extend timeframes may be problematic because this is by definition a case that the enrollee's health is at risk. Therefore, we believe that unless the enrollee actually has determined that an extension is in their interests and requests an extension, there should be no extensions in expedited cases, and we accept the commenters' recommendation that

extensions be eliminated to this extent. In this final rule with comment period, therefore, for appeals that are expedited, only the enrollee may request an extension. This is an added protection for enrollees who are appealing to receive services without which their health may be jeopardized.

Comment: Several commenters strongly favored the adoption of standardized timeframes for Medicaid that conform with those for Medicare.

Response: We have retained the same timeframes for Medicaid that are used for Medicare. Appeals must be resolved as quickly as the enrollee's health condition requires, or no later than 30 days for standard appeals, and 72 hours for expedited appeals. As under the Medicare+Choice program, we permit 14 day extensions for both standard and expedited appeals when requested by the enrollee. In the case of a standard appeal a 14-day extension may also be obtained if the MCO or PHP justifies to the State Medicaid agency that it is in the enrollee's interests. As noted in response to the previous comment, we have eliminated extensions in expedited cases unless requested by the enrollee.

In response to the above comment favoring the adoption of Medicare timeframes, we are extending the extent to which this final rule with comment period follows Medicare timeframes by providing in §§ 438.408(j)(3)(ii) and 431.244(f)(2)(ii) and (iii), for an expedited State fair hearing in cases of expedited appeals. Specifically, we require that the State fair hearing decision be made within 72 hours, that is the same timeframe used for Medicare for expedited appeals to the Center for Health Dispute Resolution (CHDR), the current Medicare contractor for external independent review under Medicare+Choice. The fair hearing process is the Medicaid counterpart of CHDR review, in that in both cases it is the first ''independent'' and ''external'' review of a managed care organization's decision.

Comment: Comments on standardized timeframes differed. Some commenters believed that consistent timeframes are especially important in expedited appeals when the enrollee's health condition needs to be taken into consideration. Other commenters supported the adoption of standardized timeframes, but called for them to be shorter. One commenter believed that the timeframes in the proposed rule might violate Constitutional due process because the timeframes outlined do not adequately protect beneficiaries.

Other commenters criticized the standardized timeframes. Several commenters found the timeframes unreasonable, unrealistic, subjective, and too prescriptive and asked for more State flexibility to set timeframes. One commenter wanted the timeframes to begin when all documentation is received from providers. One commenter noted that most States already have expedited timeframes and changing these requirements may be confusing for beneficiaries and may not provide any additional protections to enrollees. One commenter found the extensive and varying timeframes for resolutions confusing and believed that it would be difficult to administer.

Response: We continue to believe that the regulation should establish timeframes for steps in the internal appeal process and that an expedited timeframe is necessary when the use of standard timeframes may jeopardize the enrollee's health. This is an important beneficiary protection and is necessary to ensure that the overall timeframe of 90 days for a decision at the State fair hearing (excluding the time the beneficiary takes to file for a State fair hearing) can be met in all cases. In § 438.408(a) we provide for States to establish timeframes that ''may not exceed'' the timeframes specified in this final rule with comment period. States may establish shorter timeframes.

Comment: Several commenters believed that mandatory timeframes might be difficult to meet if enrollees fail to submit timely information, or are not available for an in-person presentation to the MCO or PHP. These commenters asked that a limit be placed on the number of days MCOs and PHPs are responsible for providing continued services pending final determination.

Response: We believe that the timeframes included in the regulation will result in timely decisions on appeals. Enrollees must be informed of the timeframes, and provided an opportunity to present evidence and appear in person before an MCO or PHP representative. However, if they do not provide information to support their appeal, the MCO or PHP is responsible for deciding the appeal on the basis of available information within the timeframes set out. Continuation of benefits for already authorized services must continue throughout these periods until the final decision at the MCO, PHP, or State is made, whichever is later. Given the limits on timeframes for decision in this rule, we do not believe that ''time limits'' are necessary. We note that there are no such limits under fee-for-service Medicaid.

Comment: Several commenters thought that MCOs and PHPs should be required to receive written approval from the State before extending the timeframes.

Response: We are not requiring that MCOs and PHPs receive prior approval from the State for extensions, as we do not believe that this would be practical, given the number of cases and the timeframes involved. However, States are required to monitor MCO and PHP use of extensions and may require that MCOs and PHPs provide justification for any extension.

Comment: Several commenters believed that the enrollee should be forwarded a concurrent copy of the MCO's or PHP's written request given the opportunity to respond to the MCO's or PHP's request for a time extension, and provided a concurrent copy of the State's response. One commenter warned that requiring prior approval would be burdensome.

Response: We agree that enrollees should be informed when an MCO or PHP grants an extension, and in response to this comment have provided for this in § 438.408(d)(2) of this final rule with comment period. The MCO or PHP notice must include the reasons for the delay and inform the enrollee of the right to file a grievance if the enrollee disagrees with the decision to extend the timeframes. We do not believe that this requirement will unduly burden MCOs and PHPs, as we believe that most appeals will be decided within the time period allowed before an extension is needed. We note that our decision to not permit MCOs or PHPs to extend the timeframe for an expedited appeal absent a request by an enrollee is also responsive to the commenters' concerns about an enrollee being informed of extensions and having the opportunity for input.

Comment: One commenter requested that we require the MCO or PHP to give a written justification to the enrollee whenever the MCO or PHP extends the 14-day timeframe, and that a copy be included in the case file. Another commenter noted that the MCO or PHP does not need to obtain prior approval before granting itself an extension, and as currently drafted, the enrollee appears to have no recourse other than to file a grievance with the MCO or PHP, even in situations when the enrollee's life may be jeopardized. They believe that due process and fundamental fairness require MCOs and PHPs to provide notice to the enrollee, and that the enrollee should have the right to object and have the dispute immediately decided by an impartial decision maker. A delay in decision making constitutes a delay in providing the service. and is subject to Constitutional requirements

and *Goldberg* v. *Kelly* in this commenter's view.

One commenter also requested that physicians (in addition to enrollees) should have a right to request a 14-day extension.

Response: We agree that MCOs and PHPs, upon granting themselves an extension, should notify the enrollee in writing of the extension and of the enrollee's right to file a grievance if the enrollee disagrees with an extension of the timeframes. We do not believe that providers need to be given the right to seek an extension. The provider is associated with the MCO or PHP that can grant itself an extension in a non-expedited case if the standard is met. The MCO or PHP must also provide justification for the extension to the State, if required. We note that the commenter's concern about ''situations when the enrollee's life may be jeopardized'' by an MCO or PHP-initiated extension has been addressed by our decision to eliminate the opportunity for the MCO or PHP to extend the deadline in expedited cases absent an enrollee request.

Comment: One commenter believed that the timeframes should begin when the appeal initially is made, not when it is submitted in writing.

Response: We agree that timeframes should begin when the enrollee first appeals the action, regardless of whether the appeal is made orally or in writing. When setting the timeframe for resolving appeals in § 438.406(b)(3) of this final rule with comment period, we refer to the date that the MCO or PHP first ''receives'' an oral or written appeal as the point that the time for resolving the appeal has begun. We note, however, that the enrollee must follow a standard oral appeal for a request with a written request.

Comment: Several commenters recommended that the timeframe for making a decision on a request to authorize a service should be less than the 14 days proposed.

Response: We continue to believe that 14 days is an appropriate outer limit for the time allowed for an MCO or PHP to authorize a service. We have retained the provision of the NPRM that requires this decision to be make more quickly if required by the enrollee's health needs. In addition, in this final rule with comment period, when a determination is made that a case meets the standards for an expedited appeal, the MCO or PHP must decide an appeal of this decision no later than 72 hours after the appeal is filed.

Comment: One commenter agreed with our decision stated in the preamble to the proposed rule not to require MCOs and PHPs to automatically resolve any dispute in the enrollee's favor that the MCO or PHP did not resolve within a defined timeframe. Other commenters supported requiring that appeals be resolved automatically in the favor of the enrollee if not completed within a specific time period. These commenters reported ongoing problems of MCOs and PHPs denying services for months while multiple requests for information are made.

Several commenters reported that some State laws provide safeguards when decisions on medical care are not made within required timeframes, including deeming the failure to make a timely decision an adverse decision subject to appeal or automatic approval of the service.

Several commenters pointed out that in HCFA's Medicare+Choice regulations, the failure of a Medicare+Choice organization to meet initial determination and reconsideration timeframes is automatically considered an adverse decision and automatically referred to the next level of review.

Response: We are not requiring that appeals be resolved automatically in the favor of the enrollee if not completed within a specific time period. Instead, non-compliance will be considered an adverse decision, and automatically referred to the next level of review (the State fair hearing process). For service authorization requests, an MCO or PHP not completing authorizations within the specified timeframes would be required to send a notice of adverse action explaining the enrollee's appeal rights. As the commenters noted, this is consistent with Medicare's policy for reconsiderations not acted upon within the required timeframes. That is, the Medicare+Choice organization's failure to act is considered an affirmation of its adverse decision and the file must be sent to the independent entity for an independent outside review. This first level of independent review under Medicare+Choice is analogous to fair hearing review under this final rule with comment period.

Comment: One commenter asked that the words ''title of staff person'' be substituted for ''name of staff person'' to protect MCO and PHP staff members from possible retaliation by enrollees.

Response: We agree and have changed ''name'' to ''title'' in this final rule with comment period.

6. Expedited Resolution of Grievances and Appeals (Proposed § 438.410)

Proposed § 438.410 required that each MCO and PHP establish and maintain an expedited review process for appeals (called grievances in the proposed rules) and set forth requirements for the resolution of expedited grievances and appeals including, responses to oral or written requests if the MCO or PHP determines, or the provider indicates that the time for a standard resolution could seriously jeopardize the enrollees's life, health, or ability to regain maximum function.

Comment: Some commenters applauded our inclusion of an expedited grievance process similar to that under Medicare+Choice and-then-proposed the Department of Labor regulations. Others argued for State flexibility and contended that prescriptive Federal requirements preclude States from taking into account other expedited processes that they have implemented with respect to clinical aspects of appeals, for example, preauthorizations.

Response: We believe that expedited resolution is necessary to ensure that appeals of situations that potentially place an enrollee's health in jeopardy are not delayed. The Consumer Bill of Rights and Responsibilities (CBRR) and beneficiary advocates have both recommended the adoption of expedited procedures. Although States have historically instituted different processes to protect beneficiaries, HCFA believes that standardized expedited appeal processes are needed to protect beneficiaries in a capitated health care delivery system.

Comment: One commenter requested that ''retain function'' be added to the criteria for expedited grievances and appeals. The commenter stated that retention of less than full function is often the goal for beneficiaries with long-term disabilities who cannot expect to regain full function but should be protected against further loss of function. Other commenters wanted the expedited process to apply when the enrollee has significant pain or side effects, and for children with special health care needs.

Response: In response to this comment, we have revised the language for expedited appeals to include all instances for which the time needed for standard resolution could ''seriously jeopardize the enrollee's life or health, or the ability to attain, maintain, or regain maximum function.'' With this revision, the Medicaid criteria are more inclusive than those for Medicare. We believe that these criteria are sufficient to address situations that the enrollee is in significant pain or is having significant side effects. Finally, we do not agree that children with special health care needs should automatically receive expedited appeals in all cases

solely on the basis of being in that category. We believe that the criteria we have established will ensure that expedited appeals will be available when they are needed.

Comment: Several commenters suggested that the regulations allow the beneficiary to obtain an expedited review based on the beneficiaries' own attestation that the standard for expedited review has been met. They believed that MCOs and PHPs should not be given control over the situation because their financial arrangements with physicians may provide an incentive to deny services. One commenter supported the ability of an enrollee to obtain an expedited resolution if the enrollee obtains the support of a physician.

Response: We do not agree that an enrollee's attestation should be sufficient to require an expedited appeal. The enrollee may not be objective in this determination or may not have the knowledge to draw a correct conclusion. It is not clear what would preclude enrollees under this approach from attesting that the standard is met in every case simply to get faster action on all appeals. We are including in this final rule with comment period a provision that if a provider makes the request, or supports the enrollee's request for expedited review, the review must be expedited. We believe this sufficiently protects enrollees.

Comment: Several commenters noted that the rule should prohibit retaliation by the MCO or PHP against physicians who support their patients' requests for expedited appeals.

Response: We intend that providers who advocate on behalf of their patients should be protected against retaliation by MCOs and PHPs in all circumstances. In response to this comment, we expressly prohibit any retaliation in § 438.402(b)(5) of this final rule with comment period.

Comment: One commenter expressed concern regarding the logistics of requiring MCOs and PHPs to give prompt oral notice to an enrollee of any denial of an expedited request. They noted that some Medicaid enrollees may not be accessible by telephone.

Response: We are aware that some Medicaid enrollees may not have telephones. Nevertheless, MCOs and PHPs must make reasonable efforts to notify enrollees orally of decisions not to expedite the appeal and follow up with a written notice within two calendar days. MCOs and PHPs should request information from enrollees about how and where they can be contacted.

Comment: Several commenters recommended that the State Medicaid agency be required to hear all expedited appeals and issue decisions within specified timeframes. One commenter recommended we include a requirement that decisions be made within 24 hours; another suggested two days.

Response: This final rule with comment period requires the State to conduct a fair hearing and make its decision within 72 hours for service authorization denials that meet the criteria for expeditious handling. We have limited this requirement to initial denials of authorization for a service because in the case of a decision to reduce or terminate benefits, benefits continue through the State fair hearing decision. The enrollee's health is protected during the time it takes for the State fair hearing decision to be made. We have chosen to use the same 72-hour standard that applies to MCO or PHP review in expedited cases because we do not believe it would be reasonable to expect the State to complete review of all expedited cases in 24 hours. We also note that this 72-hour timeframe is employed in Model guidelines established by the National Association of Insurance Commissioners (NAIC), in Department of Labor regulations governing Retirement Income Security Act (ERISA) health plans, and at both the Medicare+Choice organization and independent external review levels in the Medicare+Choice program.

Comment: Several commenters pointed out that proposed § 438.410 (c)(2) allowed a physician to request an expedited appeal. They suggested that we broaden this provision to allow other health care professionals to make these requests.

Response: We agree that all health care professionals who provide services to Medicaid beneficiaries should be permitted to request expedited appeals. As discussed above, we have made this change in this final rule with comment period.

7. Information About the Grievance System (Proposed § 438.414)

Proposed § 438.414 required that MCOs and PHPs provide information about the grievance system to enrollees, potential enrollees (as provided by the State), and all providers at the time they enter into a contract with the MCO and PHP. It also specified that the content of the information include a description of the grievance process that is developed or approved by the State, and that it include the following: (1) specification of what constitutes grounds for a complaint (now grievance) grievance (now appeal) or State fair hearing; (2) an explanation of how to file for each; (3) an explanation of the assistance available; (4) toll-free numbers (with TTY and interpreter capability) for enrollees to register grievances and appeals; (5) titles and telephone numbers of persons responsible for the functioning of the grievance process and with authority to require corrective action; (6) assurance that filing an appeal or requesting a State fair hearing will not negatively affect or impact the way the MCO or PHP, their providers, or the State agency treat the individual; and (7) information on how to obtain care or services during the grievance or fair hearing processed. Section 438.414 also requires that the MCO or PHP to provide enrollees and potential enrollees with aggregate information regarding the nature of enrollee appeals and their resolution.

Comment: One commenter believed that we underestimated the true burden associated with MCO and PHP grievance information requirements.

Response: We address the issue of burden in the Burden Statement to this final regulation.

Comment: Several commenters requested that we explicitly require notices and information about the grievance system to be written at a fourth grade level, translated into prevalent languages, and accessible to persons with hearing and sight impairment.

One commenter requested us to require MCOs, PHPs, and PCCMs to use at least one of the following reference materials: (1) Fry Readability Index; (2) PROSE: The Readability Analyst; (3) Gunning FOG Index; or (4) McLaughlin SMOG Index.

Response: In this final rule with comment period, we require that notices meet the formatting and language requirements at § 438.10. We believe that it is appropriate that we include a general requirement for material to be written in easily understood language and formatted likewise. We also provide that material must be translated into the prevalent languages in the MCO's or PHP's service area. In the preamble to the proposed rule, we provided examples of standards States can use to determine prevalence. We are not requiring that material be written at a specific grade level because no single level is possible or appropriate for all material.

Comment: One commenter believed that additional State flexibility was necessary regarding how and when information should be distributed to enrollees. Another commenter asked for more clarification about the detail of the information that must go to all enrollees

and the time that information must be sent. One commenter requested that States develop standard language that MCOs and PHPs be required to use in their member handbooks. Several commenters supported the amount of detail in the regulation regarding information because it ensures that information about beneficiary protections is provided more uniformly to enrollees.

Response: We are not mandating that States require the use of standard language because, we believe that States should be permitted to decide this based on State circumstances. With respect to the timing of the provision of information, § 38.10(d), (e), and (f) set forth requirements as to when information about the grievance system must be provided to enrollees and potential enrollees. With respect to the information on grievances and appeals addressed in § 438.414, for enrollees, § 438.10(e)(1) requires that this information (referenced in § 438.10(e)(2)(x)) be provided within a reasonable time after the MCO or PHP receives notice of enrollment, and once a year thereafter. In the case of potential enrollees, § 438.10(f)(7) requires that the information described in paragraphs (d) and (e) of § 438.10 (including the grievance information described in § 438.10(e)(2)(x)) be provided only upon request. In § 438.414(a)(1) and (3), we require MCOs and PHPs to provide information about the grievance system to enrollees, and to providers and subcontractors (at the time of entering into a contract). In section 438.414(a)(2), we require that the State, a State contractor, or MCOs and PHPs provide this information to potential enrollees. In § 438.404 we require that information about the grievance system be sent to enrollees as part of the notice of action.

Comment: One commenter believed that the State fair hearing process should be explained clearly to enrollees at the time of enrollment, and annually thereafter. Several commenters asked that MCOs and PHPs be required to give enrollees information on the right to be represented by counsel, and the availability of free legal assistance. One commenter requested that beneficiaries be informed of their rights during the grievance process at every stage.

Response: We have revised this regulation to clarify that the beneficiary's State fair hearing rights must be explained, including the fact that enrollees have the right to represent themselves, or be represented by legal counsel, a relative, a friend, or other spokesperson. We do not require MCOs and PHPs to inform beneficiaries about the availability of free legal counsel. This is consistent with the current policy in fee-for-service. In the State Medicaid Manual (SMM 2900.3), we require States to maintain a list of available free legal services and to notify beneficiaries of their right to legal assistance, including free legal assistance. States may, at their option, require MCOs and PHPs to maintain copies of this list and make it available to enrollees.

Comment: Several commenters thought that we should require MCOs and PHPs to provide grievance, appeal, and State fair hearing information to potential enrollees, upon request, and to enrollees upon initial enrollment, and whenever the grievance system is changed by the MCO, PHP, or the State. Several commenters wanted aggregate information on grievances and their resolution to be given to consumers as part of their initial and annual enrollment choice information. Several commenters wanted grievance data to be available to the general public, as well as, to enrollees and potential enrollees. One commenter encouraged us to have consistent requirements for Medicaid and Medicare.

Response: As noted above, we require the State to ensure that information on grievances and appeals is provided to potential enrollees upon request, either by the State or its contractor (for example, an enrollment broker), or by the MCO or PHP. MCOs and PHPs also are required to provide this information to enrollees at the time of enrollment, and annually thereafter. Information will also be provided as part of notices of actions. We believe that this will provide enrollees with the information they need to exercise their rights.

We agree with the commenter that MCOs and PHPs should provide aggregate information on grievances and appeals to enrollees, potential enrollees, and the general public upon request. In response to this comment, § 438.414(d) of this final rule with comment period provides that aggregate information be released to the public upon request.

Comment: One commenter requested that HCFA require that information about the grievance system be provided to subcontractors as well as to contracting providers.

Response: In § 438.414(a)(3) of this final rule with comment period, we specify that this information must be provided to subcontractors as well as to contractors.

8. Recordkeeping and Reporting Requirements (Proposed § 438.416)

Proposed § 438.416 required that MCOs and PHPs comply with specified record keeping requirements, that also had to be done in compliance with confidentiality requirements in § 438.324. Specifically, MCOs and PHPs were required to—

- Maintain a log of all grievances and appeals (called complaints and grievances in the proposed rule).
- Track each appeal until its final resolution.
- Record any disenrollment and the reason for it, even if it occurs before the appeal process is complete.
- Retain the records of grievances and appeals (including their resolution) and disenrollments for three years, and make them accessible to the State or if any litigation, claim negotiation, audit or other action is started before the end of this three year period, the MCO or PHP must retain the records until completion of the action and resolution of the issues, if later than three years.
- Analyze the collected information and prepare and send to the State a summary as often as the State requests, but at least annually—

++ The number and nature of all complaints and grievances.

++ The timeframes within which they were resolved, and the decisions.

++ A listing of all grievances that have not been resolved to the satisfaction of the affected enrollee.

++ The number and nature of grievances for which the MCO or PHP provided expedited resolution, and the decisions.

++ Trends relating to a particular provider or a particular service.

Comment: One commenter believed that HCFA underestimated the true burden associated with MCO and PHP record keeping and reporting requirements.

Response: We address the issue of burden in the section of the preamble titled Collection of Information Requirements.

Comment: Several commenters suggested that the State be allowed to determine the specific data elements to collect on grievances and appeals, and how and when reports are to be submitted to the State. Other commenters supported the inclusion of the elements included in the proposed rule.

Response: We believe that a minimum set of data should be available from all MCOs and PHPs to facilitate monitoring. We have changed this final rule with comment period to remove the requirement in proposed § 438.416(e)(3) that MCOs and PHPs submit a list of all appeals not resolved to the satisfaction of the enrollee. We believe that this requirement is unnecessary now that MCOs and PHPs will be required to forward all appeals not resolved to the

satisfaction of the enrollee to the State for a fair hearing. We note that States have the flexibility, at their option, to set record keeping and reporting requirements in addition to these Federal minimums. For example, States may establish a minimum number of categories of grievances and appeals that MCOs and PHPs must report (for example, delays in receiving referrals, delays in access to specialists or services, dissatisfaction with quality of care, and waiting times for appointments).

Comment: Several commenters wanted the regulation to specify that MCOs and PHPs should collect and report information on the number and nature of requests for expedited review.

Response: We agree that we should require that MCOs and PHPs collect and report information on the number of requests for expedited review, and in response to this comment have provided in § 438.416(b) of this final rule with comment period that grievances and appeals must be classified in terms of whether the disposition was standard or expedited. We have retained the requirement in proposed § 438.416(e)(1) (now § 438.416(d)(1)) that information be reported on the ''nature of all grievances and appeals,'' whether expedited or standard.

Comment: Several commenters wanted grievances to be tracked, sorted by type, number and resolution, and reported to the same extent as appeals. They believed that this would be useful in identifying problems with education and outreach.

Response: This final rule with comment period requires that grievances, as well as appeals, be tracked and reported. In response to the comment favoring additional tracking, we have added a requirement to the regulation that MCOs and PHPs must track and report on the time frames for acknowledging to the enrollee the receipt of grievances and appeals.

Comment: Several commenters objected to the requirement in proposed § 438.416(c) that MCOs and PHPs record any disenrollments and the reason for them, because these commenters believed that the State controls the disenrollment process and maintains data regarding disenrollments. Therefore, these commenters believed that States, not MCOs and PHPs, should be required to maintain disenrollment records. One commenter noted that requiring the collection of disenrollment information is good and that it should also be classified

Response: We have removed the requirement for an MCO or PHP to ''record any disenrollment and the reason for it'' from the proposed provisions at § 438.416 because this was duplicative of the requirement at proposed § 438.342(a) that the State ensure that each MCO and PHP maintain a health information system that collects, integrates and reports data on areas including disenrollments. However, in response to this comment, we recognize that there is a distinction between disenrollments from an MCO or PHP due to loss of Medicaid eligibility and other disenrollments initiated by the enrollee of the MCO or PHP. Given that information regarding disenrollments due to loss of Medicaid eligibility is not typically known by MCOs or PHPs, in response to this comment, we have modified the reference to disenrollment in § 438.242 to refer to ''disenrollment for other than loss of Medicaid eligibility.''

Comment: One commenter requested that we clarify that the regulation requires MCOs and PHPs to provide the State only with information about grievances and appeals of Medicaid enrollees, not all enrollees.

Response: We believe that the regulation is clear that this information must be supplied only for Medicaid enrollees, as it references grievance and appeal mechanisms that are only available to enrollees.

Comment: We received several comments regarding the annual disclosure of information. One commenter believed that annual disclosure of aggregate data was appropriate, but that reporting trends relating to a particular provider or particular service was not. Commenters urged us not to require such information to be reported. They were very concerned that these reports would have a detrimental effect on existing quality improvement and peer review processes.

Response: We agree that Federal reporting of trends relating to particular providers may not be appropriate, and in response to this comment have deleted this requirement from this final rule with comment period. States, at their option, may develop provider grievance and appeal profiling requirements consistent with State laws.

Comment: Several commenters asked that State Medicaid agencies and ombudsman programs have access to MCO and PHP logs. In addition, commenters urged that the regulation require States to provide members of the public, upon request, with MCO and PHP summaries. Another commenter recommended that HCFA require MCOs and PHPs to identify trends on grievances and appeals for particular enrollee sub-populations. One commenter wanted the regulation to require MCOs and PHPs to computerize their grievance and appeal logs and report to the State on a quarterly rather than annual basis.

Response: States have the authority to require that MCOs and PHPs make available to the State grievance and appeal logs or other MCO and PHP grievance system documents. In the final regulation we are requiring that States must make information on MCO and PHP grievances and appeals available to the public. We do not agree that we should be more prescriptive in the regulation about reporting requirements. States, at their option, may require MCOs and PHPs to provide ombudsman programs access to grievance and appeal logs, to include information about all systemic issues that emerged from grievances and appeals, to report on their response to systemic problems, to report grievance and appeal data on particular subpopulations of enrollees including persons with special needs, to computerize logs, or to report on a more frequent basis. In designing their quality strategies, States should consider what additional information they or others will need to support those strategies.

9. Continuation of Benefits Pending Resolution of a State Fair Hearing Decision (Proposed § 438.420)

Proposed § 438.420 set forth requirements for MCOs and PHPs, in the case of an appeal from the termination or reduction of services currently being provided to continue services upon a timely appeal while the MCO or PHP considers the appeal, and through the end of any State fair hearing. As used in this section, ''timely'' means filing on or before the time limit specified by the State and communicated in the notice of intended action, or before the effective date of the MCO's or PHP's proposed action, whichever is later. Although the benefit is to be continued during the resolution process, enrollees who lose their appeal at either the plan or State fair hearing levels will be liable for the cost of all appealed services from the later of the effective date of the Notice of Intended Action or the date of the timely filed appeal, through the date of the denial of the appeal.

Comment: Commenters expressed concern that the regulation may be read to permit benefits to be stopped after the appeal to the MCO or PHP, but before the State fair hearing.

Response: We intend for benefits to continue through the enrollee's final appeal at the State fair hearing when requested by the enrollee. Section 438.420(d)(1) of this final rule with

comment period makes it clear that benefits must continue without interruption, if elected by the enrollee, through the conclusion of the State fair hearing process if the case is not favorably resolved at the MCO or PHP level.

Comment: One commenter thought that requiring continuation of benefits through the State fair hearing decision was inappropriate because the enrollee may be liable for payment for services provided during this period if the appeal is ultimately denied at the State fair hearing.

Response: We provide that enrollees must request to have benefits continue during the appeal process because of their potential financial liability in the event that they are unsuccessful. In § 438.404(b)(7) of this final rule with comment period, we require that the notice of action inform the enrollee of the potential financial liability for services continued during appeal. Likewise, in § 438.408(g)(4)(iii), we require a written notice to the enrollee that the enrollee may request that benefits be continued and of the potential financial liability if the benefits continue.

Comment: We received many comments regarding enrollees' rights to continuation of benefits during the MCO and PHP appeal process. Several commenters thought that the regulations should include a provision to require MCOs and PHPs to continue benefits when the appeal involves services that are being terminated or reduced. Several commenters felt that continuation of benefits pending resolution of an appeal or State fair hearing without financial risk, is one of the most important protections needed for managed care enrollees.

Several commenters were opposed to extending continuation of benefits to the MCO and PHP appeal process. One contended that this requirement would have significant cost implications. Another believed that benefits should be continued only at the point when an enrollee requests an external fair hearing.

One commenter thought that requiring MCOs and PHPs to continue benefits would place them in an untenable position with their providers, compromising their ability to manage care and cost. They expressed concern that this provision may damage managed care programs and believed it unnecessary given the requirement of expedited review of appeals in cases in which a delay could jeopardize health.

One commenter argued that requiring continuation of benefits during an MCO or PHP appeal, as opposed to a State fair hearing, was not consistent with this commenter's interpretation of the statute and case law. It appeared to this commenter that a beneficiary would obtain double benefits in this situation. The commenter requested clarification to explain the duration of continuation of benefits when they are provided during the MCO and PHP appeal process. The same commenter also felt that continuation of benefits would make it difficult for the State to track the case and determine the beneficiary's eligibility for continuation of benefits at the point of the State fair hearing.

Response: Because we allow States to require exhaustion of the MCO and PHP appeal before receiving a State fair hearing, we believe that, in order for the right to continued benefits during a fair hearing to be meaningful, that continuation of benefits must begin with the filing of the appeal and continue until the State fair hearing decision. Continuation of benefits at the MCO and PHP level thus is not a ''double'' benefit, but part of the same longstanding right to continuation of benefits that has existed for Medicaid beneficiaries when services are reduced or terminated.

As in fee-for-service, under managed care, the right to continuation of benefits is not exercised without financial risk to the beneficiary of payment for services provided should he or she lose the appeal. The enrollee may choose not to request continuation of benefits because of the potential liability. The notice of adverse action must include an explanation of this choice.

While expedited appeals will decrease the amount of time MCOs and PHPs are liable to continue benefits for enrollees with pending appeals, the expedited appeal process does not substitute for the protection provided to Medicaid beneficiaries of the right to continuation of benefits pending the outcome of a State fair hearing decision.

If the benefit is a Medicaid covered service, but not a MCO or PHP covered service, the State, not the MCO or PHP is responsible for providing those services pending the outcome of the State fair hearing.

It is not clear why the last commenter believes that providing continued benefits through the fair hearing level is inconsistent with the statute or case law. We believe that it simply gives MCO and PHP enrollees the same Medicaid fair hearing rights that all other enrollees have under the program. To the extent that we are aware of case law on this issue, courts have supported continuation of benefits in the managed care context.

Comment: One commenter requested that this section should make clear that re-authorization of a service at a lower level than previously received, or a denial of re-authorization, is a termination or reduction of the service requiring the continuation of benefits pending appeal.

Response: We believe that the expiration of an approved number of visits does not constitute a termination for the purposes of notice and continuation of benefits. If an enrollee requests re-authorization for services and the MCO or PHP denies the request or re-authorizes the services at a lower level than requested, the MCO or PHP must treat this request as a new service authorization request and provide notice of the denial or limitation. The MCO or PHP is not obligated to provide continuation of benefits in this circumstance. This policy is consistent with that in fee-for-service.

Comment: One commenter objected to requiring MCOs and PHPs to cover the service pending appeal if the enrollee is no longer eligible for Medicaid and there is no emergency.

Response: The policy for continuation of benefits does not apply when an enrollee loses Medicaid eligibility.

Comment: We received many comments regarding the requirements in proposed § 438.420(b) that a MCO or PHP physician with authority under the MCO or PHP contract must have authorized the enrollee's services in order for them to be continued.

Several commenters believed that benefits should be continued in all cases in which a dispute involves a service covered under the Medicaid State plan. They argued that conditioning continuation of benefits on the benefits having been authorized was inconsistent with constitutional due process requirements. They contended that the rule could lead to an interruption in services when services are prescribed by an out-of-plan emergency room physician or by an out-of-network provider who is treating a Medicaid beneficiary because the MCO or PHP does not have an available provider in the network; the MCO or PHP pays for the service although it is prescribed by an out-of-network provider; a beneficiary is receiving out-of-network family planning services; or an enrollee, while continuously eligible for Medicaid, either changes MCOs or PHPs or joins an MCO or PHP (from fee-for-service or PCCM) during a course of treatment.

Several commenters recommended that the regulation be amended to trigger continued services regardless of whether the provider requests the

service. They contended that there is a direct financial conflict of interest between a provider employed by a MCO or PHP (or contracting with a MCO or PHP) and the patient. These commenters also said that MCO and PHP doctors base treatment decisions, in part, on MCO and PHP guidelines and receive bonuses if they meet performance goals that may include utilization criteria.

Response: For continuation of services to apply, the services must have been previously authorized. This final rule with comment period uses the term ''authorized provider'' rather than ''MCO or PHP physician'' to address some of the concerns expressed by the commenters. We note, with respect to the example of emergency services cited by the commenters, that in section 1932(b)(2)(A)(ii) of the Act, the Congress has provided MCOs with the right to decide whether to authorize out of network ''post-stabilization services'' once an emergency medical condition has been stabilized. The Congress contemplated that services would only be covered by Medicaid if authorized by the MCO, or covered under the post-stabilization guidelines in cases in which the MCO does not respond timely to a request for coverage authorization. To the extent the MCO or PHP does not authorize continued services by a non-network provider, it must assume responsibility for the services through a network provider, so there would be no interruption in needed services.

Where services were not covered in the first place because they were not authorized or covered as emergency services or post-stabilization services, there could be no ''right'' to continuation of coverage, even if the services would be covered under the State plan for a beneficiary not enrolled with an MCO or PHP. We therefore disagree with the commenters who suggested that it violated due process to require MCOs and PHPs to provide continuation of services only when the services in question were authorized in the first place.

However, if services are covered under Medicaid, under this final rule with comment period, benefits must be continued if the beneficiary timely appeals a decision to terminate, reduce or suspend the services, regardless of whether or not the beneficiary is enrolled in a MCO or PHP. We note that this includes instances in which the services were begun by a provider under the fee-for-service system, but a MCO or PHP made a decision to terminate, reduce, or suspend them. These beneficiaries' rights to continued care are addressed under regular fee-for-service rules, and it is the State that is obligated to ensure that these rights are enforced. States should specify in their contracts with MCOs and PHPs whether the MCO, PHP, or the State will assume financial responsibility for these services under these circumstances. We note that § 438.62(b) requires that States have a mechanism in effect to ensure continued access to services when an enrollee with ''ongoing'' health care needs is transitioned from fee-for-service to managed care.

Benefits must be continued by the MCO or PHP in the following situations, (this assumes that the benefits are included in the MCO or PHP contract): (1) the MCO or PHP pays for services prescribed out-of-plan; (2) services are prescribed by an outside specialist who is treating the enrollee with the MCO's or PHP's knowledge and consent; (3) family planning services are being received from a provider who is not part of the MCO or PHP network, and family planning services are covered under the MCO or PHP contract; and (4) in rural areas, where individuals are, by law, permitted to seek out-of-network services/providers, for example when the service or provider is not available within the MCO or PHP. If the benefit is not included in the MCO or PHP contract, the State must pay to continue the benefits.

Comment: Several commenters requested that we delete the requirement that the beneficiary must request continued benefits. They contended that this requirement was constitutionally defective in that they believed continued benefits, without pre-requisites to obtaining them, to be a cornerstone of due process.

The commenters noted that the existing regulation at 42 CFR 431.230(b) provides for the possibility of recoupment, yet benefits are continued when an appeal is filed timely. The commenters found no reason to change this long-standing rule for beneficiaries who are receiving services through an MCO or PHP.

Response: We do agree with the commenters view that beneficiaries should not be required to specifically request continuation of benefits. We continue to believe that beneficiaries should have to request continuation as they may be held liable for services if the final decision is not in their favor. We have provided that enrollees be notified that they may incur a financial liability if their appeal is unsuccessful. As in the case of the fee-for-service regulations, benefits will only be continued if the enrollee files a timely appeal. This is a ''prerequisite'' to obtaining them which has been upheld in the courts as consistent with due process.

Comment: Several commenters expressed concern that beneficiaries may request continuances of State fair hearings, and extend the period during which benefits will continue. They recommended that the final regulation specify the grounds on which an enrollee may request a hearing continuance. If a continuance is granted for reasons other than good cause, these commenters believed that the MCO or PHP should not be obligated to continue to provide services during the period of the continuance.

Response: We do not agree that we should specify when a State fair hearing officer may grant a continuance, as we believe that this should be left to the hearing officer's discretion, as is the case under fee-for-service Medicaid. The State Medicaid Manual at 2900 permits the State fair hearing officer to grant one continuance of up to 30 days.

Comment: Several commenters recommended that we establish parameters for the liability of MCOs and PHPs for care provided pending the outcome of the hearing. Commenters wanted to work with HCFA to develop this provision. They stated that MCOs and PHPs should be compensated appropriately if they are required to provide services, and the hearing decision upholds the MCO's or PHP's determination.

Some commenters believed that it would be unrealistic to assume that an MCO or PHP would be able to collect payment for services from an enrollee if the final decision is not in their favor. They noted that Medicaid beneficiaries generally do not have the financial resources to pay, and MCOs and PHPs thus should be able to recoup payment from a provider, with the provider then billing the enrollee. They believed that this process would add to the administrative burden of the MCO or PHP and the provider.

One commenter recommended that MCOs and PHPs should be paid their costs for providing services during the hearing process if the enrollee is unsuccessful at the State fair hearing and the MCO or PHP is unsuccessful in collecting from the enrollee.

Another commenter recommended that MCOs and PHPs be reimbursed on a fee-for-service basis for services provided during the time taken for the appeal and State fair hearing.

One commenter asked that this section be amended to limit the responsibility of enrollees for services provided that are the subject of the appeal, rather than all services provided during this time period.

Several commenters were concerned that MCOs and PHPs would use the requirement that enrollees be told of their potential liability for payment for services continued to intimidate enrollees from using the grievance process. These commenters noted that, under the fee-for-service system, States seldom try to recover the cost of services from a beneficiaries, but under a managed care system, the MCOs and PHPs are more likely to attempt recovery to avoid financial losses.

Response: States, in their contracts with MCOs and PHPs, have the flexibility to determine what entity is responsible to cover costs of services continued through an appeal. We believe that States are in the best position to decide what entity should pay. They may prefer to take this into account in setting capitation rates for MCOs and PHPs or may prefer to pay for these services directly.

The current requirement in the Medicaid fee-for-service program is that beneficiaries who lose their appeal at the State fair hearing level are liable for the costs of the services continued during the appeal. Enrollees must be told of their potential liability in order for them to make an informed choice about whether or not to accept continued services. Section 438.408(i)(4) of this final rule with comment period thus requires written notice of this potential liability, and the option to refuse continued benefits. Enrollees are not liable for all services provided during this time period, but only for services continued because of their appeals. We have clarified the language on this point in the regulation (§ 438.420 (e)). FFP is available to States for payments for services continued pending a State fair hearing decision. Likewise, if the MCO or PHP is unable to collect from the enrollee after a good faith effort, FFP is available to the State under § 431.250(a) for payments for services continued pending a hearing decision.

10. Effectuation of Reversed Grievance Resolutions (Proposed § 438.421)

Proposed § 438.421(a) provided that if the MCO or PHP decides an appeal (called a grievance in the proposed rule) in favor of the enrollee, the MCO or PHP was required to authorize or provide the service under dispute as expeditiously as the enrollee's health condition requires, but no later than 30 calender days after the date the MCO or PHP receives the request for reconsideration. Furthermore, under proposed § 438.421(b), if the MCO's or PHP's decision on a appeal was reversed under the State fair hearing process, the MCO or PHP must authorize or provide the disputed service as expeditiously as the enrollee's health condition requires within time frames established by the State, but no less than 60 calendar days from the date the MCO or PHP receives notice reversing the MCO's or PHP's decision to deny.

Comment: Several commenters disagreed with the time frames in the proposed rule for providing a service, which depended on whether the beneficiary won the appeal at the MCO or PHP (30 days to provide the service), or at the State fair hearing (60 days to provide the service). Another commenter believed that the time frames should take into consideration the appropriateness of the procedure or treatment for the individual, as there may be cases in which providing the service within 30 days may not be clinically appropriate for the enrollee. The commenter further noted that external factors for example, scheduling and bed availability may affect the time frame for providing treatment. Several commenters supported the elimination of time frames because in the view of these commentators, beneficiaries with successful appeals should not have to wait at all following the decision.

Response: We agree that MCOs and PHPs should remove barriers to receipt of the services and take into account the needs of the individual. Therefore, in response to the above comments, we are eliminating the time frames in proposed § 438.421 (§ 438.424 in this final rule with comment period), and requiring that the services be provided as soon as required to meet the needs of the beneficiary. This is consistent with the State fair hearing policy in 42 CFR 431.246.

Comment: One commenter asked that we hold States, MCOs, and PHPs financially responsible for the cost of services inappropriately withheld if the enrollee obtains them outside the network and their appeal is upheld. The commenter believed that failure to provide for this remedy could encourage States, MCOs, and PHPs to refuse expensive care until after an appeal is resolved.

Response: We agree with these commenters. In response to this comment, we have provided in § 438.424(b) of this final rule with comment period that the State, MCO, or PHP must pay for services denied to an enrollee when the enrollee received the services and later won an appeal of the denial.

11. Monitoring the Grievance System (Proposed § 438.422)

In proposed § 438.422, we required the MCO, PHP, and the State to use the grievance and appeal logs (called complaint and grievance logs in the proposed rule) and annual appeal summary required under § 438.416 for contract compliance and quality monitoring. At a minimum, proposed § 438.422 required that the contract between the State and the MCO or PHP require that logs be reviewed and summarized for trends in grievances and appeals by provider or by service, and the requirement that MCOs and PHPs conduct follow up reviews, report results to the State, and take corrective action when necessary.

Comment: One commenter requested that HCFA either define the term ''undesirable trend'' or delete the term.

Response: We agree that the term ''undesirable trend'' is vague. We now require in § 438.426(b) that when the MCO or PHP identifies through trends in the data collected in § 438.416(b) that systemic changes are needed, the MCO or PHP must investigate, report the results to the State, and take corrective action.

Comment: One commenter requested that we mandate that States conduct random reviews of service denial notifications to ensure that MCOs and PHPs are notifying members in a timely manner.

Response: We agree that States should monitor service denial notifications to ensure that MCOs and PHPs are notifying members in a timely manner. This should be an integral part of each State's Quality Improvement Strategy and contract compliance monitoring. We believe that States are in the best position to determine the timing for this monitoring.

Comment: Several commenters requested that we modify this section to require States to require MCOs and PHPs to take corrective action if numerous grievances are filed concerning the same issue.

Response: As part of the State's quality strategy, which includes monitoring MCO and PHP grievances and appeals, States are required to take corrective action when needed to remedy problems.

Comment: Several commenters felt that the requirement to identify trends by provider constitutes a serious breach under State law of the peer review processes and legal privileges. They believed that these issues can be monitored appropriately by the States without requiring reports.

Response: We agree that Federal requirements that require MCOs and

PHPs to report on undesirable trends relating to providers is not appropriate, and we have revised the rule to delete this requirement. States, at their option, may develop provider grievance and appeal profiling requirements that are consistent with State laws concerning peer review.

12. Consequences of Noncompliance (Proposed § 438.424)

Comment: We received many comments that this section confused readers, particularly with respect to the types of sanctions States could impose on MCOs and PHPs.

Response: We have eliminated this proposed section from this final rule with comment period. This section was intended to emphasize the importance of MCOs' and PHPs' compliance with the provisions of this Subpart. It did not convey any authority or responsibility to the States, MCOs, or PHPs.

F. Certifications and Program Integrity Protections (Subpart H)

Background

We believe it is important for MCOs to develop effective internal controls to fight fraud and abuse and to ensure quality of health care services to Medicaid beneficiaries. Administrative and management procedures, including a compliance plan, address specific areas of concern or potential areas of risk for MCOs. It is in the best interest of MCOs, State agencies, and HCFA to make a commitment to an effective administrative and management arrangement that will significantly aid in the elimination of fraud and abuse.

By requiring certification of the accuracy of data used to determine payments, of information contained in contracts, proposals, and other related documents submitted to State agencies, and of administrative and management procedures designed to prevent fraud and abuse, we are working to promote program integrity, protect Medicaid managed care enrollees, and protect Medicaid government funds.

Subpart H of proposed part 438, Certifications and Program Integrity Provisions, contains safeguards to promote program integrity within Medicaid managed care programs. We have proposed that these rules apply only to MCOs, as they were not made applicable to PHPs under proposed § 438.8.

Proposed § 438.600 sets forth the statutory basis for the requirements in subpart H, which is based on section 1902(a)(4) of the Act. Proposed § 438.600 permits us to find methods of administration that are ''necessary for proper and efficient administration'' of the plan. The requirements in subpart H are also based on section 1902(a)(19) of the Act, which requires that States provide safeguards necessary to ensure that eligibility will be determined and to provide services in a manner consistent with simplicity of administration and the best interests of recipients.

Proposed § 438.602 requires that when State payments to an MCO are based on data submitted by the MCO, which include enrollment information and encounter data, the MCO must, as a condition for receiving payment, attest to the data's accuracy, completeness, and truthfulness. Proposed § 438.606 requires that an entity seeking an MCO contract have administrative and management arrangements or procedures designed to prevent fraud and abuse, which include reporting to the State, HCFA, or OIG (or both) credible information on violations of laws by the MCO or its subcontractors or enrollees. In the case of enrollee's violations, this proposed requirement only applies if the enrollee's violations pertain to his or her enrollment, or to provision or payment for health services.

Proposed § 438.608 sets forth a separate certification requirement, requiring that MCOs certify the accuracy, completeness, and truthfulness of information in contracts, requests for proposals, and other related documents specified by the State.

Comment: One commenter suggested that the program integrity requirements in subpart H apply to all MCOs/primary care case managers (PCCMs), not just MCOs.

Response: We agree with the commenter that the requirements in subpart H should have applicability beyond MCOs. The commenter suggested that primary care case managers should be subject to these requirements. We agree with this recommendation to the extent the PCCM is paid on a risk basis as the MCOs that were the subject of subpart H. In this case, payments may also be based on encounter data submitted by the entity, and the same types of incentives and potential for fraud and abuse apply. However, in the case of a PCCM paid a fixed monthly case management fee, payments for services furnished to an enrollee are paid under the existing State plan payment process, which is subject to existing fraud and abuse protections that apply generally to providers that bill Medicaid. In order to identify only those PCCMs and other non-MCO entities that are paid on a risk basis, we are revising § 438.8 to require that PHPs comply with the program integrity requirements in subpart H.

Comment: One commenter requested clarification as to whether subpart H applies only to MCOs operated under a State plan option or to both those operated under a State plan option and those operated under a waiver program.

Response: The requirements of subpart H apply to MCOs, whether the MCO or PHP operates under a waiver program, a mandatory managed care program, or a voluntary program.

Comment: Several commenters believe that requiring certification of data as 100 percent accurate and complete is unworkable and not customary. The commenters suggested that this provision does not recognize the impossibility of meeting an absolute standard, that this provision should be changed to correlate with more commonly accepted standard language on certifications and to correlate with the language adopted by the Medicare+Choice program.

Response: We recognize that requiring attestation that data is 100 percent accurate may not be feasible. We believe that it is important to ensure accurate data submissions. Because this information may directly affect the calculation of payment rates, we are amending the regulation to be consistent with the current language being adopted in the Medicare+Choice provisions; that is, we will require that attestations be ''based on best knowledge, information, and belief.'' We have restructured and recodified some of the provisions of proposed subpart H. The revised certification requirement containing the Medicare+Choice language is now in § 438.606(b). These certifications will assist HCFA, State agencies, and OIG in combating fraud and abuse and in investigating and prosecuting suspected cases of fraud as authorized by the False Claims Act.

Comment: One commenter believes that the relationship between the submission of data and Medicaid payments is neither clear nor uniform and that there may be a tenuous connection between the State's reliance on the substance of the data and its payments to the MCO. The commenter also believes that certification of data fails to address incentives for underutilization and permits Medicaid payment for coverage of services that the MCO may not actually be providing. This commenter recommended that the MCO's payments be based upon filing a ''claim'' for these payments, certifying the data on which payments may be based, and whether the MCO substantially meets its contract requirements.

Response: Not all States base payments to MCOs on encounter data or on enrollment data submitted by the MCO. In this case, the certification requirement in proposed § 438.604(a) would not apply as it only applies to data when payments are based on the data. If it is not clear that there is a connection between given data and payment, those data may not have to be certified. We believe it is important that data are certified as accurate, at least to the best of the MCO's belief, if payment to that MCO will be based on these data. Submission of data that are complete and accurate will provide the State with information needed to set actuarially sound capitation rates. We disagree with the commenter that underutilization is not addressed at all, as encounter data can be used by States to identify and address underutilization and the potential for payments made for services not furnished. While we do not require States to collect encounter data from MCOs, we believe this is becoming a State requirement. It is unclear how the commenter's first recommendation concerning basing payment on filing a claim and certifying data associated with the claim relates to the commenter's concern for underutilization or how the recommendation differs from the requirements in subpart H. We agree with the commenter that MCOs should be required to certify that services are being provided in substantial compliance with their contracts, since under § 438.802(c) of this final rule (discussed in section II.H of this final rule) FFP is only available in contract payments if the MCO is in substantial compliance with its contract. We have revised §§ 438.604 and 438.606 to provide for this certification.

Comment: Several commenters believe the data should be certified by the Chief Executive Officer (CEO) or the Chief Financial Officer (CFO) whom they believe would have actual knowledge of the accuracy, completeness, and truthfulness of the data and believe that this requirement would force the MCOs to establish procedures and protocols to ensure that the information is correct. These commenters believe that problems arise when the person signing the certification may not have direct information concerning these facts, and that the CEO or CFO should certify the accuracy of the data on a document, a requirement similar to that in the Medicare+Choice program.

Response: We agree with these commenters that an accountable individual such as the CEO or CFO should sign the certification, and we accept the commenters' suggestion that the Medicare+Choice requirement be adopted. Under § 422.502(l) of the Medicare+Choice regulations, certifications must be signed by ''the CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to such officer.'' We have adopted this language in § 438.606(a)(2) of this final rule.

Comment: Several commenters urged that related entities, contractors, or subcontractors that generate these data should be required to certify the accuracy, completeness, and truthfulness of the data.

Response: We agree with these commenters, and we are providing (1) in § 438.602 that an MCO ''and its subcontractors'' must comply with the certification requirements in subpart H; and (2) in §thnsp;438.606(a)(1) that MCOs must require subcontractors to certify the data they submit to MCOs if the data are used in determining the MCO's payment.

Comment: Another commenter believes that the large majority of data on which payment is based is determined by the State agency and not by the MCO. Regardless of the billing data submitted by the plan, the commenter believes the State determines the payment to the MCO based on information within the State system and the certification of the accuracy of the data should be applied equally to the State agency.

Response: The purpose of the certification requirement with respect to data submitted to the State by the MCO is to ensure that MCOs do not submit false or inaccurate data that might result in inappropriate higher payment amounts. It is a protection for the State and HCFA against being defrauded, or paying an MCO more than the amount to which it should be entitled. The State has no incentive to pay more than the amount dictated by accurate information, and has existing incentives to use accurate data. A major purpose of the certification requirement is to facilitate possible cases under the False Claims Act. States are not subject to the False Claims Act. States are subject to detailed requirements in § 438.6(c) requiring that payments are accurate and appropriate. We do not believe that States should have to certify data. However, if payment is based solely on State data, and an MCO does not submit any data upon which its payment is based an MCO would not have to sign certifications under subpart H.

Comment: One commenter believes that data integrity is critical but was still unclear on certification requirements.

Response: We believe that this final rule clearly spells out which data must be certified (§ 438.604), who must certify the data (§ 438.606(a)), and to which data the certifying individual is attesting (§ 438.606(b)). We believe that the requirements of these regulations are clear. We believe that imposing more detailed requirements than already set forth in this final rule would be overly prescriptive and that States should have flexibility in applying these requirements.

Comment: One commenter believes that the State Medicaid Fraud Control Units (MFCUs) should be added to the list of parties to whom the MCO must submit the reports required in § 438.606.

Response: We did not identify the MFCUs as a recipient of the reports on the violations of law because States are already required under 42 CFR 455.21 to refer to the MFCU all cases of suspected provider fraud, including such materials as records or information kept by the State Medicaid Agency or its contractors, computerized data stored by the Agency, and any information kept by providers to which the State Medicaid Agency is authorized access. States already have established relationships with MFCUs relative to referring cases of suspected fraud and abuse. We believe this requirement is already sufficiently addressed, and we have not revised this aspect of the proposed rule.

Comment: One commenter suggested that administrative and management arrangements or procedures should include specific plans for the method by which the MCO intends to discover and discourage fraud and abuse and that these specific plans should be submitted to the State Medicaid Agency for review and prior approval before execution of any contract. The commenter believes that specific plans would eliminate subjective determinations by each MCO of that which constitutes effective arrangements and management procedures.

Response: We believe that it is appropriate to allow States flexibility in determining their requirements for MCOs in this regard. We also note that States may have laws that govern this authority, and we wish to respect those laws.

Comment: One commenter noted differences between the language in proposed § 438.606 requiring only that MCOs have a process for reporting violations of law and language in §422.501(b)(3)(vi) of the Medicare+Choice interim final rule published on June 28, 1998 requiring that Medicare+Choice organizations have a comprehensive compliance plan

that includes an ''adhered-to'' process for reporting credible information to HCFA and/or OIG. The commenter recommended that HCFA adopt the Medicare+Choice language in §422.501(b)(3)(vi). The commenter believes consistency between Medicare and Medicaid will reduce the regulatory burden on managed care plans that elect to participate in both programs by eliminating any uncertainty as to what standard of conduct applies. A few commenters raised concerns about the general requirement that MCOs have ''administrative and management arrangements or procedures designed to guard against fraud and abuse.'' Instead of imposing Federal requirements in this area, such as self-reporting, the commenter believes the rule should allow States to take the lead in working with MCOs to combat fraud and abuse in the Medicaid program.

Response: We agree with the first commenter that maintaining consistency with Medicare+Choice will eliminate unnecessary burden on plans and that administrative and management procedures that include a compliance plan will work toward that end. We have included a compliance plan that includes the same elements as those listed in the Medicare+Choice final rule published on June 29, 2000 (65 FR 40170). We disagree with the second commenter that there should be no Federal requirements, but, consistent with the commenter and consistent with the Medicare final rule, which deleted the mandatory self-reporting requirement in§422.501(b)(3)(vi)(H), we have deleted this requirement. The Medicaid MCO requirements and Medicare+Choice requirements are now consistent on this issue.

Comment: A few commenters raised concern over the term ''credible'' information. One commenter believes the word ''credible'' should be replaced with the standard contained in § 455.15, specifically that if there is ''reason to believe that an incident of fraud or abuse has occurred,'' MCOs are required to report this to the State. One commenter believes the word ''credible'' should be eliminated entirely so that MCOs are not penalized for reporting in good faith information that is later found not to be credible.

Response: We have deleted the Federal self-reporting requirement containing the word ''credible,'' so these comments are moot.

G. Sanctions (Subpart I)

Section 1932(e)(1) of the Act requires, as a condition for entering into or renewing contracts under section 1903(m) of the Act, that State agencies establish intermediate sanctions that the State agency may impose on an MCO that commits one of six specified offenses: (1) Failing substantially to provide medically necessary services; (2) imposing premiums or charges in excess of those permitted; (3) discriminating among enrollees based on health status or requirements for health care services; (4) misrepresenting or falsifying information; (5) failing to comply with physician incentive plan requirements; and (6) distributing marketing materials that have not been approved or that contain false or materially misleading information. In the case of violation number 6, the statute imposes sanctions against PCCMs as well as MCOs. Proposed § 438.700 contains the above provisions from section 1932(e)(1)of the Act.

In section 1932(e)(2) of the Act, the Congress provided specific sanction authority under which State agencies may impose civil money penalties in specified amounts for specified violations, take over temporary control of an MCO, suspend enrollment or payment for new enrollees, or authorize enrollees to disenroll without cause. These provisions are reflected in proposed § 438.702(a). Given the extraordinary nature of the sanction of taking over management of an MCO, we proposed in § 438.706 that this sanction be imposed only in the case of ''continued egregious behavior,'' in situations in which there is ''substantial risk'' to enrollee health, or when the sanction is ''necessary to ensure the health of enrollees.''

Although these sanctions are referenced in section 1932(e)(1) of the Act as sanctions to be imposed on MCOs and on PCCMs only in the case of marketing violations, section 1932(e)(2)(C) of the Act refers to a ''managed care entity,'' while paragraphs (D) and (E) that follow refer to ''the entity'' and provide for suspension of enrollment or suspension of payment after the date the Secretary notifies ''the entity'' of a determination that it has violated ''section 1903(m) or * * * section [1932].'' While only an MCO could violate section 1903(m) of the Act, a PCCM could violate requirements of section 1932 of the Act that apply to MCOs and PCCMs generally or to PCCMs specifically. In proposed § 438.702(b)(2), we interpret the foregoing language to mean that the sanctions in sections 1932(e)(2)(D) and (E) of the Act are available in the case of a PCCM that violates ''any requirement'' in section 1932 of the Act. The general intermediate sanction authority in paragraphs (D) and (E) of section 1932(e)(2) of the Act is reflected in § 438.702(b)(1) with respect to MCOs. In light of the foregoing interpretation, paragraphs (b)(4) and (b)(5) of § 438.702 use the term MCO or PCCM rather than MCO only, even though the only ''determinations'' that apply to PCCMs are terminations under proposed § 438.700(a)(6) (marketing violations) or the general violations of section 1932 of the Act that are addressed in § 438.702(b)(2). Under the codification in the proposed rule, these latter determinations technically are not ''determinations under § 438.700,'' and are not included under paragraphs (b)(4) and (b)(5) of § 438.702. As recodified in this final rule, these determinations are addressed in § 438.700(d).

Section 1932(e)(3) of the Act requires that, for MCOs with chronic violations, the State impose temporary management and allow disenrollment without cause. This provision is implemented in proposed § 438.706(b).

Section 1932(e)(4) of the Act authorizes State agencies to terminate the contract of any MCO or PCCM that fails to meet the requirements in sections 1932, 1903(m), or 1905(t) of the Act. This authority is implemented in proposed § 438.708. Under section 1932(e)(4)(B) of the Act, before terminating a contract, the State is required to provide a hearing. Proposed § 438.710 sets forth this hearing requirement as well as procedures for the hearing. Under section 1932(e)(4)(C) of the Act, enrollees must be notified of their right to disenroll immediately without cause in the case of any enrollee subject to a termination hearing. Proposed § 438.722 reflects this provision.

Section 1932(e)(5) of the Act contains a general requirement that States provide ''notice'' and ''such other due process protections as the State may provide'' in the case of sanctions other than terminations, which are governed by section 1932(e)(4)(B) of the Act. Section 1932(e)(5) of the Act also provides that ''a State may not provide a managed care entity with a * * * hearing before imposing the sanction'' of temporary management. Proposed § 438.710(b) reflects this statutory language.

In proposed § 438.724, we proposed that States be required to notify HCFA whenever they impose or lift a sanction.

The new sanction authority in section 1932(e) of the Act represents the first time that the Congress has granted Medicaid sanction authority directly to State agencies. Under section 1903(m)(5) of the Act, which the Congress has left in place, HCFA has authority to impose sanctions when Medicaid-contracting MCOs commit

offenses that are essentially the same as those identified in section 1932(e)(1) of the Act. In proposed § 438.730, we retain the existing regulations implementing section 1903(m)(5) of the Act, which is currently codified at § 434.67.

Comment: A few commenters recommended that we add the requirement: ''States shall develop criteria to guide them in their determinations of when and how to use specific sanctions individually or in conjunction with each other.''

Response: While section 1932(e) of the Act mandates that States establish intermediate sanctions, it grants States flexibility to determine which sanctions to impose and when to impose them, stating that State sanctions ''may include'' those identified in section 1932(e)(2) of the Act and that the State ''may impose'' these sanctions. We believe that the Congress intended to give States discretion and flexibility in this area. While we would expect that most States would establish specific criteria to guide their exercise of sanction authority, we believe it should be a State decision whether or to what extent it imposes sanctions. We are not including the suggested Federal criteria requirement.

Comment: One commenter suggested that we provide expressly in subpart I that sanctions be imposed for violations of proposed § 438.100, which require that contracts specify what services are included in the contract and require that States make arrangements for those not covered through the contract. The commenter believes that this would help ensure access to all Federally mandated benefits and services, including nurse-midwifery services.

Response: The Congress intended that States have flexibility in imposing sanctions, requiring only that States have sanctions in place for the specific violations in paragraphs (i) through (v) of section 1932(e)(1)(A) of the Act. Our authority under section 1903(m)(5) of the Act is similarly limited. Even under our broad interpretation of paragraphs (D) and (E) of section 1932(e)(2) of the Act, under which States may impose intermediate sanctions for any violation of sections 1903(m) or 1932 of the Act, the sanctions suggested by the commenter would not be provided for since neither of these sections mandate the inclusion of the contract terms required under proposed § 438.100(a) or impose the obligation on States under proposed § 438.100(b). If services that are included in the contract are not provided, sanctions are authorized under § 438.700(a)(1).

Comment: One commenter supported the provisions in subpart I but suggested that misrepresentation to any member of the public should also be cause for sanction.

Response: Sections 438.700(b)(4) and (5) allow States to impose sanctions on MCOs for misrepresenting or falsifying information that they furnish to HCFA, the State, an enrollee, potential enrollee, or health care provider. This provision implements section 1932(e)(1)(A)(iv) of the Act, which specifies these entities. It is not clear how a misrepresentation to a member of the public who is not a provider, enrollee, or potential enrollee would be relevant. We believe that this list covers any individual, government agency, or entity that could be affected by a misrepresentation. States are free to develop, under State law, a policy to require sanctioning for misrepresentation to any member of the general public.

Comment: One commenter had serious concerns about what the commenter perceived to be the absence of adequate Federal, as opposed to State, standards on the rights to be afforded to MCOs to contest sanctions. Although this aspect of the rule reflects section 1932(e)(5) of the Act, which leaves the decision on what due process protections to provide to MCOs to the States, the commenter believes that States should be encouraged to provide MCOs the same procedural protections that HCFA has provided to Medicare+Choice organizations before HCFA imposes sanctions.

The commenter was also concerned about potential conflicts between the intermediate sanctions required under the Act and the provisions of State law. This commenter also applauded the proposed rule allowing MCOs to be sanctioned for not providing medically necessary services to Medicaid enrollees. Regarding discrimination among enrollees on the basis of health status or need for health care services, the commenter recommended that all health insurance policies fulfill the following requirements: (1) no waiting periods for enrollment; (2) no limitation of coverage or reimbursement because of severe chronic or common recurring illnesses; (3) no premium rate increases based on experience only on community rating; and (4) guaranteed renewability and portability.

Response: The statute requires timely written notice, a hearing before terminating an MCO contract, and in the case of other sanctions for ''such other due process protections as the State may provide.'' The commenter recognizes that the Congress has expressly granted States the discretion to determine what procedures to afford to MCOs in the case of intermediate sanctions and civil money penalties. We agree with the commenter that States should be encouraged to consider offering the types of procedures offered to Medicare+Choice organizations under the Medicare regulations. We do not agree that there is a risk of conflict between the intermediate sanctions authority in subpart I and provisions of State law, because these sanctions have to be established only if State law does not cover the specified situations. With regard to the commenter's suggestion concerning discrimination, we believe that the regulations address these issues. In the case of the ''waiting period'' issue, § 438.6(c)(1) requires that enrollees be accepted in the order in which they apply without restrictions. With respect to the issues of coverage limits or premium increases based on a health condition, § 438.6(c)(1) addresses the provision prohibiting discrimination based on health status or need for health services. Section 438.6(c)(1) also addresses the issue of renewability to the extent that the individual remains Medicaid eligible and the contract remains in place. Since Medicaid only covers people who meet financial eligibility requirements, it is impossible to guarantee renewability. ''Portability'' of Medicaid benefits is similarly impossible.

Comment: A commenter suggested that subpart I should address the issue of inadvertent balance billing of Medicaid enrollees. There are no guidelines that would enable the State agency or contracting MCOs to differentiate minor technical violations from those that should result in sanctions and fines of several thousand dollars. The regulations should develop criteria to guide this kind of decision making and to protect MCOs from arbitrary State action.

Response: Under section 1932(e) of the Act, imposition of sanctions is almost entirely at a State's discretion, other than termination and temporary management rules. We believe that States are in the best position to develop criteria for when they will impose sanctions for balance billing violations, which could be sanctioned under section 1932(e)(1)(A)(ii) of the Act and § 438.700(b)(2) (codified at § 438.700(a)(2) in the proposed rule) as ''charges on enrollees'' in ''excess of'' the charges permitted under title XIX.

Comment: A commenter stated that section 438.700, which specifies the basis on which States may impose intermediate sanctions on an MCO, should include discrimination based on race, ethnicity, or language. This would

be in keeping with Title VI of the Civil Rights Act which states that ''no person in the United States shall, on ground of race, color or national origin, be excluded from participation, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance.'' Several of the commenters stated that the omission of Title VI requirements from the list of sanctionable activities reduces the likelihood that MCOs will comply with cultural competency requirements. It is also very important that the rules strengthen the requirements for both State Medicaid agencies and their managed care plans to collect data regarding the race/ethnicity of the enrollees and the care of patients with limited proficiency and/or low literacy. The commenter recommended amending proposed § 438.700(a)(3) (recodified at § 438.700(b)(3) in this final rule) to read, ''Acts to discriminate among enrollees on the basis of their health status, race, color or national origin, or requirements for health care services.''

Response: Section 438.700(b)(3) reflects the language in section 1932(e)(1)(A)(iii) of the Act, which addresses only discrimination based on health status. Since § 438.700(b) reflects the specified violations for which the Congress in section 1932(e)(1)(A) of the Act said States must have sanctions, we believe that we do not have authority under section 1932(e) of the Act to add additional grounds. The civil rights law cited by plaintiffs has its own enforcement provisions, which are administered by the HHS Office for Civil Rights. We believe that it is appropriate to inform MCOs of their obligations under this and other civil rights laws and have required under revised § 438.6(d)(4) that contracts expressly reflect these obligations. Also, § 438.100(d) specifies that the State must require MCOs to comply with Title VI of the Civil Rights Act and other civil rights laws. In addition to the Federal enforcement remedies under civil rights laws, States are free to impose sanctions on an MCO that denies services on the basis of race, color, or national origin, or establish their own rules under State law.

Comments: In general, several commenters wanted the regulation to be clear that States have the authority to impose sanctions for violations beyond those that are listed in the regulation. These commenters do not believe that the six violations listed in this section should be seen as exhaustive and that States should not be precluded from establishing and imposing separate State sanctions or from imposing other types of sanctions. These commenters believe that while our intent may have been clear in the preamble, we should set forth our policy with respect to sanctions in the regulations text. Specifically, the commenters stated that it is unclear whether the regulations allow States to broaden the parameters for imposing sanctions on MCOs or limit the States to the basis set forth in the Act and the regulations. States have made progress in developing their own protections and responses to hold MCOs accountable and should not be preempted by Federal law from using them. They stated that we recognized this concept in the preamble of the proposed rule and suggested that we incorporate this concept into the actual regulations text. They believe that the six offenses outlined in the regulation should not be the only offenses that would permit imposition of sanctions. There are numerous offenses that MCOs could commit that could affect both the integrity of the Medicaid program and the quality of care that Medicaid enrollees receive, for example, failure by the plan to submit accurate data or failure to achieve State defined quality improvement standards. The commenters believe that we should not limit a State's ability to enforce its contract and should instead give States the explicit authority to impose sanctions if an MCO performs unsatisfactorily as found during an annual medical review or audit or if an MCO does not provide complete data to a State or Federal regulator. Recommended solutions provided by the commenters included the following:

- Add a paragraph (a)(7) to § 438.700 stating that sanctions can be used for violations of 1903(m) and 1932 of the Act;
- Add a new paragraph (c) to § 438.700 that specifies: ''State agencies retain authority to provide for additional sanctions under State law or regulation that address both these specified areas of noncompliance as well as additional areas of noncompliance. Nothing in this regulation prevents State agencies from exercising that authority;''
- Add a new paragraph (a)(7) § 438.700 that allows States to impose sanctions for any breach of contract not mentioned in paragraphs (a)(1) through (a)(6);
- Amend § 438.700(a) to specify that the sanctionable violations include, but are not limited to, the specified violations;
- Add to § 438.700(a), after the word ''determination,'' ''based on findings from onsite survey, enrollee, or other complaints, financial audits, or any other means.'' This language clarifies that the State is authorized to act based on findings it has made, regardless of the source of the original information. Broad authority for the State to sanction on the basis of complaints provides enrollees with assurances that the State can hold the entity accountable for specific acts of noncompliance that enrollees or their advocates bring to the State's attention but that might not be evident on an onsite survey.

Response: We agree with the commenters that the sanctions in subpart I do not prevent States from imposing any other sanction they wish under State law, and that the regulations should clearly state that this is the case. We are adopting the commenter's suggested regulations text in a new paragraph (b) in § 438.702. We also agree that it would be useful to clarify that these sanctions may be imposed based on information obtained through enrollee complaints, audits, onsite surveys, or any other means and have added the commenter's suggested language to § 438.700(a).

We disagree with the commenters' suggestions that the list of sanctions in proposed § 438.700(a) be broadened or that the regulations provide for imposing the full range of possible sanctions in the case of any violation of section 1932 or 1903(m) of the Act. To the extent that a State is relying not on any State law, but solely on the affirmative authority enacted by the Congress in section 1932(e) of the Act, this authority is necessarily limited to that provided by the Congress. While we have broadly interpreted paragraphs (D) and (E) of section 1932(e)(2) of the Act to permit suspension of enrollment or payment for any violations of 1903(m) and 1932 of the Act (see § 438.700(d)) and the above discussion of proposed § 438.702(b), section 1932(e) of the Act does not contain authority to impose any of the other sanctions in section 1932(e)(2) of the Act for violations other than those enumerated in section 1932(e)(1)(A)(i) through (v) of the Act.

Comment: One commenter argued that we should amend § 438.700(a) to apply to PCCMs as well as to MCOs. This commenter does not believe there was a compelling argument for applying most sanctions only to MCOs. The commenter argued that PCCMs that fail to provide medically necessary services, misrepresent information provided to HCFA, the State, an enrollee, potential enrollee, or health care provider, or impose excessive premiums or charges on enrollees should be subject to sanctions. Another commenter strongly advised HCFA against drawing a

distinction between MCOs and PCCMs in granting the States authority to impose sanctions for inappropriate behavior. Other commenters also believe that the final rule should provide additional authority to impose sanctions on all MCOs and PCCMs and specifically suggested that the final rule gives States the authority to—

- Require noncompliant MCOs or PCCMs to submit a corrective action plan;
- Temporarily and permanently withhold capitation payments and shared savings in response to unsatisfactory MCO or PCCM performance during an annual medical review or an audited review;
- Make adjustments in MCO or PCCM payments;
- Mandate payment for medically necessary treatment;
- Recoup the cost of State payment for out-of-plan care from a noncompliant MCO or PCCM; and
- Arrange for the provision of health care services by third parties at the cost and expense of the delinquent MCO or PCCM.

These commenters believe that Medicaid beneficiaries in both delivery systems should receive equal protection under the law and that denying States equal authority for imposing sanctions under both delivery systems is not judicious. Conversely, one commenter found applying sanctions to PCCMs problematic because this would hold these entities to a higher standard. California PCCMs currently are not Knox-Keene licensed. This commenter was concerned that this section of the proposed rule may require PCCMs to become Knox-Keene licensed and/or their contracts may have to be amended to reflect the new higher standard.

Response: To the extent a State is relying solely on the Federal authority provided by the Congress as its authority to impose a sanction, this authority is limited to that which the Congress provided. With respect to the violations enumerated in paragraphs (i) through (v) of section 1932(e)(1)(A) of the Act, all but the marketing violations are limited to MCOs. We have already interpreted paragraphs (D) and (E) of section 1932(e)(2) of the Act broadly to permit the sanctions in those paragraphs to be imposed on PCCMs in the case of any violation of section 1932 of the Act. We do not believe that section 1932(e) of the Act can reasonably be interpreted to provide authority for the types of sanctions suggested by the commenter. Because most PCCMs are paid on a fee-for-service basis, they do not have the same incentives to deny medically necessary services that MCOs do. States may provide for sanctions against PCCMs under their own State sanction laws. With respect to the commenter concerned about applying sanctions to PCCMs, the Congress provided for this in section 1932(e) of the Act, and we do not believe that this application is inappropriate or would subject PCCMs to the Knox-Keene Act.

While States are free to adopt the specific additional enforcement strategies suggested by the commenter in the bullet points above, these strategies cannot be included in regulations implementing section 1932(e) of the Act, since there is no reasonable reading of the provisions of section 1932(e) of the Act that would authorize those remedies.

Comment: One commenter believes that HCFA should specify additional grounds for imposing intermediate sanctions and suggested that the final regulations explicitly state that States may impose sanctions when an MCO fails to comply with the grievance regulations of this part. States would be more likely to impose these intermediate sanctions rather than the options provided for in § 438.424.

Response: The sanction authority provided for by the Congress in section 1932(e) of the Act is limited. Section 1932(e) of the Act sets forth the minimum set of violations that must be subject to sanction and provides Federal authority to impose sanctions for these violations. We cannot expand on this authority by regulation. We have clarified in the preamble, and now in § 438.702(b), that States are free to impose sanctions under State law that go beyond those authorized by the Congress in section 1932(e) of the Act, including sanctions for failing to comply with grievance requirements. To the extent that an MCO violates the grievance requirements or regulations implementing section 1932(b)(4) of the Act, States could impose the limited sanctions provided for under paragraph (D) and (E) of section 1932(e)(2) of the Act and § 438.700(b).

Comment: One commenter believes that we should amend § 438.700(a)(1) to refer expressly to the failure to provide medically necessary ''items'' as well as services, since this term is included in section 1932(e)(1)(A)(i) of the Act. Alternatively, the commenter suggested that we use the term ''benefits'' rather than ''services,'' since the commenter believes that the former term would include services and items. For example, prescription drugs and durable medical equipment may not be considered ''services.''

Response: We do not use the term ''items'' in our regulations because the term ''services'' as used in the regulations includes covered ''items'' as well. While only the Medicare regulations expressly specify that ''services'' includes '' items'' (§ 400.202), section 1905(a) of the Act uses the term ''care and services'' to encompass all services or items for which Medicaid payment may be made. References in the regulations to ''services'' include covered ''items'' as well.

Comment: A few commenters were confused regarding our role in the sanction area. These commenters are unclear as to whether HCFA would be making sanction determinations, either at the request of the State or independently. The commenters are opposed to HCFA making sanction determinations without the involvement of the State.

Response: Under § 438.730 of the final rule, previously codified at § 434.67, we may impose sanctions on an MCO based on the recommendation of the State. Under paragraph (e) of § 438.730, we also retain the right to act independently with respect to sanctions. This is consistent with section 1903(m)(5) of the Act, which grants us the authority to impose sanctions against an MCO. This Federal authority was not affected by the new BBA sanction provisions in section 1932(e) of the Act. While we would not expect to impose sanctions without the involvement of the State, we believe that the regulations should reflect the fact that the Congress has authorized us to do so.

Comment: One commenter believes that additional consumer protections were needed with regard to the right to disenroll without cause when sanctions are imposed and that States should be required to educate enrollees on the circumstances that allow them to disenroll automatically. Another commenter requested that HCFA clarify that a State is free to suspend default enrollment, leaving beneficiaries to make an affirmative decision whether to enroll. Several other commenters suggested that HCFA further clarify this provision and give States the option of suspending all enrollment, not just default enrollment. According to the commenters, this clarification would not only provide States with greater flexibility but would also permit greater choice for Medicaid beneficiaries.

Response: Under § 438.702(a)(4) of the final rule, the State may suspend all new enrollment, including default enrollment, as an intermediate sanction. The State is not precluded from establishing other types of intermediate sanctions that are not included in the

regulation. With respect to the suggestion concerning information provided to enrollees, § 438.56(c) requires that information on an enrollee's disenrollment rights be provided annually, including the circumstances under which a beneficiary can disenroll ''for cause.''

Comment: Several commenters requested clarification that States still have the flexibility to establish civil money penalties beyond those listed in the regulation. One commenter specifically mentioned that the amounts of the civil money penalties seemed high but that they would not be problematic so long as the amounts were not mandatory. Another commenter mentioned that if PCCMs could be sanctioned, there should be a regulatory ceiling on the amount of the penalty.

Response: The amounts specified in this provision only apply to the extent the State is relying upon Federal law, under section 1932(e) of the Act, as its authority to act. States may, under State law, establish additional civil money penalties that may be more severe than those authorized under section 1932(e)(2)(A) of the Act or § 438.704. With respect to PCCMs, to the extent the State is relying on Federal law as its authority for the establishment of sanctions, the civil money penalties under § 438.704 would be maximum amounts. A State is not precluded from developing additional intermediate sanctions against PCCMs or MCOs, as explicitly noted in § 438.702(b).

Comment: One commenter believes that HCFA should provide additional guidance as to how the amount of the civil money penalty elected, in cases in which States have discretion to choose an amount below a specified maximum, should be related to the purported harm. The commenter believes that HCFA should provide some rationale for assessing money penalties and should discuss this section with the commenter to develop this rationale.

Response: Section 1932(e)(2)(A) of the Act establishes a relationship between the amount of the civil money penalty (as described in § 438.704 of the final rule) and the specific violations to which these penalties apply. In clauses (i) and (ii), ''maximum'' amounts are specified. We believe that by establishing a ''maximum'' amount for these violations, the Congress intended that States have the discretion to decide what amount to impose below these maximum amounts. We are allowing the States to decide the amount they wish to impose in penalties and to establish criteria for cases when particular amounts at or below the specified maximums will be imposed.

Comment: One commenter expressed confusion regarding the maximum penalty that can be imposed under section 1932(e)(2)(A)(iii) of the Act for imposing premiums or charges in excess of those permitted. Under section 1932(e)(2)(A)(iii) of the Act, for this type of violation, the penalty that can be imposed is double the amount of any excess amount charged to an enrollee with half this amount refunded to the overcharged enrollee or enrollees. The commenter asked whether this would be for the one enrollee who reported a $5 overcharge (that is, one $10 amount) or $10 per each enrollee in the plan. Another commenter suggested that the regulation should be changed to provide that it is the MCO's responsibility, not the State's, to return the amount of the overcharge to affected enrollees and that the authority to collect double the amount of the excess charge provides authority to collect more than the $25,000 limit stated in paragraph (a).

Response: Section 438.704(b)(4) of the final rule specifies that for premiums or charges in excess of the amounts permitted under the Medicaid program, civil money penalties may be imposed at an amount representing double the amount of the excess charges. This would be imposed for each instance of the violation and not necessarily calculated using the total number of enrollees in the plan. If all enrollees were charged the excess amount, this amount would be doubled for all enrollees. Since the State imposes and collects the entire fine, we believe that the State ordinarily would reimburse enrollees by distributing half the amount specified in section 1932(e)(2)(A)(iii) of the Act. We would leave it to the State's discretion, however, whether it wishes to reimburse enrollees through the MCO.

With respect to the commenter's last point about the applicability of the authority to impose $25,000 in penalties in cases of overcharges to enrollees, section 1932(e)(2)(A)(i) of the Act permits a civil money penalty of ''not more than'' $25,000 for ''each determination'' under section 1932(a)(1)(A) of the Act, ''except as provided in clause (ii), (iii), or (iv).'' We believe that this language could reasonably be interpreted in two ways. Under one reading, ''except as provided in clause (ii), (iii), or (iv)'' would be interpreted to mean that clause (i) has applicability only when the other three clauses do not apply. Under this interpretation, one would look solely to clause (ii), (iii), or (iv) to determine the amount that could be imposed in civil money penalties when those clauses apply. If the amount under section 1932(e)(2)(A)(iii) of the Act was $10,000, only this amount could be imposed in penalties. The commenter has suggested an alternative reading, under which the ''except as provided'' clause is read as an exception to the $25,000 limit in clause (i). Under this interpretation, civil money penalties of up to $25,000 could be imposed for any determination under section 1932(e)(1)(A) of the Act ''except'' to the extent that an even higher amount is permitted in the cited clauses. The $25,000 amount would, under this reading, constitute a ''floor'' authorized penalty with potentially higher ''ceilings'' under the other clauses. The $100,000 amount provided for under clause (ii) is higher than $25,000 and would constitute an exception to the $25,000 limit. The amount determined under clause (iv) would similarly be higher than $25,000, as long as just two individuals were denied enrollment based on health status (which would result in a penalty of $30,000). Under clause (iii), ''double the excess amount charged'' also could easily exceed $25,000, and thus also constitute an ''exception'' to the $25,000 limit in clause (i). We agree with the commenter that this latter interpretation is the best interpretation of the statute, in that a substantial penalty could be imposed for overcharging enrollees, even if the amount of the overcharge is not substantial. We are providing in § 438.704(b)(4) that States may impose civil money penalties of the ''higher of'' $25,000 or the amount under section 1932(e)(2)(A)(iii) of the Act.

Comment: Several commenters requested that HCFA reconcile the numerous variations between proposed § 438.704 and 42 U.S.C. 1396u2(e)(2)(A). The commenters suggested that the term ''either'' in proposed § 438.704(a) should be eliminated and replaced with the term ''any'' and that the words ''a failure to act'' in proposed § 438.704(a)(1) should be replaced with ''an act or failure to act.'' These changes would make it clear that the State is not being directed to respond to one circumstance at the expense of another and that noncompliance can be applied in both actions and failures to act.

Response: We agree with the commenter's points, and the revised version of § 438.704 does not contain the reference to ''failure to act'' without ''action,'' or the word ''either'' as referenced by the commenter.

Comment: Numerous commenters believe that we were too restrictive in our interpretation of the $100,000 cap for some of the civil money penalties

outlined in the proposed regulation. In the view of these commenters, the MCO should be fined $15,000 for each beneficiary not enrolled as a result of discrimination, plus $100,000. One commenter believes that there should not be a $100,000 cap at all, because in large areas that threshold is quickly met and enforcement could not proceed.

Response: Under section 1932(e)(2)(A)(iv) of the Act, the provision for a $15,000 penalty for each individual denied enrollment under ''a practice'' described in section 1932(e)(1)(A)(iii) of the Act is ''subject to'' section 1932(e)(2)(A)(ii) of the Act. Section 1932(e)(2)(A)(ii) of the Act limits the amount of any penalty for ''a determination under [section 1932(e)](1)(A) to $100,000.'' If section 1932(e)(2)(A)(iv) of the Act were intended to permit penalties in excess of $100,000 for a finding of discrimination under section 1932(e)(1)(A)(iii) of the Act, it would have said ''in addition to'' the amount in clause (ii) of section 1932(e)(2)(A)(ii). Instead, it says that the amount under section 1932(e)(2)(A)(iv) of the Act is ''subject to'' clause (ii). We believe this can only be read to mean that the total amount under clause (iv) is ''subject to'' the limit in clause (ii) and cannot exceed $100,000 per determination of a discriminatory practice. If there is more than one finding of a discriminatory ''practice described in'' section 1932(e)(1)(A)(iii) of the Act, a penalty of up to $100,000 could be imposed for each such finding.

Comment: All of the commenters oppose the required imposition of temporary management in the case of repeated violations. They believe that we should take a flexible approach to this provision, as it is unlikely that States would choose to impose this requirement, and in many instances this requirement would be overly burdensome. Most commenters indicated that States will be more likely to terminate an MCO's contract under these egregious circumstances in which our regulation requires the imposition of temporary management. Commenters stated that, putting aside the practical problems associated with such a remedy, they believe that a plan that is incapable of managing itself would be equally poorly run by temporary management. In the view of these commenters, this plan should have its contract terminated and should not be subject to the imposition of outside management in a probably futile attempt to salvage the operation. Another commenter stated that this provision is of great concern because the State should always have the authority to terminate the MCO's contract if the MCO meets any specified contract termination threshold. Forcing the State to continue a contractual arrangement and payment when the State has determined that termination is the most appropriate course of action strikes this commenter as imprudent. The imposition of temporary management may be very administratively complex if the State MCO licensing agency does not concur with this course of action, particularly when the MCO has lines of non-Medicaid business that would be affected. Requiring the State to work through the complexities of imposing temporary management when this does not appear to be the appropriate response would be very problematic to the State and have potentially negative ramifications for both enrollees and providers. One commenter believes that if it is appropriate for a State government agency to take over the management of a managed care plan, the appropriate agency would be the State Department of Insurance. That agency generally has far more experience in managing troubled insurers and managed care plans. The commenter recommended that HCFA convey these points to State agencies. Another commenter stated that temporary management requires extensive knowledge and should only be used sparingly. The commenter believes that the State should defer to the State insurance commissioner as temporary management should fall under his or her purview. One commenter would favor a change in the regulation to allow temporary management as an option rather than a mandate. Implementing this sanction would place a heavy administrative burden on the State. Although States would have the discretion to impose this sanction on an MCO, it is doubtful this sanction would ever be used. Authorizing the State to take over management of a commercial enterprise seems to go beyond the scope of authority available to the State, while allowing immediate disenrollment of enrollees is quite justified. The commenter also stated that it is not necessary to assume management of the MCO when other sanctions are available, including termination of the MCO's contract. This sanction is overreaching and invades the State's right to determine appropriate sanctions for its plans. Another commenter stated that in the event of continued egregious behavior by an MCO, the State would certainly terminate the contract and reassign enrollees but would not want to be put in the position of managing an MCO. Although this provision is based on statutory language, the commenter urged HCFA to recognize and to minimize the potential conflict with existing State insurance regulations, policies, and processes for monitoring and taking action against financially insecure plans. One commenter recommended that the regulations reflect the decision reached in the preamble, stating that States set the thresholds for egregious actions requiring temporary management and that the contract can be terminated rather than imposing temporary management.

Response: Section 1932(e)(3) of the Act provides that the State shall (regardless of what other sanctions are provided) impose the sanction of temporary management in cases in which an MCO has ''repeatedly'' violated section 1903(m) of the Act. To the extent that the commenters believe that the requirement in § 438.706(b) is inappropriate, their arguments are properly directed at the Congress, since this regulatory provision merely reflects the statutory requirement in section 1932(e)(3) of the Act and has no independent legal effect. We have no authority to alter or delete this requirement. We agree with some of the sentiments reflected in the above comments and intend to give States the maximum flexibility permitted by statute. The regulations permit the State to terminate a contract at any time and to do so rather than imposing temporary management. States are also free to establish a threshold in their State plan or otherwise that would have to be met before an MCO is considered to have ''repeatedly'' committed violations of section 1903(m) of the Act for purposes of the mandatory temporary management requirement in section 1932(e)(3) of the Act. Since the circumstances for each population and MCO vary greatly, we believe it is prudent to work with each State to determine a reasonable threshold. All States will have ample ability to terminate a contract, if they choose, rather than imposing the temporary management requirement.

Comment: Two commenters were concerned over the effect imposition of temporary management would have on the MCO's commercial enrollment. Another noted that, based upon the regulatory language, this provision could apply to an MCO that also has Medicare and/or commercial business. These commenters believe that this sanction provision raises serious practical concerns, especially with the lack of any due process protections other than written notice. One commenter recommended adding a new paragraph (c) to § 438.706 that says the

State shall develop criteria for who can serve as a temporary manager and shall maintain a list of individuals and entities meeting the criteria who are able and willing to serve in that capacity.

Response: We have no authority to change the requirement in § 438.706(b), since it reflects the statutory requirement in section 1932(e)(3) of the Act. States are free to develop the criteria suggested by the commenter or to maintain the list suggested. Since States are free to terminate a contract before it gets to the stage of a mandatory temporary management, and in keeping with our decision to grant States maximum flexibility in complying with section 1932(e)(3) of the Act, we do not accept the commenter's suggestion that these specific approaches be mandated. We note that for those situations in which temporary management would be mandated under whatever criteria the State develops, MCOs would have had ample warning through other intermediate sanctions and corrective action plans. Since States have the authority to terminate a contract instead of imposing temporary management, termination is more likely to be a State's sanction of choice, with MCOs receiving hearings prior to termination. Except for repeated section 1903(m) of the Act violations, the rest of this section is for use entirely at a State's option. Because we believe that States will be unlikely to exercise temporary management under § 438.706, we believe there should be no effect on an MCO's commercial or Medicare enrollment. In the unlikely event that a State takeover of management were to occur, we would expect States to take measures to limit the scope of their control to the parameters necessary to administer the Medicaid contract.

Comment: One commenter encouraged States to take into consideration the unique needs of children when determining the identification of egregious behavior and threats to enrollees and the number of offenses that would require imposition of temporary management.

Response: We encourage States to take the unique needs of children into consideration when determining when temporary management of an MCO is appropriate. We will take this into consideration when working with States that wish to develop thresholds of section 1903(m) of the Act violations.

Comment: One commenter appreciated being given the clear authority to impose temporary management on an MCO. Another group of commenters supported HCFA's guidance in § 438.706(a) regarding when the voluntary imposition of temporary management is appropriate. Voluntary imposition of temporary management is appropriate when the State finds through onsite survey, enrollee complaints, financial audits, or any other means that there is egregious behavior on the part of the MCO, substantial risk to enrollees' health, or the need to impose the sanctions to ensure the health of the MCO's enrollees.

Response: We appreciate the commenters' support and approval.

Comment: Numerous commenters were concerned over their perception of a lack of an adequate opportunity for MCOs to contest a State decision to impose a sanction. The commenters noted that while § 438.710(b) requires that a hearing be provided before a contract is terminated, § 438.710(a) requires in the case of other sanctions only that written notice be provided of the sanction and of any due process requirements that the State elects to provide. One commenter was concerned about a perceived lack of minimum procedures before the State can impose sanctions such as civil money penalties or suspension of new enrollment or payments. Another commenter had serious concerns about the absence of Federal procedural process requirements before the imposition of sanctions on MCOs. Based on the terms of the proposed rule, the State agency would have discretion to impose civil money penalties suspend new enrollment, and suspend payment without giving the MCO and PCCM an opportunity to present its views before the decision maker. One commenter believes that rather than denying the right to a hearing relative to the imposition of temporary management, as provided in section 1932(e)(5) of the Act, the entire concept should be reconsidered. One commenter suggested that minimum procedural safeguards should be included in these regulations but did not specify what these minimum safeguards should be. Another commenter recommended that HCFA require State agencies to ensure some form of procedural due process to be used prior to imposition of sanctions. Two commenters recommended that, at a minimum, MCOs be granted procedural safeguards that are the same or very similar to the procedural safeguards that HCFA has given Medicare+Choice organizations.

Response: We do not prohibit States from establishing the ''due process protections'' that they consider appropriate. As noted earlier, section 1932(e)(5) of the Act provides States with the discretion to make this decision, stating that '' * * * the State shall provide the entity with notice and such other due process protections *as the State may provide,* * * *'' (Emphasis added.) We believe it would be inconsistent with this provision to dictate that specific procedures be employed. We find one area in which our proposed rule goes beyond the requirements of the statute in potentially denying an MCO an opportunity to contest a sanction. Proposed § 438.710(b) of the Act provides that the State could not delay imposition of temporary management ''during the time required for due process procedures, and may not provide a hearing before the imposition of temporary management.'' (Emphasis added.) Section 1932(e)(5) of the Act provides for the State to afford ''due process protections,'' but precludes a State only from providing a ''hearing'' before imposing temporary management. In response to the above concerns, we have revised what is now § 438.706(c) to eliminate the reference to due process protections and to reflect the statute by prohibiting the State only from providing a hearing before imposing temporary management.

Comment: One commenter believes that when a contractor is terminated, adequate notice needs to be given to beneficiaries. The commenter recommended that we require timely notice to beneficiaries when States terminate an MCO or when an MCO withdraws from the program. This notice should include accurate information on options to enable beneficiaries to make informed choices among other available MCOs and PCCMs.

Response: We agree that Medicaid beneficiaries enrolled in an MCO or PCCM that is being terminated should receive timely notice of the termination with information on the options available to the beneficiary once the termination is effective. While the Congress provided in section 1932(e)(4)(C)(i) of the Act for notice to enrollees of a decision to terminate a contract, this notice is provided only when the State exercises its discretion to permit enrollees to disenroll immediately without cause before the termination hearing is completed. Section 1932(e)(4)(C)(i) of the Act clearly provides that States ''may'' provide such notice. We agree with the commenter that if a decision to terminate an MCO is upheld, and a termination is about to take effect, beneficiaries should be notified. Under section 1902(a)(19) of the Act, which requires that States provide safeguards necessary to assure that care and

services are provided in a manner ''consistent with * * * the best interests of recipients,'' we are adding § 438.710(b)(2)(iii) to require that notice of the termination be provided to enrollees of the terminated MCO or PCCM, with information on their options following the effective date of the termination.

Comment: We received one comment that stated that in order to avoid conferring an unintended defense to MCOs that meet the contractual standard for termination of the contract, we should specify that failure of a State to impose intermediate sanctions is no basis for objection or affirmative defense against a contract termination.

Response: States have the authority to terminate an MCO's or PCCM's contract without first having to impose intermediate sanctions, such as civil money penalties. If a State chooses not to impose intermediate sanctions before it terminates an MCO's or PCCM's contract, this action should not be used as an affirmative defense on the part of the MCO or PCCM against contract termination. We do not believe it is necessary or appropriate to make this statement in the regulation text itself.

Comment: Several commenters disagreed with the language in proposed § 438.718(a) that allows a State to terminate an MCO's or PCCM's contract if the MCO or PCCM failed ''substantially'' to carry out the terms of its contract. These commenters argued that the term substantially does not appear in section 1932(e)(4) of the Act, which is implemented in revised § 438.708, and severely restricts State flexibility in protecting Medicaid beneficiaries and the integrity of the Medicaid program. In the commenters' view, the added burden of proving substantial failure to comply is unnecessary and will add layers of litigation when a State seeks to terminate an MCO or PCCM. These commenters recommended removing the word ''substantially.''

Other commenters made the same point about our inclusion of the word ''substantially'' in proposed § 438.708, which implements the obligation in section 1932(e)(3) of the Act to impose temporary management in the case of repeated violations. Although the preamble indicates that we introduced the word ''substantially'' in order to allow States greater flexibility, there is no indication that the Congress intended for there to be greater flexibility in the application of this statutory requirement. These commenters argued that if the Congress had intended flexibility, it would not have made this provision ''mandatory'' in the first place, noted that this provision is the only mandatory requirement that sanctions be imposed, and noted that this provision is triggered only in instances in which the MCO repeatedly failed to meet requirements. These commenters found it difficult to understand why we would take what they considered the only mandatory sanction in the statute and attempt to give States greater flexibility.

Response: We agree that the word ''substantially'' is not used in section 1932(e)(4) or section 1932(e)(3) of the Act, is potentially ambiguous, and could create misunderstanding and enforcement problems. We included this term in proposed §§ 438.718(a) and 438.708 because we did not believe that termination or temporary management would be warranted for violations that are not substantive in nature, such as clerical or non-quality related reporting violations. In response to the above comments, in the final rule, we have changed ''substantially'' to ''substantive'' in both § 438.708(a) and § 438.706(b) as codified at § 438.708 in the proposed rule.

Comment: One commenter believes that the 30-to 60-day time frame for the termination hearing was insufficient and imposed an undue administrative burden. Another commenter recommended that the regulation provide notice of the intent to terminate 60 days before the effective date of the termination. The commenter also believes that the final regulation should establish criteria for when termination should be imposed and notice of when a termination decision has been made. A third commenter argued that this proposed requirement would impose a hardship on States because they are required to set the date and time for a hearing that the provider may not wish to have or be willing to attend. One commenter suggested that the termination notification should inform the MCO of its right to request a hearing and the procedures for doing so by phone or by mail. Upon the receipt of a hearing request, the State would be required to schedule the hearing not fewer than 30 or more than 60 days thereafter, unless the State agency and MCO or PCCM agree in writing to a different date.

Response: Because of legitimate concerns from many different parties, and in light of the fact that the Congress chose to provide States with their own discretion to establish due process protections, we are removing the time frames that were in the proposed rule and allowing the State to develop its hearing process and its timing.

Comment: We received several comments requesting that we require the pre-termination hearings be open to the public, since public disclosure is an important step towards ensuring accountability. These commenters stated that the Supreme Court has recognized the public policy value of having program participants most affected by an enforcement decision participate in an enforcement hearing, citing the Supreme Court's decision in O'Bannon v. Town Court Nursing Center, 447 U.S. 773 (1980). One commenter requested that we clarify who may participate in the hearing and the procedural rules that apply to the hearing. Another commenter recommended that States be required to provide potentially affected enrollees with the following: (1) written notice at least 15 days before the date of the pre-termination hearing and (2) information regarding how enrollees may testify at that hearing. Commenters stated that we should require that this notice be (1) written at no higher than a fourth grade level, (2) translated into the prevalent languages spoken by the population in the service area, and (3) accessible to persons with hearing and sight impairments.

Response: We believe that the above suggestions represent good ideas. With respect to the period prior to a decision following a hearing, the Congress has suggested that States should have discretion whether to notify enrollees of the proposed termination. Under section 1932(e)(4)(C) of the Act, the State ''may'' notify ''individuals enrolled with a managed care entity which is the subject of a hearing to terminate the entity's contract with the State of the hearing.'' We believe it would be inconsistent with Congressional intent to mandate notice at this time. We have required that notice to enrollees be provided if a decision to terminate is upheld in a hearing. Any notice the State sends to enrollees must meet the language and format requirements of § 438.10(b) and (c).

Comment: One commenter stated that sometimes it is necessary for the State to terminate a contract with a PCCM because, the PCCM has left the practice without notifying the State. In that situation, the proposed requirement for notice and hearing before termination would not allow the State to take immediate action and would cause hardship to enrollees whose access to medical care would be greatly hindered.

Response: While a State may not terminate a contract with an MCO or PCCM, unless the State provides a hearing before termination in the situation described by the commenter,

the statutory requirement for pre-termination hearing would not apply because the PCCM would have ''terminated'' the contract. Enrollees would not be adversely affected if the State gives them prompt notice and assists them to enroll in another MCO or PCCM or change to the fee-for-service program.

Comment: Several commenters recommended that we specify that States may inform enrollees of their right to disenroll any time after the State notifies the MCO or PCCM of its intent to terminate. Commenters stated that this section does not make clear at what point in the termination process States are required to notify enrollees. The commenters suggested that we explicitly require MCOs or PCCMs to provide both oral and written notification to enrollees and specify that this may be sent before completion of the hearing process. Steps should be taken to ensure that all people, including individuals with limited English proficiency, limited reading skills, visual impairments, or other disabilities are effectively notified. The final regulation should include adequate safeguards to ensure continuity of care during the time needed for enrollees to select another MCO or PCCM. Other commenters stated that this notification should be mandatory.

Response: Under § 438.722, the State may notify enrollees and authorize them to disenroll without cause at any time after it notifies the MCO or PCCM of its intent to terminate. The notice to enrollees must meet the language and format requirements of § 438.10(b) and (c). Section 438.62 requires the State agency to have a mechanism to ensure continuity of care during the transition from one MCO or PCCM to another or from an MCO or PCCM to fee-for-service. We have not required that notice be oral as well as written.

Comment: The State does not notify HCFA before imposing sanctions or once the sanction has been lifted. Why would HCFA need or want to be notified for each MCO infraction when it never has been in the past and has not needed the information? The commenter recommends that the requirement to notify HCFA of every sanction is not necessary and should be dropped.

Response: We agree that this would be burdensome. It is also unnecessary since we can access this information when needed. This requirement has been removed.

Comment: Many commenters recommended some level of public notification of imposition of sanctions. Some commenters stated that notice of the sanctions should be required to be given to current enrollees, by all enrollment brokers to potential enrollees, and to a newspaper of wide circulation in the area served by the MCO. Public information about the imposition of sanctions will contribute another layer of accountability to the extent members of the public, specifically the Medicaid population, are able to exercise choice among health care providers. Others stated that, although this section is an important provision to assist Federal oversight, enrollees, health care providers, and potential enrollees should also receive timely information concerning the following issues: (1) whether a specific MCO has been sanctioned, (2) the type of sanction, (3) the reason the sanction was imposed, and (4) what steps the enrollee can take to protect himself or herself. The independent enrollment assistant should provide potential enrollees with this information in both oral and written form, and the sanctioned MCO should be required to provide to current enrollees and health care providers in its network timely written information on sanctions. This requirement will ensure public access to critical information on quality of services. The State should also provide this information, upon request, to the general public. These notices should also meet the literacy recommendations discussed previously. Commenters further suggested that we add the following, ''prior to enrollment, the enrollment broker (or other entity conducting enrollment) shall provide each eligible recipient with information regarding which MCOs or primary care case managers have been sanctioned, the types of sanctions, and the reasons for the sanctions. In addition, this information will be publicly available, upon request, from the State.''

Response: In response to this and the preceding comment, we have revised § 438.724 so that, instead of requiring notice to HCFA, it requires States to publish public notice describing the intermediate sanction imposed, the reasons for the sanction, and the amount of any civil money penalty. We specify that the notice must be published no later than 30 days after imposition of the sanction and must appear as a public announcement in either the newspaper of widest circulation in each city with a population of 50,000 or more within the MCO's service area, or the newspaper of widest circulation in the MCO's service area if there is not, within that area, any city with a population of 50,000 or more.

Comment: Section 438.730 authorizes HCFA to impose sanctions directly on MCOs. Although this provision is authorized by the BBA, some commenters urged HCFA, except in extraordinary circumstances, to defer to States on the appropriateness of sanctions. They stated that such an approach is consistent with the roles performed by States and HCFA under the Medicaid program. The commenters were concerned about HCFA making sanction determinations without the involvement of the State and want clarification that sanctions will not be imposed by HCFA without involvement of the State.

Response: We already had sanctioning authority codified by § 434.67, which has been redesignated as § 438.730. We have no plans to deviate from our traditional role of deferring to States on the monitoring of day-to-day MCO or PCCM operations and their appropriateness. The regulation itself makes clear that our involvement would be based on the State's recommendation.

Comment: Several commenters suggested that HCFA should take a more proactive role in ensuring oversight and monitoring. The early implementation of mandatory Medicaid managed care has been plagued with problems. Neither the State nor HCFA has provided adequate oversight to protect beneficiaries. Managed care has clearly not lived up to its promise of providing quality care at lower costs. There is considerable doubt that it ever will. Unlike their wealthier counterparts, Medicaid beneficiaries cannot simply pay out-of-pocket if their managed care plan does not provide the care they need. Health care consumers across the nation are calling for greater accountability and oversight. This is extremely important to Medicaid beneficiaries. The commentors are deeply concerned that HCFA has placed too much of the oversight and enforcement responsibilities on the State Medicaid agencies. The Congress did not revoke HCFA's statutory authority to sanction MCOs or PCCMs. Although the regulations transfer much of this responsibility to the State, beneficiaries have little assurance that the State will adequately protect them, particularly since State Medicaid agencies do not have a good track record of oversight and enforcement. Reports by the GAO and OIG have called for greater Federal oversight and enforcement. This focus makes even less sense with the BBA changes than it did under preexisting authority. Why would a State interested in enforcing compliance recommend that HCFA impose a sanction that the State itself is authorized to impose? Why would a

State not interested in enforcing compliance recommend anything at all to HCFA? The proposed rule lacks any assurance that HCFA will act if the State fails to act. When will HCFA perform these functions, if they are not performed by the State? What would trigger HCFA action or will it be entirely at HCFA's discretion? Will HCFA monitor States' actions or failure to act? The commenters believe that this section should be rewritten to eliminate the State as a recommender of action to HCFA and to emphasize HCFA's independent authority to impose sanctions. As with States, the section should direct that sanctions can be imposed based on findings made through onsite surveys, enrollee complaints, financial audits, or any other means. The regulation should state that HCFA will automatically perform the functions articulated in § 438.730 if an MCO performs any of the following activities: (1) Fails to carry out the terms of its contract; (2) fails to substantially provide medically necessary services that it is required to provide; (3) imposes premiums or charges in excess of those permitted by law; (4) discriminates among enrollees on the basis of health status or requirements for health care services; (5) misrepresents information that is furnished to HCFA, the State, an enrollee, a potential enrollee, or managed care plan; (6) does not comply with physician incentive requirements; (7) distributes, either directly or indirectly, information that has not been approved by the State or that contains false or materially misleading information; (8) engages in any behavior that is contrary to any requirements of section 1903(m) or 1932 of the Act and implementing regulations; (9) places enrollee health at substantial risk; or (10) by virtue of its conduct, poses a serious threat to an enrollee's health or safety or both.

Response: We have always had independent authority to sanction MCOs but not the resources to monitor them individually. Our primary tools to influence State activities with its MCOs have been corrective action plans, specific performance actions, and denials of FFP.

Comment: Several commenters were concerned at the absence of guidelines or criteria that would be used by a State agency in determining the amount of sanctions and urge us to include these guidelines and criteria. There must be standards of reasonableness that would apply to ensure that MCOs are not arbitrarily subjected to sanctions that are excessive in comparison with the nature of the offense in question.

Response: We may not impose standards or criteria because the Federal sanctioning authority is completely a State option (other than temporary management) and we do not set criteria for States using State authority. Any extra requirements could have a chilling effect of discouraging the use of the Federal authority. The monetary amounts specified in § 438.704 are limits, giving MCOs protection against excessive fines. The only mandatory due process protections involve termination of the contract and are contained in the statute.

Comment: One commenter recommended deletion of § 438.730. The commenter stated that if the State believes that an MCO should be sanctioned, it is free to impose that sanction without HCFA involvement. The commenter also pointed out that the sanctions that HCFA may impose are the same sanctions available to the State.

Response: This section is a redesignation of § 434.67, which reflects authority granted through section 1903(m)(5) of the Act, part of the Social Security Act before enactment of the BBA. We have no authority to remove these provisions from the regulations.

Comment: Several commenters believe that HCFA should publicly report the number of times States have recommended that HCFA deny payment and the result of each of the recommendations. This information should then be updated regularly. Requiring that this information be made public and updated on a regular basis will help ensure the State's accountability to recipients and the public at large. Since a similar provision under § 434.67 has existed for several years, they would like HCFA to specify in the preamble the number of times States have recommended that HCFA deny payment and the result of each of the recommendations. They are concerned that this provision has not been implemented to the extent necessary to protect beneficiaries. They believe that information on the number of times States have recommended denial of payment is a critical element in determining how active States have been in monitoring compliance and protecting beneficiaries.

Response: We disagree that sanctions should be publicly reported. The existing longstanding sanction provision at § 434.67 does not require us to report to the public the number of recommendations by States for imposition of sanctions or actions resulting from the recommendations. We do not require regular reporting of sanctions that are imposed on MCOs through provisions of this final regulation because we do not want to discourage State use of sanctions. The preamble to this final regulation is not the appropriate place to report on activity related to the existing regulation.

H. Conditions for Federal Financial Participation (Subpart J)

Subpart J of the proposed rule set forth largely recodified versions of the regulations in part 434, subpart F. These regulations contain rules regarding the availability of Federal financial participation (FFP) in MCO contracts.

1. Basic Requirements (§ 438.802)

Proposed § 438.802 was based on the existing § 434.70 and provided that FFP is only available in expenditures under MCO contracts for periods that—(1) the contract is in effect and meets specified requirements; and (2) the MCO, its subcontractors, and the State are in compliance with contract requirements and the requirements in part 438.

Comment: One commenter noted that proposed § 438.802(c) represents a more stringent standard than the long-standing standard in § 434.70(b), arguing that the proposed standard is ''much too onerous.'' The commenter noted that under § 434.70(b), FFP could be withheld if an MCO ''substantially fails to carry out the terms of the contract,'' while under proposed § 438.802(c), FFP is based on the MCO and State being ''in compliance'' with the requirements of the contract. The commenter argued that States may hesitate to incorporate special quality initiatives into their contracts anticipating that FFP will be withheld if State or plan (or both) are not in complete compliance.

Response: Like proposed § 438.802, § 434.70(a) provided that FFP was available in contract payments ''only'' for periods that the contract ''is in effect'' and ''[m]eets the requirements of this part,'' specifically including physician incentive plan requirements. Unlike proposed § 438.802, however, § 434.70(a) is also based on FFP on meeting ''appropriate requirements of 45 CFR part 74.'' Proposed § 438.802 dropped this latter condition. Proposed § 438.802 was less stringent than § 434.70. The commenter is focusing not on the contract's compliance with requirements but on the MCO's compliance with the contract. We agree with the commenter that § 438.802(c) imposes a stricter standard than § 431.70(b) and it was not our intent to put States and plans at higher risk of FFP withholding than they were before. In this final rule with comment period,

we have substituted ''substantial compliance'' for ''compliance'' in the Basic Requirements section, both in § 438.802(c) and § 438.802(b), regarding compliance with physician incentive plan requirements.

Comment: Several commenters argued that compliance with ADA and Civil Rights Act requirements should be added to § 438.802.

Response: Entities that contract with Medicaid are required to comply with both the ADA and the Civil Rights Act as well as all other applicable law and Federal regulation. As discussed above, in § 438.6 of this final rule with comment period, we have added language requiring that contracts expressly prohibit MCOs from discrimination based on race, color, or national origin and require compliance with all applicable State and Federal laws.

Comment: A commenter argued that there is an inequity in a system that certain States pay extremely high capitation rates for disabled populations (in which FFP is awarded) but do not provide for a comparable level of FFP to cover equivalent populations in other States. This commenter found general reason for concern about which populations different States are covering and the method by which different States are providing that care (fee-for-service versus managed care).

Response: Section 1902 of the Act requires that States provide medical assistance to certain mandatory groups and provide them with a certain specified minimum level of benefits. However, States have considerable latitude in deciding which other groups to cover and what levels of payment to set for their contracting MCOs, within the parameters of actuarial soundness and the rate setting requirements in § 438.6(c). It is the nature of a State run program for benefits to vary from State to State. However, as discussed above in section II. A, § 438.6(c)(1)(i)(B) requires that payment rates be ''appropriate for the populations to be covered,'' and § 438.6(c)(1)(i)(B)(3)(iv) requires that payment and cost assumptions be ''appropriate for individuals with special health needs.'' We believe that these requirements should ensure that payments are sufficient for disabled enrollees when they are enrolled in managed care contracts.

2. Prior Approval (§ 438.806)

Proposed § 438.806 was based on § 434.71 and provided that FFP was not available in expenditures under contracts involving over a specified financial amount ($1 million for 1998, adjusted by the consumer price index for future years) ''prior approved'' by us.

Comment: Several commenters believe that the $1 million figure for 1998 was too low, and one suggested raising it to a $5 million minimum.

Response: We do not have the authority to raise the threshold amount for required prior approval of contracts, which is stipulated in section 1903(m)(2)(A)(iii) of the Act.

Comment: A commenter suggested that this final rule with comment period clarify (1) that State or county-level purchasers will not be at risk because the State has not obtained the approval required under § 438.806 by the time the contract needs to be implemented and (2) that FFP is available retroactively if approval from the HCFA Regional Office is not secured by the time of the effective date of the contract.

Response: This rule does not change our existing interpretation of the prior approval requirement. For any contract that is implemented without first obtaining approval from the HCFA Regional Office, the State is at risk for FFP in payment for those services should the contract not be approved. The risk facing county-level purchasers is a question of the degree to which a State puts its own counties at risk within the context of State law and regulations. With regard to the related question of FFP retroactive to the effective date of the contract, the revision of § 438.806(b)(1) does not expand the scope of the original regulation. It merely adjusts upward the threshold amount for prior approval, which was $100,000 before the BBA raised the cost.

3. Exclusion of Entities (§ 438.808)

Proposed § 438.808 reflects the limitation on FFP in section 1902(p)(2) of the Act under which FFP in payments to MCOs is based. FFP payments are based on the State excluding from participation as an MCO any entity that could be excluded from Medicare and Medicaid under section 1128(b)(8) of the Act, that has a substantial contractual relationship with an entity described in section 1128(b)(8)(B) of the Act, or employs or contracts with individuals excluded from Medicaid. We received no comments on this section.

4. Expenditures for Enrollment Broker Services (§ 438.810)

Proposed § 438.810 reflects the conditions on FFP for enrollment broker services set forth in section 1903(b)(4) of the Act, which was added by section 4707(b) of the BBA. This section permits FFP in State expenditures for the use of enrollment brokers only if the following conditions are met:

- The broker is independent of any managed care entity or health care provider that furnishes services in the State in which the broker provides enrollment services.
- No person who is the owner, employee, or consultant of the broker or has any contract with the broker—
  - —Has any direct or indirect financial interest in any entity or health care provider that furnishes services in the State in which the broker provides enrollment services;
  - —Has been excluded from participation under title XVIII or XIX of the Act;
  - —Has been debarred by any Federal agency; or
  - —Has been, or is now, subject to civil monetary penalties under the Act.
- The initial contract or memorandum of agreement (MOA) or memorandum of understanding (MOU) for services performed by the broker has been reviewed and approved by HCFA before the effective date of the contract or MOA.

Comment: Several commenters expressed support for this provision and indicated that it is critical that the broker remain independent and unbiased.

Response: We appreciate the commenters support and agree that this provision is of great help in ensuring that beneficiaries are able to make informed choices.

Comment: One commenter suggested that we allow a ''de minimis'' exception for certain levels of stock ownership, especially in a publicly traded company. The commenter also suggested that HCFA rules preempt similar State rules to avoid excessive application of these rules.

Response: We believe that any degree of ownership, including any amount of stock in an MCO, PHP, or PCCM or other provider, by enrollment broker owners, staff, or contractors may create the potential for bias. That is why we are not providing for exceptions in § 438.810. Although section 1903(b)(4) of the Act and § 438.810 of the regulations set forth conditions that must be met to receive FFP, States have the prerogative to set rules more stringent than the Federal rules.

Comment: Some commenters believe that § 438.810 should include safeguards to protect Medicaid beneficiaries from false and deceptive advertising. A commenter recommended that, when brokers are used to enroll Medicaid beneficiaries into managed care, States should be required to assure that they have

accurate data about the Medicaid eligibles and the availability of MCOs, PHPs, or PCCMs and any subcontracting providers.

Response: We agree that it is important for States to provide enrollment staff with accurate information about Medicaid eligibles and about MCOs, PHPs, or PCCMs and their subcontracting providers. Sections 438.10(d) and (e) require that enrollees and potential enrollees be provided with names and locations of current network providers, including identification of those who are not accepting new patients. It also emphasizes that information must be sufficient to allow an informed decision. We believe that this addresses the expressed concerns. States or enrollment brokers must make efforts to provide the most accurate and current information available. State and broker data systems differ in their capabilities, and provider and eligibility information changes daily. We ordinarily address this issue during pre-implementation review and monitoring of mandatory programs.

Comment: One commenter believes that it is not necessary for us to approve initial enrollment broker contracts or memoranda of understanding because statutory limitations are straightforward, FFP is limited, and brokers must be independent. In this commenter's view, contract approval is not necessary to ensure compliance, since the threat of civil money penalties is sufficient.

Another commenter supported our decision to require prior approval of initial enrollment broker contracts but suggested that we provide additional guidance pointing to minimum qualifications of enrollment brokers.

One commenter acknowledged the need for contract review but suggested that we impose a 30 day time limit for review in order to avoid delaying contract implementation. Once this time had elapsed, the contract would be deemed approved.

Response: We have already reviewed some broker contracts and MOAs/MOUs on a voluntary basis. Much of the current review consists of technical assistance and advice about whether contracts contain legally required provisions, as well as assurances of quality and results of noncompliance. We intend to issue contract review guidelines for our staff.

We will not impose a time limit for review of contracts since it is impossible to assess workloads and the amount of time required for review. Once mandatory contract review is implemented, we will assess the length of time required for review and recommend time frames if necessary.

Comment: One commenter believes that fiscal intermediaries for State Medicaid programs face an inherent conflict of interest, because they are paid to process claims for traditional fee-for-service Medicaid programs, and assisting Medicaid beneficiaries to enroll in a managed care entity poses a threat to these agents' primary source of revenue. In this commenter's view, the intermediaries have a strong incentive to maintain the status quo. The commenter recommended that HCFA's rules should prohibit entities from serving as enrollment brokers for States in which they serve as fiscal intermediaries.

Response: We are aware that some fiscal intermediaries have adapted to the managed care environment by performing enrollment broker functions in some States. This is often convenient for States that already have fiscal intermediary contracts in place. Since enrollment brokering has become an additional line of business for some of these agents, we believe that the incentives for bias toward fee-for-service are minimal. In addition, we anticipate that States desiring to use fiscal intermediaries in the role of enrollment brokers would consider any inherent bias during the selection process.

Comment: One commenter asked about the applicability of this provision to a public entity in which eligibility and enrollment functions might occur in one division and other divisions might be responsible for purchasing or providing some Medicaid covered services. The commenter asked whether State ''conflict of interest'' regulations, if approved by HCFA, would satisfy the intent of this section. The commenter noted that if county government employees conduct enrollment and education, and counties are also directly involved in arranging for or providing Medicaid services directly, FFP would not be payable for the county employee's enrollment services. The commenter suggested that we define ''independent'' in such a way as to allow a county employee to conduct enrollment activities as long as the county has in place adequate safeguards to protect against conflict of interest. For example, if an employee conducting enrollment is employed under a separate division or department and is not subject to supervision or discipline by a separate division or department that conducts purchasing or operates an MCO, the commenter recommended that this be considered acceptable.

Response: The managed care enrollment function is an administrative function of the State. The State may choose to contract out this function, have it done by the State or local staff, or even allow MCO staff to perform this function. The example of a county eligibility employee performing enrollment activities when the county also provides services would violate § 438.810, thus precluding payment of FFP for the enrollment activities. The Medicaid eligibility function must always be performed by State or local staff. This function cannot be contracted out to other entities. If MCO, PHP, or PCCM enrollment is contracted out to an enrollment broker, defined as an entity or individual that performs choice counseling and/or enrollment activities, the broker may not have any connection to or interest in any entity or health care provider that provides coverage of services in the same State. An enrollment broker might be a public or quasi-public entity with a contract or MOA/MOU with the State or county. In this situation, this entity may not furnish health care services in the State. For example, a State may not contract with or have an MOU with a county health department to do managed care enrollment or choice counseling because the health department provides health services. A community organization that provides health services in the State, for example, an organization providing health care to homeless individuals, may contract or subcontract to perform outreach and education, but not enrollment and choice counseling functions. An MCO, PHP, PCCM, or other health care provider that provides services in a State may not also have an interest of any sort in an organization performing Medicaid enrollment or choice counseling. This restriction is based upon the statutory language contained in section 1903(b)(4) of the Act.

In § 438.810(b)(1) of this final rule with comment period, we have clarified that an enrollment broker would not meet the test for independence if it is an MCO, PHP, PCCM or other health care provider, or owns, or is owned by an MCO, PHP, PCCM, or other health care provider in the State in which the broker operates.

A State's conflict of interest regulations ordinarily address situations in which a State or local officer, employee, or agent has responsibilities related to the awarding of contracts. Conflicts of interest involving Medicaid officials have long been prohibited under sections 1902(a)(4)(C) and (D) of the Act. This language prohibits conflict of interest by current or former State and local officers, employees, or independent contractors responsible for

the expenditure of substantial amounts of funds under the State plan. The conflict of interest language in § 438.58 applies to State and local officers and employees and agents of the State who have responsibilities relating to MCO contracts or the default enrollment process. Conversely, it specifically prohibits conflict of interest in any Medicaid managed care contracting activities, including enrollment broker contracting. Section 438.810 specifically addresses situations in which a relationship between a health care provider and an individual or entity responsible for choice counseling or enrollment may be biased by that relationship. While conflict of interest provisions would be expected to be in place in the State, § 438.810 covers an additional situation in which potential conflict of interest might influence a Medicaid recipient's choice of plan.

5. Costs Under Risk and Nonrisk Contracts (§ 438.812)

Proposed § 438.812 was transferred in its entirety from previous §§ 434.74 and 434.75 and was unchanged in the proposed rule. Proposed § 438.812 provides that States receive Federal matching for all costs covered under a risk contract at the ''medical assistance'' rate, while under a nonrisk contract only the costs of medical services are matched as ''medical assistance,'' and all other costs are matched at the administrative rate.

Comment: One commenter believes that we should provide additional guidance on what constitutes the ''furnishing of medical services'' as described in § 438.812(b)(1). The distinction between what is administrative and what is a medical service is becoming less clear in this commenter's view.

Response: We do not believe additional clarification in the regulations text is necessary. The costs of medical services are the payments made to providers for furnishing services covered under the contract. In the case of fee-for-service Medicaid, this would be the State plan payment amounts. These costs could either be in the form of payments to providers (fee-for-service, per diem, or capitation) or ''salary'' in the case of an employee. Administrative costs would include member services, claims processing, coverage decisions, and other activities that would be matched as administrative costs under fee-for-service Medicaid.

Comment: One commenter noted that the proposed rule discussion of § 438.812 did not address the Federal medical assistance percentage (FMAP) that States receive for services provided to American Indians by the Indian Health Service (IHS) and tribally operated programs. The commenter believes that the regulation should specifically address how the special matching rate for eligible IHS services will be applied and the State role in assuring that standards are met.

Response: We agree that the FMAP rate for services provided to Indians by IHS or tribally operated programs applies whether the IHS or tribal facility operates in fee-for-service or managed care. There is no need to change this regulation since, when applicable, this special FMAP rate is the ''medical assistance'' rate in that case. The regulation differentiating FMAP rates for risk and nonrisk contracts would not prohibit or in any way modify the matching rate that is required for IHS or eligible tribal facilities. Section 438.812 simply recodifies longstanding regulations and does not involve or affect HCFA policy on the application of the FMAP for IHS services in the managed care context.

In response to this and other comments received, we want to reemphasize that tribal and IHS providers are not necessarily required to be licensed by a State as long as they meet the State's or MCO's qualifications. We believe that the definition of provider in § 400.203 will ensure that these providers are not inappropriately excluded from participation in Medicaid managed care programs.

6. Condition for Federal Financial Participation (FFP) in Certain Contract Arrangements (§ 438.814)

As discussed in detail in section II. A of this regulation, this new section reflects the condition for FFP in contracts that contain incentive arrangement or risk corridors. As described in new § 438.6(c)(5) on rate setting for risk contracts, FFP is only available in these contracts to the extent that payments do not exceed 105 percent of the payment rate determined to be actuarially sound.

I. Revisions to Parts 435, 440, and 447; Miscellaneous Comments

In addition to the provisions set forth in the new part 438, and the fair hearing provisions in part 431 discussed in section II. E. above, the proposed rule contained amendments to Parts 435, 440, and 447 which we discuss below. These provisions included amendments to §§ 435.212 and 435.326 to reflect the new terminology adopted by the BBA (for example, ''MCO'' and ''MCE''). We also proposed a new § 440.168 in part 440 to include a description of primary care case management services. Amendments to part 447 not already addressed above include a new § 447.46(f) implementing the timely claims payment requirements in section 1932(f), and a new § 447.60 regulating MCO cost-sharing, which was made permissible under BBA amendments to section 1916 of the Act. In this section, we discuss the comments we received on the above regulations. We received no comments on the revisions to part 435, or on § 447.60. We also in this section address miscellaneous comments that did not relate to a specific section of the proposed regulations.

1. Guaranteed Eligibility

Section 435.212 was amended in the proposed rule to implement section 1902(e)(2) of the Act. This change will permit State agencies, at their option, to provide for a minimum enrollment period of up to six months for individuals enrolled in a PCCM or any MCO. Previously, this option was only available to enrollees of Federally-qualified HMOs.

Comment: One commenter observed that the provision in the proposed rule is inconsistent, authorizing guaranteed eligibility for individuals enrolled in any MCE (MCO or PCCM) in the introductory text of the section, while limiting the authority to MCOs elsewhere.

Response: Using both terms in the proposed rule was an inadvertent error. We have clarified this issue by using the terms MCO and PCCM throughout the final rule, as intended by the BBA.

2. Definition of PCCM Services (Proposed § 440.168)

Section 4702 of the BBA adds PCCM services to the list of optional Medicaid services in Section 1905(a) of the Act. The BBA also added Section 1905(t) to the Act. This new subsection defines PCCM services, identifies who may provide them, and sets forth requirements for contracts between PCCMs and the State agency. This means that in addition to contracting with PCCMs under a section 1915(b) waiver program or section 1115 demonstration project, or under the new authority in section 1932(a)(1) to mandate managed care enrollment, States may now add PCCMs as an optional State plan service. Regardless of the vehicle used, proposed § 438.6(j) set forth the minimum contract requirements States must have with their primary care case managers.

Proposed § 440.168(a) set forth the definition of primary care case management services, for case

management related services that include ''location, coordination, and monitoring of primary health care services,'' that are provided under a contract between the State and either (1) an individual physician (or, at State option, a physician assistant, nurse practitioner, or certified nurse-midwife), or (2) a group practice or entity that employs or arranges with physicians to furnish services. Proposed § 438.168(b) provided that PCCM services may be offered as a voluntary option or on a mandatory basis under section 1932(a)(1) or a section 1115 or 1915(b) waiver.

Comment: One commenter expressed concerns about any form of required case management.

Response: Current law, through freedom of choice waivers under sections 1915(b) and 1115 of the Act, has for many years permitted States to require that Medicaid beneficiaries obtain their care through PCCM programs. Section 4702 of the BBA provided States additional flexibility by adding PCCM services to the list of optional Medicaid services. This allows States, at their option, to provide quality health care services and to enhance access to Medicaid beneficiaries through an arrangement that has proven to be cost effective to the Medicaid program. In addition, this section sets forth new requirements for contracts between primary care case managers and the State agency that provide important protections for beneficiaries and ensure access to quality health care. We believe that these protections, along with other beneficiary protections provided for in this final rule, adequately address the commenter's concerns.

3. Timeliness of Provider Payments (Proposed § 447.46)

Section 1932(f) of the Act specifies that contracts with MCOs under section 1903(m) must provide that, unless an alternative arrangement is agreed to, payment to health care providers for items and services covered under the contract must be made on a timely basis, consistent with the claims payment procedures described under section 1902(a)(37)(A) of the Act. The procedures under section 1902(a)(37)(A) of the Act require that 90 percent of claims for payment (for which no further written information or substantiation is required in order to make payment) made for services covered under the contract and furnished by health care providers are paid within 30 days of receipt, and that 99 percent of such claims are paid within 90 days of receipt. These requirements were included in proposed § 447.46.

Comment: One commenter objected generally to the requirements in proposed § 447.46, while another argued that the provision for developing a mutually agreed upon alternative payment schedule between an MCO and provider would not resolve the issue of timely payments. This commenter recommended that the timely payment provisions should provide that payments must be made in a manner consistent with State law, or, in the absence of a State requirement, in accordance with requirements in Federal regulation. This commenter did not believe that MCOs should be free to negotiate alternative arrangements. Another commenter contended that delayed payments for both managed care and fee-for-service programs have long been a problem in State Medicaid programs. This commenter felt that physicians, hospitals, and health systems should be paid for the covered services they provide to Medicaid beneficiaries in a timely manner, and that chronic payment delays by Medicaid programs and plans discourage physician and provider participation, are disruptive to the patient-physician relationship, and could adversely affect patient access. This commenter recommended that HCFA adopt a standard that would require payment to health care providers within 14 days for uncontested claims which are filed electronically and within 30 days for paper claims which are uncontested. In addition, the commenter recommended that for capitated payment systems, HCFA should require MCOs to make capitated payment to physicians and providers shortly after the beneficiary's enrollment, and also promulgate a standard time frame for payments by States to physicians and other providers of services under Medicaid fee-for-service programs.

Response: Congress was very specific in section 1932(f) to incorporate the standards set forth in section 1902(a)(37)(A), and provide that parties could also agree to an alternative payment schedule. We do not have the discretion to change the timeframes in section 1902(a)(37)(A), or to eliminate the right to negotiate an alternative schedule, as these are mandated by statute. We note that if an alternative payment schedule is established, it must be stipulated in the contract according to § 447.46(c)(3). The statute does not address the timing of capitation payments, which we believe should be negotiated between the parties.

4. Miscellaneous Preamble Comments

a. Effective Date of the Final Rule

In the proposed rule, we stated our intention to make the final rule effective 60 days following publication. However, those provisions which must be implemented through contracts would be effective for contracts entered into or revised on or after 60 days following the effective date, but no longer than 12 months from the effective date.

Comment: Several commenters asked us to clarify or revise the proposed effective date. In particular, the commenters were concerned that adequate time was not allowed for implementing the many changes proposed in the regulation. One commenter suggested that HCFA give States an additional year from final publication of the regulation to bring contracts into compliance. Another commenter recommended that HCFA consider allowing States at least 120 days to implement the final regulation.

Response: In recognition of the significant changes within this final rule, we have set the implementation date of this final rule to take effect 90 days following publication. Although we believe that it is important to provide BBA protections as soon as possible, we believe that changing the effective date will help to ease the State burden of implementing these provisions. Further, those provisions of the final rule that must be implemented through contracts with MCOs, PHPs, HIOs or enrollment brokers must be reflected in contracts entered into or revised on or after 90 days following the publication date, but no longer than 12 months from the effective date. Because a substantial number of the provisions of the final rule are implemented through contract revisions, the effective date for many provisions will be delayed in many States. Of course, some provisions in this final rule reflect statutory requirements that are already in effect. HCFA has provided State agencies with guidance on implementing these provisions through a series of letters to State Medicaid Directors. These letters appear on the HCFA Home Page and can be accessed at http:www.hcfa.gov.

b. Absence of FQHC and RHC Provisions in the Proposed Rule

Comment: Several commenters requested that HCFA address the new FQHC and RHC reimbursement requirements set forth in section 4712(b) of the BBA. One of the commenters was concerned that unless these provisions were included in the regulation there would be no mechanism to ensure State

and MCO compliance. The commenter acknowledged that HCFA had undergone a process to inform State Medicaid Directors of their new obligations under the BBA through a series of letters. However, without this requirement in the regulation, the commenter was concerned that both MCOs and States would disregard the Federal statutory protections intended to preserve FQHCs and RHCs as vital Medicaid providers. Moreover, the commenter argued that regulations have the force of law, whereas States have challenged in the past whether they are legally bound by guidance in letters to State Medicaid Directors. By placing these requirements in its regulations, the commenter believed that HCFA could ensure that States or MCOs that fail to comply with BBA's requirements would be subject to sanctions by HCFA. The remaining commenters questioned HCFA's interpretation of the FQHC/RHC statutory provision and believe that this area should be clarified in regulation and open to public comment.

Response: This rulemaking primarily implements Chapter 1 of Subtitle H of the BBA, titled ''Managed Care.'' The provisions relating to FQHC/RHC payment are set forth in Chapter 2, ''Flexibility in Payment of Providers,'' and thus arguably are outside the scope of this rulemaking. Even if this rule were the appropriate vehicle for regulations implementing these FQHC/RHC provisions, we do not believe that such regulations would be warranted. The rules in question are ''transitional'' in nature, as the 100 percent cost payments described will eventually be phased out over the next several years. We do not believe it appropriate to promulgate regulations that will be obsolete in a relatively short period of time.

Moreover, we do not believe regulations are necessary, as the statutory requirements are straightforward and self-implementing, and HCFA has provided guidance to all States, through State Medicaid Director Letters on April 21, 1998 and October 23, 1998, on FQHCs and RHCs. We disagree with the commenter that there is no ''enforcement mechanism'' for these requirements. The requirements in question, as interpreted by HCFA in State Medicaid Director Letters, are fully enforceable. A State that fails to fulfill its obligations under section 1902(a)(13)(C)(ii) to make required quarterly supplemental payments to FQHCs/RHCs that subcontract with MCOs would be subject to a compliance enforcement action under section 1904. If an MCO fails to comply with section 1903(m)(2)(A)(ix) by paying at least what it pays other providers, HCFA would disallow Federal financial participation (FFP) in payments under the MCO's contract. Thus, the FQHC/RHC requirements in question are self-implementing and fully enforceable. HCFA's interpretations of these requirements are also enforceable, and entitled to deference from courts.

c. General Comments on the Proposed Rule

Comment: Several commenters supported HCFA in its implementation of the BBA, and were pleased to see the proposed rule reflect many of the recommendations from the Consumer's Bill of Rights and Responsibilities (CBRR). These commenters also believed that the proposed rule was a thoughtful implementation of the BBA provisions, which adequately reflected the intent and hope of the Congress and provides functional guidance to States without becoming overly burdensome or demanding. Other commenters believed that the regulation is a positive step toward improving quality for Medicaid beneficiaries in managed care and that the regulation is brief, simple and written at a readable level.

However, several other commenters criticized HCFA for creating regulations that they perceived as overly burdensome that did not allow sufficient State flexibility. These commenters also argued that the proposed regulations went beyond the statutory intent and authority of the BBA, and that the regulations would lead to increased administrative costs for Medicaid MCOs. These commenters believed that HCFA was micro-managing its approach to Medicaid managed care, and the proposed regulations, if finalized, would make it increasingly difficult for State Medicaid agencies to provide access to quality health care through MCOs, since MCOs would not be willing to participate. Another commenter believed that the proposed regulations did not reflect the approach of a purchaser, but the approach of a unilateral regulator particularly with respect to the CBRR and other beneficiary protections.

Response: The regulation was developed to provide States with an appropriate level of flexibility that we believe to be consistent with necessary beneficiary protections. Thus, State flexibility had to be balanced against statutory requirements of the BBA, and a Presidential directive that required Medicaid program compliance to the extent permitted by law, with the recommendations in the CBRR. In response to specific comments regarding the over-prescriptiveness or burden of certain provisions, we have made some changes to promote even greater flexibility, and also added requirements in response to other commenters. Further, the regulation has been designed to provide a framework that allows HCFA and States to continue to incorporate further advances for oversight of managed care, particularly as it pertains to beneficiary protection and quality of care. With respect to HCFA's statutory authority, we summarize each provision of the effected regulations followed by our response.

Comment: In general, a few commenters were concerned that what they believe to be over-prescriptiveness of the regulation would result in MCOs leaving the Medicaid managed care market. These commenters believed that the prescriptive mandates of the regulation would limit and hinder negotiations with MCOs, because of the additional requirements that would have to be met for Medicaid members as opposed to commercial members. As a result, the commenters argued that these requirements would be administratively burdensome for MCOs. In addition, the commenters believed that the financing of these administrative requirements was so inadequate MCOs would be forced out of the Medicaid market due to financial reasons.

Response: We will be reviewing this issue as we are also concerned about the continued viability of MCOs in the Medicaid managed care market. However, we also recognize the importance of quality care and consumer protections for Medicaid beneficiaries enrolled in Medicaid managed care and are unwilling to sacrifice these very necessary protections. In this final rule we have also revised the upper payment limit requirement, which may result in increased levels of funding for MCOs.

d. Beneficiary Protections in FFP

Comment: Commenters expressed concern that the proposed rule did not extend its numerous beneficiary protections to the fee-for-service (FFP) delivery system, and that many of the protections within the regulation have no corollary protections in FFP. The commenters noted that in FFP Medicaid, there were no rights afforded to providers who will coordinate care, nor was there adequate quality assurance activities, information on participating providers, or detailed grievance procedures. The commenters believed that the proposed regulation makes it difficult to make meaningful comparisons between FFP and managed care. Another commenter felt that the proposed rule did not adequately

recognize that managed care is not the only system that States will be using to provide health services to beneficiaries, as many States will continue to operate a FFP system. The commenter believed that it is the clear intent of Federal legislation that all Medicaid beneficiaries should receive the same protections and advantages without respect to the type of provider that is under contract. Therefore, in the commenters opinion, the regulations that apply to MCOs should also apply to the State Medicaid agencies in their operation of FFP systems.

Response: While HCFA agrees that beneficiary protections are also important for beneficiaries receiving care under fee-for-service arrangements, this rulemaking primarily implements Chapter 1 of Subtitle H of the BBA, titled ''Managed Care.'' These statutory provisions do not apply to FFP Medicaid, and cannot be extended to FFP arrangements in this final rule, since the proposed rule did not indicate that fee-for-service Medicaid provisions were at issue in this rulemaking. However, States do have the flexibility to develop beneficiary protections similar to those presented in this regulation for those still receiving care through fee-for-service.

e. Use of Examples in the Preamble

Comment: Some commenters were concerned over the use of examples in the preamble to the September 29, 1998 Notice of Proposed Rule Making (NPRM) and the potential applicability of these examples in a court of law. These commenters requested that HCFA clarify that the examples in the preamble to the proposed rule would not be standards enforceable by law. They believed that the use of examples could lead to unintended interpretations of the final rule. One commenter suggested that HCFA make a clear statement ''that the preamble that accompanied the proposed rule was intended to spark discussion, not provide guidance for further interpretations.''

Response: The examples provided in the preamble to the NPRM were intended to be just that, examples. They were included in the preamble discussion to provide options for States when implementing the provisions within the proposed rule. We did not include these examples in the regulation text itself, as they were intended to be illustrative in nature and States always retain the flexibility to deviate from these examples.

f. Consistency with Medicare

Comment: Several commenters disagreed with our guiding principle that, where appropriate, we would promote consistency with the Medicare+Choice program in developing this regulation. One commenter argued that the Medicaid statute is not designed to promote consistency with Medicare. The commenter did not believe that consistency between Medicare and Medicaid is a valid reason to deviate from the principle of State flexibility. The commenter believed that Title XIX provides Federal funds for various State medical assistance programs that are to be administered by States within broad Federal rules, and noted that those Federal rules, as found in Title XIX, contain no general requirement for consistency with Medicare. The commenter further noted that the preamble to the proposed rule also states that ''the regulations were written to support State agencies in their role as health care purchasers * * * and * * * to provide State agencies with the tools needed to become better purchasers.'' The commenter found this to be a ''paternalistic'' approach, which in the commenter's view was inconsistent with the nature of the Medicaid program as one administered by States within broad Federal rules. Portions of the proposed regulations intended to ''support'' States as health care purchasers, but which do not implement any requirement under Title XIX, should in the commenter's view be issued as guidance or advice to States, not as additional requirements in Federal regulations. Finally, the commenter found the ''uniform national application'' of ''best practices,'' as defined by HCFA, to be inconsistent with the nature of the Medicaid program as one administered by States within broad Federal rules.

Several other commenters, however, supported the guiding principle of consistency with the Medicare+Choice program, and believed that it would help relieve the administrative burdens imposed on MCOs, because to the extent that the Medicare and Medicaid programs are consistent with each other, administrative efficiencies result. The commenters also felt that establishing uniform industry standards was beneficial not only to MCOs and primary care case managers, but also for consumers receiving services and providers who contract with those MCOs or primary care case managers to deliver health care services. The commenters commended HCFA for recognizing that while it is imperative that there be consistency and uniform application of standards, some areas require a unique approach by States; as a result, the commenters support HCFA's efforts to allow States the flexibility in developing such programs.

Response: It was our intent to create consistency with Medicare+Choice program requirements in order to ensure that the managed care industry would not have to comply with multiple sets of standards. However, where there was a clear need for State flexibility or where consistency with the Medicare+Choice program was not appropriate for Medicaid managed care, we deviated from Medicare+Choice policy. We believe that this final rule effectively balances the need for flexibility and consistency, while providing States with the broad tools they need to become more efficient purchasers of health care. As we developed this final rule, we continued to work with our Medicare colleagues to coordinate changes to provisions in this final rule that had counterparts in the Medicare+Choice regulations. While we have promoted uniform national application of knowledge and best practices learned, the Medicaid statue has always given States the flexibility to design their own Medicaid programs.

g. Applicability of BBA Provisions to Waiver Programs

Section 4710(c) of the BBA provides that nothing in the managed care provisions of the BBA (Chapter 1 of subtitle H) shall be construed as affecting the terms and conditions of any waivers granted States under section 1915(b) or 1115 of the Act. The Conference Report on the BBA clarifies that this exemption is intended solely for waivers that are approved or in effect as of August 5, 1997 (the date of enactment). We indicated in the preamble to the proposed rule that we interpreted this exemption to apply to 1915(b) waivers only for the period of time for which a waiver has been approved as of August 5, 1997, at which time the State would be required to comply with the BBA provisions. In the case of waivers under section 1115 demonstration projects approved as of August 5, 1997, the terms and conditions are similarly ''grandfathered'' under section 4710(c) of the Act only for the period of time for which the waivers were approved as of August 5, 1997. However, unlike section 1915(b) waivers, these demonstration projects are subject to another BBA provision that affects the applicability of BBA managed care provisions. Section 4757 of the BBA added a new section 1115(e), providing for a three year

extension of demonstrations if certain conditions are met. If a section 1115 demonstration approved on or before August 5, 1997 is renewed under the terms of section 1115(e), the terms and conditions that applied on the last day approved under the original demonstration remain in effect during the three year extension period. Thus, if terms inconsistent with the BBA managed care provisions were still in effect by virtue of section 4710(c), these terms were extended for three years if there an extension was granted under section 1115(e).

Comment: Many commenters felt that HCFA's interpretation of section 4710(c) as applicable only for periods for which waivers were approved on August 5, 1997 was inconsistent with the commenters' view of the intent of this provision. These commenters felt that States had developed specific provisions of their waivers and demonstrations to address specific issues within the State, doing so in consultation with all appropriate stakeholders, and that to require changes in the programs now would result in confusion for enrollees and providers, disruptions in the delivery system, and increased administrative costs for both the States and health plans.

Response: We disagree with the commenters' view of this provision. Language in the Conference Report on the Balanced Budget Act of 1997 specifically states the intent of Congress as limiting the exemption contained in section 4710(c) to waivers ''either approved or in effect'' as of the date of enactment. Since section 1915(b) waivers are specifically limited by statute to no more than 2 years and section 1115 demonstration waivers are typically granted for periods of no more than 5 years, the waiver which is ''approved'' or ''in effect'' as of the date of enactment expires at some point thereafter. While States may request renewals of section 1915(b) waivers for up to 2 years, these additional waiver periods cannot be seen to have been ''approved'' or ''in effect'' on August 5, 1997. This is similarly the case with respect to standard extensions of a section 1115 demonstration approved after August 5, 1997. As explained above, however, in this latter case, a totally separate provision of the BBA created section 1115(e) of the Act, that requires the terms and conditions in effect on the date before a section 1115 demonstration would otherwise expire be extended for three years. Section 1115 demonstrations that do not qualify for an extension under the authority in section 1115(e)(1) do not maintain the same exemption, and would be subject to all BBA provisions in effect at the time of the expiration of the 1115 authority approved as of August 5, 1997 (in the absence of new waiver or matching authority under section 1115(a) exempting a State from BBA requirements).

We have provided some flexibility to States in phasing in BBA requirements by permitting exemptions for any provisions addressed in the State's waiver proposal, statutory waivers, special terms and conditions, operational protocol, or other official State policy or procedures approved by HCFA, rather than limiting the exemption solely to specific ''Special Terms and Conditions'' negotiated between HCFA and the States. We believe that HCFA has balanced the need to implement important beneficiary protections contained within the BBA with the flexibility that States need to effectively phase-in these requirements in programs designed to meet specific needs within the State.

Comment: Some commenters felt that the terms and conditions agreed to by HCFA and the State should continue to be the applicable rules under which a waiver program is operated.

Response: As indicated above, not only the special terms and conditions, but any other policies, procedures or protocols approved by HCFA will remain in effect for the period the State is entitled to an exemption under this provision. With the exception of section 1115 demonstrations extended under section 1115(e) of the Act, we believe that Congress limited this exemption to the time period of the waiver approved or in effect as of August 5, 1998.

Comment: Several commenters argued that the BBA provisions were intended to apply to managed care programs established under State plan amendments authorized by section 1932(a) of the Act, and should not apply at all to waiver programs.

Response: The BBA provisions on managed care in sections 4701 through 4710 of the BBA that are limited in their application to mandatory managed care under the State plan contain a specific reference to that section of the Act. Both the definition of PCCM services in section 1905(t) (in section 1905(t)(3)(F)), and section 1903(m)(2)(A), in the case of MCOs, require compliance with applicable provisions in section 1932. Thus, when a provision in section 1932 applies to an MCO or MCE, and is not limited to a program under section 1932(a)(1), it applies regardless of the authority under which the managed care program in which they participate operates. Thus, these provisions apply to all types of managed care—voluntary or mandatory, State plan or waiver.

Comment: Some commenters felt that HCFA inappropriately limited this exemption by applying it only to provisions that were ''specifically addressed'' in approved State documents, rather than to the entire waiver program.

Response: We believe that we have adopted a broad interpretation of the applicability of section 4710(c). Section 4710(c) states that the managed care provisions shall not be construed to affect the ''terms and conditions'' of waivers. As noted above, this could have been interpreted to apply only to provisions set forth in actual formal ''terms and conditions.'' We have interpreted this to refer to anything addressed in the State's approved waiver materials. In such cases, no determination need be made as to whether the State's policy or procedures meet or exceed the BBA requirement during the duration of the waiver period approved as of August 5, 1997 (or an extension under section 1115(e) in the case of a section 1115 demonstration). We note that the BBA contains provisions such as fraud and abuse protections, some of the quality provisions, a prudent layperson's definition of emergency, and the extension of guaranteed eligibility to PCCMs, which would not usually be addressed in a State's waiver materials. We believe it is important to implement these provisions which can provide beneficiary protections beyond that already provided for in a State's waiver.

Comment: One commenter questioned the impact of this exemption on a State which is phasing-in a waiver on a county-by-county basis, where parts of the State would be exempt from BBA requirements, while other parts of the State would be subject to them.

Response: A State that is phasing-in a waiver which was approved prior to August 5, 1997 maintains exemptions from the BBA for the whole service area of its waiver program as it is implemented, not merely the areas which were implemented prior to that date. The language in the Conference Report provides the exemptions for any waiver which is ''approved or in effect.''

Comment: One commenter believed that HCFA should provide additional clarification as to how this exemption from BBA provisions applies to section 1115 demonstrations.

Response: HCFA Regional Offices have been working with section 1115 States to identify those areas that need to come into compliance with BBA provisions. These decisions will have to be on a State-by-State basis, determined

by the specific provisions in effect in each State's waiver program. Once HCFA has determined which BBA provisions apply and which do not apply, the exemptions will remain in place until the current approved period of the waiver expires, or if it is extended under section 1115(e), the end of the three year extension. At this time States will need to come into compliance with all BBA provisions that are currently in effect. The only exception is for a State that receives an extension of its section 1115 authority under section 1115(e)(1) which, as indicated above, requires the same terms and conditions to be in place when the waiver is extended for up to three years.

Comment: One commenter felt that the BBA provisions should be applied immediately to all new and existing waiver programs.

Response: Section 4710(c) provides that nothing in the BBA provisions on managed care ''shall be construed as affecting the terms and conditions of any waiver . . . under section 1115 or 1915(b) of the Social Security Act.'' We believe that this language precluded us from applying these provisions in an inconsistent manner with such waiver terms and conditions.

h. Comments Relating to American Indians and Alaskan Native Populations

Comment: We received several comments that specifically addressed the relationship of the proposed regulation to the American Indian and Alaskan Native (AI/AN) populations. Most of the commenters were concerned that the tribal health care systems would be drastically impacted by the proposed regulation. Because of this impact, one commenter recommended that the Indian Health Service (IHS) and the tribal system be exempted from the proposed regulations, and that we consult with IHS and tribal organizations before including them in the proposed regulations. Another commenter indicated that States should recognize the inherent sovereignty of Indian Tribes and Nations and the special status of health programs for American Indians under Federal law. This commenter recommended that States implementing Federal programs need to develop a consultation policy that ensures tribal participation in developing health care programs. Another commenter stated that the proposed regulation showed concern for consumer protection in general, but gave little attention to the specific needs and circumstances of AI/AN consumers and Indian health providers. In the commenter's opinion, the best way to ensure that this happens is to require States to engage in meaningful tribal consultation. Several other commenters specified that the proposed rule does not mention or discuss the special relationship that exists between the United States and its indigenous peoples, namely American Indians, Alaskan Natives, Aleuts, Eskimos and Native Hawaiians. These commenters believed that it is important to specifically include language that acknowledges this relationship and allows the Federal government to provide services for these groups. This would be done not on the basis of race or ethnicity, but rather upon the Federal government's historical relationship with native peoples and their governments who live in areas which are not portions of States of the United States but who have had affinities to these areas long before these States came to be part of the United States. The commenters also noted the importance of including language in the final rule that recognized the trust responsibilities of the Federal government to indigenous peoples and their respective tribes in developing program standards, including defining cultural competence, enrollment policies and procedures, marketing, access, grievances, quality assurance and sanctions for MCOs providing health services to their peoples and not the States.

Response: While we are aware of, and concerned about, the impact of this final rule on IHS and tribal health systems, we are not exempting them from its application when they operate as Medicaid managed care entities or subcontract with Medicaid managed care entities. First, there is no basis in the statute for such an exemption. We also believe that Medicaid beneficiaries who use such systems are entitled to the protections and safeguards embodied in this rule whether or not they use IHS and tribal systems. We do however understand that IHS and tribal health systems have unique circumstances, and we have consulted with IHS and tribal governments on many issues. These consultations have resulted in some adjustments to the rule. We will continue the consultation process as we interpret and implement this final rule to ensure that we address the concerns of IHS and tribal health systems. We do not believe, however, that this rulemaking is an appropriate vehicle to address the full range of Federal treaty relationships with tribal groups cited, since its scope is limited to the Medicaid managed care provisions in Chapter 1 of Subtitle H of the BBA.

Comment: One commenter strongly suggested that efforts be made by Tribal, Federal and State officials to implement the IHS/HCFA Memorandum of Agreement (MOA). The commenter believed that MOA provisions for 100 percent FMAP for tribally operated facilities should be honored under any State managed care system in the views of this commenter. The commenter believed that States operating Medicaid managed care programs should carve out IHS and tribal programs as Medicaid providers eligible for the ''pass-through'' reimbursement. Another commenter stated that Indian health facilities should be paid by Medicaid for every visit in which Medicaid covered services are provided to a Medicaid beneficiary. This would apply to the Indian Health Service direct service facilities, tribally operated facilities, and urban Indian clinics, collectively known as the I/T/U. The commenter believed that the I/T/U should be paid by Medicaid at a rate that covers the cost of delivering services, considering that there is little opportunity to shift costs to other third party payers. The commenter further stated that barriers to participation should be eliminated for AI/AN populations for health care programs that receive any Federal funding. Recognizing the limitations in funding, the commenter believed that resources should be used to the maximum extent for direct patient care and prevention activities while keeping administrative functions as efficient as possible.

Response: As discussed above in the discussion of comments on Subpart J section II. H., issues of Federal matching funding levels are outside the scope of the proposed rule or this final rule, which has no effect on matching rates for services furnished by IHS or tribal facilities. We note that the commenter is mistaken in suggesting that the cited MOA requires any particular payment levels to IHS or tribal facilities (and further note that it does not address urban Indian facilities at all). We recognize, however, that IHS and tribal health systems and providers may have unique circumstances in contracting with such programs. We intend to continue to work with IHS and the tribes to minimize barriers to participation in Medicaid managed care programs, and to address the matching rate issues raised by the commenters.

i. Miscellaneous Comments

Comment: One commenter recommended that the final rule address the administration of non-emergency MCO transportation services. The commenter believed (based on recommendations made by HCFA's Transportation Technical Advisory Group) that coordination with

transportation agencies and other human service providers increased the efficiency of the transportation system, helped control costs, and can provide better service to Medicaid and non-Medicaid users of the transportation system. The commenter noted that it is in the interest of the community, State, and the health care and transportation industries to develop coordinated networks of transportation. Further, according to the commenter, States should have the ability to operate their non-emergency transportation services with Federal matching funding comparable to the optional medical service match to improve the States' capacity to coordinate transportation services, thereby saving Medicaid related costs while supporting the existing public transportation network.

Response: The issue of non-emergency transportation services is not an issue that is unique to managed care. This regulation only pertains to the Medicaid managed care provisions in the BBA, and thus, non-emergency transportation is beyond the scope of this regulation and the statute it implements.

Comment: One commenter disagreed with the deletion of the requirement that no more than 75 percent of enrollees in risk contracts be eligible for Medicare or Medicaid. Although it is not clear why this would be the case, the commenter apparently believed that this deletion would result in MCOs decreasing the numbers of Medicaid beneficiaries.

Response: First, the 75/25 enrollment requirement is a limit on the percentage of enrollees eligible for Medicaid, and therefore there is no reason to believe it would result in decreased Medicaid enrollment. Any changes that resulted from its elimination would presumably increase Medicaid enrollment. More importantly, this change was made by Congress in the BBA, and we thus had no discretion in this rulemaking to retain it. We note that this requirement was previously used as a rough ''proxy'' to ensure quality services by requiring that an MCO attract commercial customers. This ''proxy'' has been replaced in the BBA with more direct quality requirements implemented in this final rule.

Comment: We received one comment urging that the proposed rule deal with the effects on Medicaid of the law prohibiting ''public benefits'' going to individuals who are not citizens or permanent residents.

Response: This subject is outside the scope of this rulemaking.

Comment: A few commenters suggested that HCFA require State agencies to consult with beneficiaries and the physician community at all stages of the planning and implementation of new managed care initiatives. The commenters believed that physician organizations can offer significant input into the development of professional standards effecting patient care delivery, evaluating the adequacy of provider networks, and assessing quality of care delivered. Further, the commenters believed that we should continuously monitor and evaluate State experiences with physician participation and serve as a clearinghouse of information for States on successful strategies.

Response: We realize that public and physician consultation are important factors in the development of Medicaid managed care initiatives and encourage stakeholder input at all stages of managed care development. However, we are not requiring a specific requirement for stakeholder involvement since States, based on the uniqueness of their Medicaid managed care programs, are in the best position to determine how this involvement should be structured. Each State is required to have a Medical Care Advisory Committee (MCAC) established for the purpose of advising the Medicaid agency about health and medical services. This committee, by regulatory definition, is required to include physicians and beneficiaries. We encourage States to continue to use the MCAC as a mechanism for obtaining input on managed care issues. Likewise, under § 438.302, we are requiring public consultation in development of the State's quality strategy, though we are not specifying the structure of this consultation.

Comment: One commenter expressed concern with the lack of discussion in the preamble and proposed regulation text of requirements or directions to States regarding long term care services and support delivered by MCOs. The commenter believed that this was of particular concern since the elderly and people with disabilities account for the majority of Medicaid spending.

Response: While long-term care services were not explicitly addressed in the regulation, we believe the regulation was written in such a manner to encompass all the types of services delivered under managed care including long-term care. Long-term care issues were considered in discussions during the development of the final regulation.

Comment: Several commenters were concerned with what they believed to be a lack of clarity and specificity in the proposed rule concerning children and children with special health care needs. These commenters believed that the final rule should be more specific on child health requirements separate from adult health requirements, since children have distinct medical and developmental health care needs. The commenters also stated that the proposed rule offered no special protection for children with special health care needs. One commenter stated that when Congress enacted section 1932(a)(2)(A) of the Act, it intended that HCFA develop standards and protections for special needs children above and beyond the managed care standards and protections provided to all beneficiaries. The commenter further indicated that because children with special health care needs are the most vulnerable, it was essential that HCFA provide specific regulations that protects these children in managed care environments.

Response: We agree that children, and particularly children with special health care needs, have unique needs that differ from the adult population. While this final rule establishes a general framework for States to use when developing managed care programs to serve all of its enrolled populations, as discussed in section II. D. above, it also takes into account and implements recommendations set forth in HCFA's report to Congress on special needs beneficiaries required under section 4705(c)(2) of the BBA. We note that section 1932(a)(2)(A) specifically exempts special needs children from being mandatorily enrolled in the State Plan Option for Medicaid managed care. In addition, under 1915(b) waivers HCFA has established new interim criteria that States must meet when establishing programs for children with special health care needs. These criteria require additional reporting and monitoring for children with special health care needs. And finally, the terms and conditions for 1115 waiver programs also contain specific areas that address the needs of these types of children.

Comment: One commenter was concerned about the impact of Medicaid managed care on the nation's dental schools and other hospital-based or allied dental education programs. The commenter urged HCFA to recognize the special role of dental education institutions in serving the Medicaid population and to use the regulations to strengthen the Medicaid program by improving access to dental prevention and treatment services. Finally, this commenter recommended that the proposed regulations be revised to amplify the specific requirements of law related to the access of diagnostic,

preventive and treatment services for children under Medicaid's EPSDT program. The commenter was specifically concerned about the impact of managed care on the utilization rate for children's dental services.

Response: We recognize the importance of the nation's dental schools and other hospital-based dental education programs in serving the dental needs of the Medicaid population. At this time, we do not believe it is necessary to develop a separate regulation to address access to dental prevention and treatment services. This final rule is designed to address access issues related to all Medicaid managed care services. For example, an MCO that delivers dental services to Medicaid beneficiaries must comply with the access requirements in the regulation. The MCO must ensure that it offers an appropriate range of services and that it maintains a network of providers that is sufficient to meet the needs of its enrollees. Further, according to § 438.206(a), each State must ensure, through its contract with an MCO, that all of the covered services are accessible for all the beneficiaries enrolled with the MCO. We are also optimistic that managed care will facilitate increased utilization in the area of dental services.

Comment: Several commenters recommended that HCFA develop a final rule which ensures that States, MCOs and PCCMs will develop Medicaid managed care programs that protect the rights of enrollees who are homeless, promote their access to an appropriate range of services, and improve the quality of care available to them.

Response: We believe this final rule protects the rights of all beneficiaries, including persons who are homeless. For example, § 438.206 requires that the delivery network meet the needs of the population served and that access to services be guaranteed, while under § 438.100 all beneficiaries must be treated with dignity and respect. We recognize that persons who are homeless face unique difficulties in receiving information needed to make appropriate choices among MCO or PCCM options due to transience, lack of mailing address, and other circumstances. Under § 438.56(d)(2)(i), persons who are homeless, and who have been automatically assigned at their initial enrollment into an MCO or PCCM, may disenroll and re-enroll with a different MCO or PCCM at any time. We believe this will give persons who are homeless the opportunity to learn more about managed care when they need medical services and make the most effective choice of MCOs or PCCMs at that time.

Comment: One commenter recommended that there should be some form of consumer assistance programs to help enrollees navigate the managed care system.

Response: We agree that there must be adequate and appropriate consumer assistance programs available to enable beneficiaries to navigate the managed care system. We also agree that it is a State's responsibility to ensure that consumer assistance is available to its beneficiaries. However, because consumer assistance can be accomplished in many different ways, and should be designed by each State to meet the unique characteristics of its managed care population and program, we are not imposing a Federal requirement for this. Some States already use toll free hotlines for consumer assistance, while others have developed ombudsman programs. We do require that MCOs must give enrollees reasonable assistance they need in completing forms or other procedural steps in the grievance process.

Comment: Several commenters believed that the regulation should clearly respond to the special needs of medically vulnerable beneficiaries with acute, chronic and disabling conditions and contain specific definitions of these diagnoses, as well as clear definitions of ''mental illness'' and ''addictive disorders'' so that coverage for these conditions are included under the service plan. One commenter recommended the inclusion within all Medicaid mental health managed care benefit packages of psychosocial rehabilitative services, self-help services and peer supports, and other non-medical services designed to help consumers improve their level of functioning, increase their ability to live independently and cope with ongoing symptoms and side effects of medications. Further, the commenter contended that States should be required to establish the methodology necessary to measure the prevalence of chronic mental illness, acute mental illness, or substance abuse per county, taking into account the predicted health care needs of the population to be enrolled. Another commenter believed that the regulation should incorporate a requirement that each Medicaid managed care behavioral health plan name and provide a full continuum of addiction treatment services in the network including: hospital and non-hospital detoxification, hospital and non-hospital rehabilitation, short and long term rehabilitation, outpatient, partial hospitalization services and treatment for the family. This commenter also recommended that a particular university be given a strong role in review of these provisions, and that this role should be written into regulation.

Response: The regulation was intended to address needs and protections for all Medicaid beneficiaries in managed care. The information requirements at § 438.10 require that the State must, directly, or through the MCO, PHP, or PCCM, provide information on any benefits to which the beneficiary is entitled under the Medicaid program, but that are not covered under the MCO, PHP, or PCCM contract, and specific instructions on where and how to obtain those benefits, including how transportation is provided. Further, we are not identifying specific types of treatment and services in the regulation for one type of service category. Each State has the flexibility to determine the services that will be covered under their own State Medicaid program. This regulation pertains only to the delivery of services, not the benefits provided under the State's Medicaid program. With respect to the last comment on the role of a specified university, we do not believe it would be appropriate to grant an outside private body government oversight authority.

Comment: One commenter suggested that MCO, PHP, and PCCM contracts should specify the services that the entity is responsible to provide, and that the State should be required to make arrangements for providing other State plan services, and give beneficiaries written information on how to obtain them.

Response: As noted above in section II. C., § 438.210(a) requires that contracts specify the services the entity is required to provide, and § 438.206(c) requires that if an MCO contract does not cover all of the services covered under the State plan, the State must make available those services from other sources and instruct all enrollees on where and how to obtain them, including how transportation is provided. Further, the information requirements under § 438.10 require that the State must, directly or through the MCO, PHP, or PCCM, provide to Medicaid beneficiaries information on any services to which they may be entitled under the Medicaid program, but that are not covered under the MCO PHP, or PCCM contract and specific instructions on where and how to obtain those services, including how transportation is provided.

Comment: One commenter recommended that a new paragraph should be included (titled ''Americans with Disabilities Act'') to require that each MCO must ensure that: (1) the physical and mental disabilities of enrollees and potential enrollees are reasonably accommodated, including flexible scheduling, extra assistance and specialized staff training; (2) enrollees with disabilities receive services in the most integrated setting appropriate to their needs, including community based services to enable them to live in community settings instead of institutions or residential treatment facilities; (3) no eligibility criteria, service authorization procedures, utilization review practices or other methods of administration are employed that defeat or substantially impair, with respect to individuals with disabilities, accomplishment of the objectives of the State's medical assistance program; and (4) qualified individuals with disabilities be provided services, benefits and aids that are as effective in affording equal opportunity to obtain the same result, to gain the same benefit or to reach the same level of achievement as that provided to others.

Response: We do not feel it is necessary to add a separate provision as other areas of the regulation respond to this issue. Section 438.100 requires that the State must ensure that each MCO and PHP comply with any and all Federal laws pertaining to enrollee rights, including the Americans with Disabilities Act. Further, § 438.6(f) requires that all contracts must comply with all applicable State and Federal laws and regulations, including Title VI of the Civil Rights Act of 1964; Title IX of the Education Amendments of 1972 (regarding education programs and activities); the Age Discrimination Act of 1975; the Rehabilitation Act of 1973; and the Americans with Disabilities Act.

Comment: One commenter was concerned with what will happen to people with mental retardation should an MCO, PHP, or PCCM withdraw from the Medicaid market. The commenter stated that if a Medicaid MCO or PHP leaves the Medicaid market, there must be protections in place to ensure continuing access to medically necessary services for individuals with mental retardation and other disabilities who critically need access to these health and health related services and supports to live in the community.

Response: It is the State's ultimate responsibility to ensure access to Medicaid covered services. In the event that an MCO or PHP withdraws from the Medicaid market, the State must ensure that services are delivered to all Medicaid beneficiaries either through another Medicaid MCO or PHP, or through fee-for-service arrangements.

Comment: One commenter found it disturbing that managed care consumer protections and quality measures for the Medicare population have more ''teeth'' than those required for Medicaid. The commenter felt that this perceived distinction in the requirements of Medicare managed care and Medicaid managed care continues what the commenter believed to be ongoing discrimination against people who are poor and disabled.

Response: It was our intent to create consistency with the Medicare+Choice requirements to lessen the impact that multiple regulatory and administrative standards exert on the managed care industry. However, where there was a clear need for greater beneficiary protection or where consistency with the Medicare+Choice program was not appropriate for Medicaid managed care, we deviated from the Medicare+Choice policy. We believe that this final rule balances the need for flexibility and consistency, while providing States with the broad tools necessary to become better purchasers of health care. We believe that this final rule contains protections for enrollees that are equal to or exceed those in the Medicare+Choice final rule. This includes sanction and civil money penalty authority similar to that in the Medicare+Choice rule. We thus disagree with the commenter's premise about the Medicare+Choice rule having more ''teeth.''

Comment: Several commenters urged HCFA to provide special attention to the effect of these regulations on people with disabilities. The commenters believed that the regulations must provide specific protections for special needs populations, such as those with spinal cord injury or dysfunction when enrollment in Medicaid managed care is mandatory. One commenter believed a methodology should be developed which would allow States to inventory disabled populations on a per county basis in order to ensure that adequate numbers of providers, especially specialists, would be available to serve the enrolled special needs population.

Response: The regulation was intended to address the needs and protections for all Medicaid beneficiaries in managed care, including persons with disabilities. The regulation was written in a manner to establish a general framework for States to use when developing managed care programs to serve all of its enrolled populations. We believe the regulation allows greater access to quality health care services delivered through managed care arrangements for persons with disabilities. As noted above in section II. C., § 438.206(d) requires that MCOs and PHPs take into account the anticipated enrollment of persons with special health care needs in establishing their provider network, and must have the appropriate numbers and ''types'' of providers in terms of training and experience to meet these needs. We believe these provisions directly address the commenters' concerns.

Comment: One commenter suggested that the final regulation make clear that all States are free to adopt more rigorous standards of consumer protections in Medicaid managed care.

Response: The consumer protections in this regulation were not designed to prevent States from developing more rigorous standards. States retain the flexibility to develop more restrictive consumer protection provisions that go beyond those contained in this regulation.

Comment: Several commenters noted that the issue of low physician participation in Medicaid does not appear to have been addressed in the proposed rule, and believed that this has always been a concern under the Medicaid program. Some of the commenters believed that because of inadequate funding and administrative requirements, physicians have minimized their participation in the Medicaid program. These commenters believed that financial incentives may be an appropriate mechanism to entice physician participation. On the other hand, a commenter felt that financial incentives that may prevent the delivery of medically necessary services may be partially controlled by prohibiting any financial incentives. Another commenter recommended that in addition to physician incentive plans that place physicians at substantial financial risk for services they do not provide, having to conduct enrollee surveys, and provide adequate and appropriate stop loss protection, HCFA should also state that financial risk will reside with the plan in instances where a plan decision results in a limit on the services provided. Finally, one commenter felt that there was a need to develop financial incentives for managed care plans to compete on the basis of quality rather than the basis of price. This commenter believed that it is important for Medicaid managed care regulations to establish rewards for MCOs based on quality, not merely cost reductions.

Response: The general issue of relatively low levels of physician participation in the Medicaid program is

outside the scope of this rulemaking. We note, however, that levels of participation in managed care settings have been higher than under fee-for-service Medicaid, and that a managed care enrollee is ensured access to a primary care provider under this final rule. Thus, to the extent managed care is involved, physician participation is guaranteed under this final rule to the extent necessary to meet access requirements. Specifically, § 438.207 requires that each MCO and PHP must ensure that it maintains a network of providers that is sufficient in number, mix and geographic distribution to meet the needs of the anticipated number of enrollees in the MCO's or PHP's service area. Further, under § 438.214, the State must ensure that each MCO and PHP have a process for formal selection and retention of providers that does not discriminate against those that serve high risk populations or specialize in conditions that require costly treatment. With respect to financial incentives for MCOs and PHPs, these are addressed in § 422.6(c)(5) as part of the discussion of actuarially sound rates. See section II. A. above. Beyond these limits, we believe States should have flexibility in this area. With respect to financial incentives for individual physicians, § 438.6(h) requires that MCO and PHP contracts provide for compliance with the physician incentive plan requirements.

Comment: One commenter wrote to express concerns regarding the quality of care delivered by a particular managed care program. The commenter was concerned about the introduction of managed care for persons with disabilities and persons with chronic conditions. The commenter contended that they were misled by their health plan, and the organization denied and reduced care when not appropriate.

Response: We anticipate that the new consumer protections, quality provisions and grievance system requirements in this final rule will work to alleviate problems in the areas addressed by the commenter.

Comment: One commenter believed that the final rule should maintain an adequate safety net to guarantee the continued viability of Medicaid managed care and to allow for reasonable alternatives. The commenter cautioned States moving towards mandatory managed care that they must avoid the tendency to make the area fit MCOs rather than the MCOs address the area. The commenter felt that ''cookie cutter'' approaches will not work in large rural States, and it might be difficult to develop health plan networks in rural areas.

Response: We recognize that States are unique and have different needs for their enrolled populations. This final rule was designed to maintain State flexibility as much as possible, so that States can implement managed care programs that meet the needs of their beneficiaries.

VI. Collection of Information Requirements

Under the Paperwork Reduction Act (PRA) of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval.

In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Therefore, we are soliciting public comments on each of these issues for the information collection requirements discussed below.

The following information collection requirements and associated burdens are subject to the PRA. For purposes of this requirement, we incorporated pertinent managed care data from the 1999 Medicaid enrollment report. As of June, 1999, there were 375 managed care organizations (MCOs) (this includes 2 HIOs that must adhere to the MCO requirements of this regulation), 37 primary care case management systems (PCCMs), 412 managed care entities (MCOs and PCCMs combined), and 129 prepaid health plans (PHPs). There were a total of 24,470,583 beneficiaries enrolled in these plans (some beneficiaries are enrolled in more than one plan) in forty-eight States and the District of Columbia (Wyoming and Alaska do not currently enroll beneficiaries in any type of managed care).

A. Section 438.6 Contract Requirements

1. Section 438.6(c) Payments Under the Contracts

a. Requirement

In summary, § 438.6(c) modifies the rules governing payments to MCOs and PHPs by doing the following: (1) eliminates the upper payment limit (UPL) requirement; (2) requires actuarial certification of capitation rates; (3) specifies data elements that must be included in the methodology used to set capitation rates; (4) requires States to consider the costs for individuals with chronic illness, disablility, ongoing health care needs, or catastrophic claims in developing rates; (5) requires States to provide explanations of risk sharing or incentive methodologies; and (6) imposes special rules, including a limitation on the amount that can be paid under FFP in some of these arrangements.

b. Burden

We believe that the burden of providing additional information to support the actuarial soundness of a State's capitation rates will be offset by the elimination of the UPL requirement. States will no longer be required to extract fee-for-service (FFP) data and manipulate that data by trending and other adjustments in order to establish a FFP equivalent for purposes of comparison to capitation rates.

2. Section 438.6(i)(2) Advance Directives

a. Requirement

This paragraph requires that MCOs and PHPs (States may determine that it is inappropriate to require this of some PHPs) provide adult enrollees with written information on advance directives policies and include a description of applicable State law.

b. Burden

The burden associated with this requirement is the time it takes to furnish the information to enrollees. We assume that this information would be furnished with the rest of the information required by other regulations sections and is therefore subsumed under those requirements.

B. Section 438.8 Provisions That Apply to PHPs

Section 438.8(a) Contract Requirements

a. Requirement

This section imposes most of the contract requirements contained in § 438.6 on PHPs, including advance

directives (in most instances) and physician incentive plan requirements.

2. Burden

PHPs have not previously been required to maintain written policies and procedures with respect to advance directives. This requires the PHP to provide written information to enrollees of their rights under this provision and the PHP's policies with respect to the implementation of those rights. We project 8 hours for each of the 129 PHPs to establish this policy and 2 minutes per enrollee for provision of this information, and acceptance of this right to each of approximately 8.1 million individuals enrolled in PHPs. The total time for this would be 271,032 hours.

Under the physician incentive plan provision, PHPs, like MCOs, will be required to provide descriptive information to States and HCFA to determine whether or not there is substantial financial risk in their subcontracts. In addition, enrollees must be surveyed and provided information on the risk arrangements when substantial risk exists.

We are basing our projections of burden upon information published in the **Federal Register** on March 27, 1996 and December 31, 1996 (61 FR 13445 and 61 FR 69049) which contained the original regulatory provisions on physician incentive plans for Medicare and Medicaid HMOs. Based on those assumptions, we believe no more than one third of the approximately 130 PHPs use incentive or risk payment arrangements with their subcontracting providers. Affected PHPs would be required to provide detailed responses to State surveys regarding their payment mechanisms and amounts. At the projected 100 hours per response for approximately 43 PHPs the total burden would be 4300 hours. For those PHPs with substantial financial risk, there are other requirements such as stop loss insurance and beneficiary surveys. We believe there would be minimal additional burden as a result of these requirements (because many already comply with these requirements) and that this would apply to no more than one fourth of those PHPs with risk or incentive payments, or a total of 11. We estimate an additional 10 hours per plan for a total of 110 hours. Altogether, we estimate 4,410 hours of burden through imposition of this requirement on PHPs.

C. Section 438.10 Information Requirements

1. Section 438.10(b), (d), (e), and (f)

a. Requirement

In summary, § 438.10(b), (d) and (e) state that each State, MCO, PHP, and PCCM must furnish information to enrollees and potential enrollees, to meet the requirements of this section. Paragraph (b) requires that the State notify enrollees and potential enrollees, and require each MCO, PHP, and PCCM to notify its enrollees and potential enrollees that oral interpretation and written information are available in languages other than English and how to access those services. The basic information listed in paragraph (d) and (e) of this section must be provided to each enrollee or to any potential enrollee upon request, by the MCO or PHP (unless the State chooses to furnish it directly), within a reasonable time after it receives from the State notice of the beneficiary's enrollment. This information must be provided on an annual basis thereafter, the MCO or PHP must notify enrollees of their right to obtain this information upon request. The information that must be provided includes the following:

Information for potential enrollees

General information must be provided about the basic features of managed care, which populations are excluded from enrollment, subject to mandatory enrollment, or free to enroll voluntarily in an MCO or PHP, and MCO and PHP responsibilities for coordination of enrollee care.

Information specific to each MCO and PHP serving an area that encompasses the potential enrollee's service area must be provided. This includes information on benefits covered; cost sharing if any; service area; names, locations, and telephone numbers of current network providers, including at a minimum information on primary care physicians, specialists, and hospitals, and identification of providers that are not accepting new patients; and benefits that are available under the State plan but are not covered under the contract, including how and where the enrollee may obtain those benefits, any cost sharing, and how transportation is provided.

Information for enrollees

The State must give each enrollee written notice of any change (that the State defines as ''significant'') in the information specified at least 30 days before the intended effective date of the change and make a good faith effort to give written notice of termination of a contracted provider, within 15 days after receipt or issuance of the termination notice, to each enrollee who received his or her primary care from, or was seen on a regular basis by, the terminated provider.

Required information:

- Kinds of benefits, and amount, duration, and scope of benefits available under the contract; enrollee rights as specified in § 438.100.
- Procedures for obtaining benefits, including authorization requirements.
- Names, locations, and telephone numbers of current network providers, including information at least on primary care physicians, specialists, and hospitals, and identification of providers that are not accepting new patients.
- Any restrictions on the enrollee's freedom of choice among network providers.
- The extent to which, and how, enrollees may obtain benefits, including family planning services, from out-of-network providers.
- The extent to which, and how, after-hours and emergency coverage are provided.
- Policy on referrals for specialty care and for other benefits not furnished by the enrollee's primary care provider.
- Cost sharing, if any.
- Grievance, appeal, and fair hearing procedures for enrollees, including time-frames, required under § 438.414(b).
- Any appeal rights that the State chooses to make available to providers to challenge the failure of the organization to cover a service.
- Any benefits that are available under the State plan but are not covered under the contract, including how and where the enrollee may obtain those benefits, any cost sharing, and how transportation is provided. The State must furnish information about how and where to obtain the service.
- Information on how to obtain continued services during a transition, as provided in § 438.62.
- The rules for emergency and post-stabilization services, as set forth in § 438.114.
- Additional information that is available upon request, and how to request that information.

At least once a year, the MCO or PHP, or the State or its contracted representative, must notify enrollees of their right to request and obtain the information listed above.

In addition, § 438.10(f) requires that information related to the licensure, certification, and accreditation status of MCOs, PHPs, and their providers be

furnished to each enrollee and each potential enrollee.

b. Burden

We believe the burden placed on States, MCOs, PHPs, and enrollment brokers as a result of this requirement is the time associated with modifying the content of existing information materials, as well as the time associated with distributing the materials to enrollees as specified by the regulation. We estimate that it will initially take 12 hours for each MCO or PHP to modify existing information materials to conform with the requirement above. We further estimate that there are approximately 375 MCOs and 129 PHPs, equating to an initial modification burden of approximately 6,048 hours. After the initial modification, we estimate that it will take MCOs and PHPs approximately 4 hours each to annually update the information materials, equating to an annual total burden of approximately 2,016 hours.

We expect that it will take MCOs, PHPs, or States approximately 5 minutes per enrollee to mail the initial packet, for an estimated 20.2 million enrollees. The total burden associated with this requirement is approximately 1,683,000 hours, approximately 3,340 hours per MCO or PHP, or 34,000 hours per State.

We similarly estimate that it annually will take MCOs, PHPs, or States 5 minutes per enrollee to mail information materials upon request. We estimate that 10 percent of enrollees and potential enrollees will request information annually, equating to approximately 2,020,000 enrollees and potential enrollees. The annual mailing burden associated with this requirement is estimated to be 2,020,000 individuals multiplied by 5 minutes per person, for a total burden of approximately 168,300 hours (approximately 330 hours per MCO or PHP, or 3,400 hours per State).

Finally, we estimate that it will annually take MCOs, PHPs, or States 5 minutes per enrollee to notify enrollees of their right to receive information. Five minutes multiplied by an estimated total enrollee population of 20,200,000 individuals equates to an annual burden of approximately 16,830,000 hours or approximately 3,300 hours per MCE or PHP or 33,400 hours per State.

2. Section 438.10(g)

a. Requirement

Section 438.10(g) requires that each primary care case manager (PCCM) (and PHPs that operate like PCCMs) provide similar types information to potential enrollees including information on provider names and locations, benefits, grievance procedures, and procedures for obtaining services during the appeals process.

b. Burden

The burden associated with this requirement is the amount of time required by States or their contracted representative to mail the required information to potential enrollees. We believe that it will take the 30 States approximately 5 minutes per enrollee to mail this information. We estimate that there are a total of approximately 4,274,000 PCCM enrollees, and that 10 percent of those enrollees will request this information. This equates to an annual burden of 5 minutes multiplied by 427,400 enrollees, or approximately 35,600 hours (approximately 962 hours per primary care case manager).

3. Section 438.10(h)

a. Requirement

In summary, § 438.10(h) states that if a State plan provides for mandatory MCO, PHP, or PCCM enrollment under section 1932(a)(1)(A) of the Act, the State or its contracted representative must provide information in a comparative, chart-like format, to potential enrollees and at least once a year thereafter. The information must include the MCO's, PHP's or PCCM's service area, the benefits covered under the contract, any cost sharing imposed by the MCO, PHP, or PCCM and, to the extent available, quality and performance indicators, including but not limited to disenrollment rates and enrollee satisfaction.

b. Burden

We believe that the additional burden on States (for example those not yet captured in the above provisions) is the length of time associated with creating the comparative chart. We estimate that it will take States approximately 4 hours each to create the comparative chart. We further estimate that approximately 8 States per year will avail themselves of the State Plan Option, for a total annual burden of approximately 32 hours.

D. Section 438.12 Provider Discrimination Prohibited

a. Requirement

This section requires that if an MCO or PHP declines to include individual or groups of providers in its network, it must give the affected providers written notice of the reason for its decision.

b. Burden

The burden associated with this requirement is the time it takes the MCO or PHP to draft and furnish the providers with the requisite notice. We estimate that it will take an hour to draft and furnish any given notice. We estimate that on average each MCO and PHP will need to produce 10 notices per year for a total of 5,040 hours.

E. Section 438.50(b) State Plan Information

a. Requirements

Each State must have a process for the design and initial implementation of the State plan that involves the public and have methods in place to ensure ongoing public involvement once the State plan has been implemented.

b. Burden

The burden associated with this section includes the time associated with developing the process for public involvement, including annual updates. We estimate that it will take 40 hours per State to develop the process for, and involving, the public for a total burden of 1960 hours (48 States and D.C.). We estimate that ensuring ongoing public involvement will take another 20 hours per State annually for a total annual burden of 980 hours.

F. Section 438.56z Disenrollment: Requirements and Limitations

1. Section 438.56(b)

a. Requirement

All MCO, PHP, and PCCM contracts must—

(1) Specify the reasons for which the MCO, PHP, or PCCM may request disenrollment of an enrollee;

(2) Provide that the MCO, PHP, or PCCM may not request disenrollment because of a change in the enrollee's health status, or because of the enrollee's utilization of medical services, diminished mental capacity, or uncooperative or disruptive behavior resulting from his or her special needs; and

(3) Specify the methods by which the MCO, PHP, or PCCM ensures the agency that it does not request disenrollment for reasons other than those permitted under the contract.

b. Burden

The burden of submitting this supporting documentation when MCOs, PHPs, or PCCMs request disenrollment of beneficiaries would be two hours per request. We calculate that approximately one-tenth of one percent of enrollees (24,470) would be affected, or 43 per MCO, PHP, or PCCM annually. The total burden would be 48,940 hours, or 87 hours per MCO, PHP, or PCCM.

2. Section 438.56(d)(1)

a. Requirement

In order to disenroll, the beneficiary (or his or her representative) must submit an oral or written request to the State agency (or its agent) or to the MCO, PHP or PCCM where permitted.

b. Burden

We believe that the burden associated with this requirement is the length of time it would take enrollees to submit in writing a disenrollment request, if they choose to use the written format. We estimate that it will take approximately 10 minutes per enrollee to generate a written disenrollment request. We estimate that approximately 5 percent of MCO, PHP, and PCCM enrollees will request that they be disenrolled from an MCO, PHP, or PCCM. Approximately one-fourth of the enrollees will choose a written rather than an oral request. This equates to an annual burden of approximately 10 minutes multiplied by 306,000 affected enrollees (one-fourth of the 1,221,000 enrollees requesting disenrollment), or approximately 51,000 hours.

3. Section 438.56(d)(3)

a. Requirement

When MCOs, PHPs, or PCCMs are processing disenrollment requests and do not act to approve them, they must submit written notice to the State and then the State takes action. When a State is acting on a for-cause disenrollment request, they may request written information from the MCO, PHP, or PCCM to determine the outcome. In addition, if the MCO, PHP, or PCCM approves the disenrollment for cause, it must give the enrollee and the State agency written notice of its determination.

b. Burden

We believe that the burden associated with this requirement is the time taken for MCOs, PHPs, or PCCMs to submit written notice to the State and beneficiaries.

Of the 1,221,000 affected enrollees, we calculate that one-fifth (244,000) will not be approved. If each notice takes 15 minutes to produce, the total burden would be 61,000 hours. Of the 244,000 enrollees not approved, we calculate that three-fourths (183,000) will involve the State requesting information from the MCO, PHP, or PCCM justifying the denial. At one hour per request, the total burden on MCOs, PHPs, or PCCMs would be 183,000 hours.

We estimate that the MCOs, PHPs, and PCCMs will need to produce notices for the remaining four-fifths of enrollees requesting disenrollment (977,000) and the States to approve the request for disenrollment. As this notice will probably be a short form letter, with attachments as necessary, we believe that it will take ten minutes per request to send out the notices, or an annual burden of 163,000 hours.

G. Section 438.102 Enrollee-Provider Communications

a. Requirement

Section 438.102(c) states that the general rule in paragraph (b) of this section does not require the MCOs and PHPs to cover, furnish, or pay for a particular counseling or referral service if the MCO or PHP objects to the provision of that service on moral or religious grounds; and makes written information on these policies available to (1) prospective enrollees, before and during enrollment and, (2) current enrollees, within 90 days after adopting the policy with respect to any particular service.

b. Burden

The above information collection requirement is subject to the PRA. However, we believe the burden associated with these requirements is captured in the general information requirements in § 438.10.

H. Section 438.114 Emergency Services

a. Requirement

Section 438.114(b) states that at the time of enrollment and at least annually thereafter, each MCO, PHP, and State (for PCCMs) must provide, in clear, accurate, and standardized form, information that, at a minimum, describes or explains (1) What constitutes an emergency, with reference to the definitions in paragraph (a) of this section, (2) the appropriate use of emergency services, (3) the process and procedures for obtaining emergency services, including use of the 911 telephone system or its local equivalent, (4) the locations of emergency settings and other locations at which MCO physicians and hospitals provide emergency services and post-stabilization care covered under the contract, and (5) the fact that prior authorization is not required.

a. Burden

The following information collection requirement is subject to the PRA. However, we believe the burden associated with these requirements is captured in the general information requirements in § 438.10.

I. Section 438.202 State Responsibilities

a. Requirement

Each State contracting with an MCO or PHP must have a strategy for assessing and improving the quality of managed care services offered by the MCO or PHP, document the strategy in writing and make it available for public comment before adopting it in final, and conduct periodic reviews to evaluate the effectiveness of the strategy at least every three years. Each State must also submit to HCFA a copy of the initial strategy and a copy of the revised strategy whenever significant changes are made. In addition, States are required to submit to HCFA regular reports on the implementation and effectiveness of the strategy, consistent with the State's own periodic review of its strategy's effectiveness, but at least every three years.

b. Burden

The burden associated with this section is limited to those States offering managed care through MCOs or PHPs (49) and includes the time associated with developing the proposed strategy, publicizing the proposed strategy, incorporating public comments, submitting an initial copy of the strategy to HCFA prior to its implementation and whenever significant changes are made, and submitting regular reports on the implementation and effectiveness of the strategy at least every three years. We estimate that it will take 40 hours per State to develop the proposed strategy for a total burden of 1960 hours. We estimate that publicizing the proposed strategy will take 2 hours per State for a total burden of 98 hours. We estimate that incorporating public comments for the final strategy will take another 40 hours per State for a total burden of 1960 hours. We estimate it will take one hour per State to submit an initial copy of the strategy to HCFA and whenever significant changes are made for a total of 49 hours. We estimate it will take 40 hours per State to create and submit a report on the implementation and effectiveness of the strategy. We assume that these reports will be submitted at least every three years for a total annual burden of 653 hours.

K. Section 438.204 Elements of State Quality Strategies

a. Requirement

In this final rule we have added a new requirement at § 438.204(b)(1)(iii) that a State identify the race, ethnicity, and primary language spoken by each MCO

and PHP enrollee and report this information to each MCO and PHP in which each beneficiary enrolls at the time of their enrollment.

b. Burden

We believe that most States currently track race and ethnicity data in their eligibility systems. If States do not, minor changes in their software will be needed. With respect to primary language of enrollees, there will likely be additional programming needed for all States. We estimate that this would require 2 hours of programming for each of the 49 jurisdicitons for a total of 98 hours.

L. Section 438.206 Availability of Services

a. Requirement

Paragraph (c) of this section requires that if an MCO, PHP, or PCCM contract does not cover all of the services under the State plan, the State must make those services available from other sources and provide to enrollees information on where and how to obtain them, including how transportation is provided.

b. Burden

The burden associated with this requirement is the time it takes to provide the information. This burden of this requirement is included in the general disclosure requirements in § 438.10.

M. Section 438.207 Assurances of Adequate Capacity and Services

a. Requirement

Section 438.207 requires that each MCO and PHP must submit documentation to the State, in a format specified by the State and acceptable to HCFA, that it has the capacity to serve the expected enrollment in its service area in accordance with the States' standards for access to care and meets specified requirements.

Section 438.207(c) requires that this documentation be submitted to the State at least annually, and specifically at the time the MCO or PHP enters into a contract with the State and at any time there has been a significant change (as defined both by the State and this regulation) in the MCO's or PHP's operations that would affect adequate capacity and services.

Section 438.207(d) requires the State, after reviewing the MCO's or PHP's documentation, to certify to HCFA that the MCO or PHP has complied with the State's requirements for availability of services, as set forth at § 438.206.

b. Burden

We believe that MCOs and PHPs already collect and provide this information to State agencies as part of their customary and usual business practices and that the only additional burden on MCOs and PHPs is the length of time required for MCOs and PHPs to compile this information in the format specified by the State agency, and the length of time for the MCOs and PHPs to mail the information to the State and the HCFA. We estimate that it will take each MCO and PHP approximately 20 hours to compile the information necessary to meet this requirement, for a total of 20 hours multiplied by 504 MCOs and PHPs, or approximately 10,000 hours. In addition, we estimate that it will take MCOs and PHPs approximately 5 minutes each to mail the materials associated with this burden to the State for an annual burden of approximately 5 minutes multiplied by 502 MCOs and PHPs, or approximately 42 hours.

In this final rule we have added requirements to the types of assurances that MCOs and PHPs must provide (for example assurances that the MCO or PHP has policies and practices to address situations where there are: (1) unanticipated needs for providers with particular types of experience; and (2) unanticipated limitations on the availability of such providers. In addition, we have added new requirements under § 438.206(d) that when establishing and maintaining provider networks, each MCO and PHP must consider the anticipated enrollment with respect to persons with special health care needs and the experience of providers required to furnish contracted services. Documentation to support assurances by each MCO and PHP that they have considered the anticipated enrollment of persons with special health care needs and have recruited or are in the process of recruiting experienced providers is part of the assurances that must be provided to the State. We do not believe that it is customary, or part of the ususal business practice of MCOs and PHPs to collect data that includes totals for projected enrollment of persons with special health care needs and their specialized provider requirements. We estimate that obtaining information on: (1) the numbers and types of persons with special health care needs that could be anticipated to enroll in the MCO or PHP; (2) the types of experienced providers they would require; (3) the experience of the existing providers in the MCO's or PHP's network; and (4) the numbers and types of additional experienced providers needed, would require an estimated 40 hours of work for each of the 504 MCOs and PHPs for a total estimated burden of 20,160 hours.

N. Section 438.240 QualityAssessment and Performance Improvement Program; Performance Improvement Projects

a. Requirement

Section 438.240(c) states that each MCO and PHP must annually measure its performance using standard measures required by the State and report its performance to the State. In this final rule we have added a requirement that the State must include any minimum performance measures and levels specified by HCFA. In addition to using and reporting on measures of its performance, in § 438.240(d)(3) States are to ensure that each MCO and PHP initiates each year one or more performance improvement projects. In § 438.240(d)(10) each MCO and PHP is required to report the status and results of each such project to the State as requested.

B. Burden

This regulation would require States to require each MCO and PHP to annually produce at least two performance measures. Based on discussions with the 17 States with the largest Medicaid managed care enrollments, all 17 States are already doing so. Because the use of performance measures in managed care has become commonplace in commercial, Medicare and Medicaid managed care, we do not believe that this regulatory provision imposes any new burden on MCOs, PHPs, or States.

With respect to the requirements for performance improvement projects in § 438.240(d), we expect that, in any given year, each MCO and PHP will complete two projects, and will have four others underway. We further expect that States will request the status and results of each MCO's and PHP's projects annually. Accordingly, we estimate that it will take each MCO and PHP 5 hours to prepare its report for each project, for an annual total burden of 30 hours per MCO and PHP. In aggregate, this burden equates to 30 hours multiplied by an estimated 504 MCOs and PHPs, or approximately 15,120 hours.

O. Section 438.242 Health Information Systems

a. Requirement

Section 438.242(b)(2) requires the State to require each MCO and PHP to collect data on enrollee and provider characteristics as specified by the State, and on services furnished to enrollees, through an encounter data system or other such methods as may be specified by the State. Section 438.242(b)(3) states that each MCO and PHP must make all collected data available to the State and to HCFA, as required in this subpart, or upon request.

b. Burden

The above information collection requirements are subject to the PRA. However, we believe that the burden associated with these information collection requirements is exempt from the Act in accordance with 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with these requirements would be incurred by persons in the normal course of their activities.

P. Section 438.402 General Requirements

a. Requirement

In summary, § 438.402 requires each MCO and PHP to have a grievance system, sets out general requirements for the system, and establishes filing requirements. It provides that grievances and appeals may be filed either orally or in writing, but that oral appeals (except those with respect to expedited service authorization decisions) must be followed by a written request.

b. Burden

We estimate that approximately 1 percent of 20.2 million MCO and PHP enrollees (202,000) annually will file a grievance with their MCO or PHP and that approximately .5 percent (101,000) annually will file an appeal. For these cases, we estimate that the burden on the enrollee filing a grievance or appeal is approximately 20 minutes per case. The total annual burden on enrollees is 101,000 hours.

Q. Section 438.404 Notice of Action

a. Requirement

In summary, § 438.404 states that if an MCO or PHP intends to deny, limit, reduce, or terminate a service; deny payment; deny the request of an enrollee in a rural area with one MCO or PHP to go out of network to obtain a service; or fails to furnish, arrange, provide, or pay for a service in a timely manner, the MCO or PHP must give the enrollee timely written notice and sets forth the requirements of that notice.

b. Burden

We estimate that the burden associated with this requirement is the length of time it would take an MCO or PHP to provide written notice of an intended action. We estimate that it will take MCOs and PHPs 30 seconds per action to make this notification. We estimate that approximately 5 percent (1,010,000) of the approximately 20.2 million MCO and PHP enrollees will receive one notice of intended action per year from their MCO or PHP (2,004 hours per MCO or PHP) for a total burden of approximately 8417 hours.

R. Section 438.406 Handling of Grievances and Appeals

a. Requirement

In summary, § 438.406 states that each MCO and PHP must acknowledge receipt of each grievance and appeal.

b. Burden

The above information collection requirement is not subject to the PRA. It is exempt under 5 CFR 1320.4(a) because it occurs as part of an administrative action.

S. Section 438.408 Resolution and Notification: Grievances and Appeals

a. Requirement

In summary, § 438.408 states that for grievances filed in writing or related to quality of care, the MCO or PHP must notify the enrollee in writing of its decision within specified timeframes. The notice must also specify that the enrollee has the right to seek further review by the State and how to seek it. All decisions on appeals must be sent to the enrollee in writing within specified timeframes and, for notice of expedited resolution, the MCO or PHP must also provide oral notice. The decision notice must include the MCO or PHP contact for the appeal, the results of the process and the date it was completed, and a summary of the steps the MCO or PHP has taken on the enrollee's behalf to resolve the issue. For an oral grievance that does not relate to quality of care, the MCO or PHP may provide oral notice unless the enrollee requests that it be written.

This section also provides, for expedited appeals, that MCOs and PHPs must submit delayed and adverse appeal decisions to the State fair hearing office along with all supporting documentation.

b. Burden

The above information collection requirements are not subject to the PRA. They are exempt under 5 CFR 1320.4(a) because they occur as part of an administrative action.

T. Section 438.410 Expedited Resolution of Grievances

1. Paragraph (c)

a. Requirement

Paragraph (c), Requirements for appeals, requires each MCO and PHP to document all oral requests in writing and maintain the documentation in the case file.

b. Burden

The above information collection requirement is not subject to the PRA. It is exempt under 5 CFR 1320.4(a) because it occurs as part of an administrative action.

2. Paragraph (d)

a. Requirement

Section 438.410(d) states that if an MCO denies a request for expedited grievance, it must automatically transfer the request to the standard time frame process and give the enrollee prompt oral notice of the denial and follow up, within 2 working days, with a written letter.

b. Burden

The above information collection requirements are not subject to the PRA. They are exempt under 5 CFR 1320.4(a) because they occur as part of an administrative action.

U. Section 438.414 Information About the Grievance System

a. Requirement

Sections 438.414(a) and (b) state that each MCO and PHP must provide information about the grievance system, as specified in § 438.10 and this subpart to: (1) Enrollees, (2) potential enrollees (as permitted by the State), and (3) all providers and contractors, at the time of subcontracting. The information must explain the grievance system through a State-developed or State-approved description and must include the information set forth in § 438.414 (b)(1) through (6).

In addition, § 438.414(c) states that upon request, the MCO or PHP must provide enrollees and potential enrollees with aggregate information derived from the collected information in § 438.416(e), regarding the nature of enrollee grievances and their resolution.

(c) Requirements for appeals. Each MCO and PHP must meet the following requirements with respect to appeals:

(1) Establish a convenient and efficient means for an enrollee or a provider to request expedited resolution of an appeal;

(2) Provide expedited resolution of an appeal in response to an oral or written request if the MCO or PHP determines (with respect to a request from the enrollee) or the provider indicates (in making the request on the enrollee's behalf or supporting the enrollee's request) that taking the time for a standard resolution could seriously jeopardize the enrollee's life or health or ability to attain, maintain, or regain maximum function.

(3) Document all oral requests in writing; and

(4) Maintain the documentation in the case file.

b. Burden

These information collection requirements are subject to the PRA. However, we believe the burden associated with these requirements is captured in the general information requirements in § 438.10.

V. Section 438.416 Recordkeeping and Reporting Requirements

a. Requirement

Sections 438.416 (a) and (c) state that each MCO and PHP must maintain a log of all complaints and grievances and their resolution, and retain the records of complaints, grievances (including their resolution) and disenrollments for three years, in a central location, and make them accessible to the State.

In addition, § 438.416(d) states that each MCO and PHP must, at least once a year, send to the State a summary that includes the following information, (1) the number and nature of all grievances and appeals, (2) the time frames within which they were acknowledged and resolved, and (3) the nature of the decisions. This material is available to the public upon request under § 438.10.

b. Burden

We estimate that approximately .5 percent of the approximately 20.2 million MCO and PHP enrollees will file a grievance with their MCO or PHP (200 per MCO or PHP). The recording and tracking burden associated with each grievance is estimated to be 1 minute per request (3.4 hours per MCO or PHP), for a total burden of 1,680 hours (1 minute multiplied by an estimated 101,000 enrollees who would file a grievance).

This section also contains the applicable requirements that MCOs and PHPs must follow to submit the annual summary of complaints and grievances. Every MCO and PHP (approximately 504 organizations) must submit an annual report. We estimate that the burden on the MCO or PHP for collecting information and preparing this summary will be approximately 4 hours per MCO/PHP or approximately 2,016 hours total.

W. Section 438.604 Data That Must Be Certified

a. Requirement

When payments from States to MCOs and PHPs are based on data submitted by the MCO or PHP that include, but are not limited to, enrollment information, encounter data, or other information required by the State, the MCO or PHP must attest to such data's accuracy, completeness, and truthfulness as a condition of receiving such payment. Each MCO and PHP must certify that it is in substantial compliance with its contract. Certification is required, as provided in § 438.606, for all documents specified by the State.

b. Burden

While the requirement for MCOs and PHPs (and their contractors) to attest to the accuracy of enrollment information encounter data or other information required by the State is subject to the PRA, as is the requirement for MCOs and PHPs to certify the accuracy, completeness, and truthfulness of all information provided in contracts, requests for proposals, or other related documents specified by the State, the burden associated with these requirements is captured during the submission of such information. Therefore, we are assigning one token hour of burden for this requirement.

X. Section 438.710 Due Process: Notice of Sanction and Pre-termination Hearing

1. (a) Due Process: Notice of Sanction and Pre-Termination Hearing

a. Requirement

Section 438.710(a) states that before imposing any of the sanctions specified in this subpart, the State must give the affected MCO or PCCM written notice that explains the basis and nature of the sanction. Section 438.724 also requires all intermediate sanctions to be published in a newspaper in order to notify the public.

b. Burden

The above information collection requirements are not subject to the P.A. They are exempt under 5 CFR 1320.4(a) because they occur as part of an administrative action.

2. (b)(1) Due Process: Notice of Sanction and Pre-Termination Hearing

a. Requirement

Section 438.710(b)(1) states that before terminating an MCO's or PCCM's contract, the State must give the MCO or PCCM written notice of its intent to terminate, the reason for termination, and the time and place of the hearing.

b. Burden

The above information collection requirement is not subject to the PRA. It is exempt under 5 CFR 1320.4(a) because it occurs as part of an administrative action.

Y. Section 438.722 Disenrollment During Termination Hearing Process

a. Requirement

Section 438.722(a) states that after a State has notified an MCO or PCCM of its intention to terminate the MCO or PCCM's contract, the State may give the MCO's or PCCM's enrollees written notice of the State's intent to terminate the MCO's or PCCM's contract.

b. Burden

States already have the authority to terminate MCO or PCCM contracts according to State law and have been providing written notice to the MCOs or PCCMs. States are now given, at their discretion, the option of notifying the MCO's or PCCM's enrollees of the State's intent to terminate the MCO's or PCCM's contract. While it is not possible to gather an exact figure, we estimate that 12 States may terminate 1 contract per year. We estimate that it will take States 1 hour to prepare the notice to enrollees, for a total burden of 12 hours. In addition, we estimate that it will take States approximately 5 minutes per beneficiary to notify them of the termination, equating to a burden of 5 minutes multiplied by 12 States multiplied by 40,080 beneficiaries per MCO or PCCM, for a burden of approximately 40,080 hours. The total burden of preparing the notice and notifying enrollees is 40,096.

Z. Section 438.810 Expenditures for Enrollment Broker Services

a. Requirement

Section 438.810(c) requires that a State contracting with an enrollment broker must submit the contract or memorandum of agreement (MOA) for services performed by the broker to HCFA for review and approval prior to the effective date of services required by the contract or MOA.

b. Burden

The burden associated with this requirement is the length of time for a State to mail each contract to HCFA for review. We estimate that the burden associated with this requirement is 5 minutes per enrollment broker contract, for a total annual burden of approximately 3 hours per year (5 minutes multiplied by an estimated 35 enrollment broker contracts in the States using brokers).

We have submitted a copy of this proposed rule to OMB for its review of the information collection requirements described above. These requirements are not effective until they have been approved by OMB.

If you comment on these information collection requirements, please mail copies directly to the following: Health Care Financing Administration, Office of Information Services, DHES, SSG, Attn: Julie Brown, HCFA–2001–F, Room N2–14–26, 7500 Security Boulevard, Baltimore, MD 21244–1850; and Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Brenda Aguilar, Desk Officer.

VII. Provisions of the Final Rule

For reasons specified in the preamble, we have made the following changes to the proposed rule:

Part 400—Introduction; Definitions

Section 400.203

We have revised this section to include three new provisions. First, we specify that *PCCM* stands for primary care case manager. Second, we specify that *PCP* stands for primary care physician. Third, we have revised the definition of *provider* to clarify that, for the fee-for service program, it means any individual or entity furnishing Medicaid services under an agreement with the Medicaid agency and for the managed care program, it means an any individual or entity that is engaged in the delivery of health care services and is legally authorized to do so by the State in which it delivers the services.

Part 430—Grants to States for Medical Assistance

Section 430.5

We have revised this section by removing the definition of *clinical laboratory,* moving the definition of *authorized representative* to this section from § 438.2, and moving the definitions of *capitation payment, federally qualified HMO, health insuring organization, nonrisk contract, prepaid health plan,* and *risk contract* from this section to § 438.2. We have revised the definition of *authorized representative* to provide that the term will be defined by each State consistent with its laws, regulations, and policies.

Part 431—State Organization and General Administration

Section 431.200

We have revised paragraph (c) to include a reference to section 1819(f)(3) of the Act.

Section 431.201

We have defined service authorization request to mean a managed care enrollee's request for the provision of a Medicaid-covered service.

Section 431.244

We have revised paragraph (f) regarding time frames for State fair hearings to include a requirement for an expedited hearing for certain service authorization requests. We have redesignated paragraph (g) as (h) and included a new paragraph (g) which permits States to allow a hearing officer to grant an extension of the time frames under certain circumstances.

Part 434—Contracts

Section 435.212

We revised this section to replace ''HMO,'' wherever it appears, with ''MCO and PCCM'' rather than ''MCO.''

Section 435.1002

We revised paragraph a to include a reference to § 438.814.

Part 438—Managed Care Provisions

Subpart A—General Provisions

Section 438.2

We have revised this section by moving the definition of *authorized representative* to § 430.5 and moving the definitions of *capitation payment, federally qualified HMO, health insuring organization, nonrisk contract, prepaid health plan,* and *risk contract* from § 430.5 to this section. We have revised the definition of *capitation payment* to clarify that the State agency makes the payment regardless of whether the particular recipient receives services during the period covered by the *payment,* rather than a *fee.* We have clarified the definition of health insuring organization (HIO) so that it does not appear to require that an HIO's subcontractors be capitated. Since we have decided to specify within each regulatory provision, whether it applies to MCOs, PHPs, and/or PCCMs, we no longer use the term managed care entity, and have deleted that definition. We have revised the definition of *nonrisk contract* to clarify that the term refers to a contract under which the contractor is not at financial risk for changes in utilization or for costs incurred under the contract that do not exceed the upper payment limits specified in § 447.362 of this chapter. In addition, under a nonrisk contract, the contractor may be reimbursed by the State at the end of the contract period on the basis of the incurred costs, subject to the specified limits. Finally, we have clarified the definition of PHP to indicate that PHPs may be reimbursed by any non-state plan methodology, not just capitation.

Section 438.6

We have revised this section to include a new paragraph (a) that provides for regional office review of all MCO and PHP contracts including those that are not subject to the prior approval requirements in § 438.806. We are making significant revisions to paragraph (c). We have extended the rate setting requirements to all risk contracts. We are removing the requirement that rates not exceed the upper payment limit (UPL) set forth in § 447.361 and substituting an expanded requirement for actuarial soundness including certification of capitation rates by an actuary. We specify data elements to be included in the methodology used to set capitation rates and require States to consider the costs for individuals with chronic illness, disability, ongoing health care needs, or catastrophic claims in developing rates. We also require States to provide explanations of risk-sharing or incentive methodologies and impose special rules, including a limitation on FFP, in contracts utilizing some of these arrangements. These changes are being made as a Final Rule with a 60-day period for submission of comments.

We have revised paragraph (d) to clarify that the provision applies to MCOs and PHPs, not MCEs. Paragraph (i)(2) is revised to clarify that MCOs and PHPs are not required to provide adult enrollees with oral information on advance directives.

Section 438.8

We have revised paragraph (a) to provide that the requirements for advance directives specified in § 438.6 apply to all PHPs except where the State believes that they are not appropriate, for example, if the PHP contract only covers dental services or non-clinical services such as transportation. We have also expanded the PHP requirements to include compliance with the physician incentive plan rules and all of the State

responsibility provisions of Subpart B (except for the State plan provisions in § 438.50).

Section 438.10

We have revised this section to include the substantive requirements from § 438.318. We have also made several minor wording and organizational changes that served to clarify the requirements of this section. We have clarified how these rules apply to PHPs, whereby PHPs that have PCCM contracts are subject to the rules governing PCCMs, but all other PHPs are subject to the rules governing MCOs.

In paragraph (c), we have clarified that informational material must be available in alternative formats and in a manner that takes into consideration special needs, such as visual impairment or limited reading proficiency. In addition, paragraph (c) provides that the State and MCE must provide instructions to enrollees and potential enrollees regarding how they may obtain information in an appropriate format.

We have revised paragraph (d) to require the State or its contracted representative to provide information to potential enrollees regarding which populations are excluded from enrollment, subject to mandatory enrollment, or free to enroll voluntarily.

We have included a new provision in paragraph (e)(1)(ii), which requires an MCO to inform enrollees regarding any significant changes in any of the information that was furnished to them. The MCO must furnish the information within 90 days after the effective date of the change. We have included regulatory language in paragraph (e)(2) requiring the information provided to enrollees to include names and locations of current network providers, including information at least on primary care physicians, specialists, and hospitals, and identification of providers that are not accepting new patients. In paragraph (e)(3), we have revised the annual notice requirement to provide that at least once each year, the MCO, the State or its contracted representative must notify enrollees of their right to request and obtain specified information.

In paragraph (g), we have clarified that the time frames for furnishing information are the same for both PCCMs and MCOs.

We have revised paragraph (f) to provide that enrollees and potential enrollees may request and receive information on requirements for accessing services, including factors such as physical accessibility.

Section 438.12

We have revised paragraph (b) to permit different reimbursement amounts for the different specialties or for the same specialty.

Subpart B—State Responsibilities

Section 438.50

We have revised this section by including paragraph (b)(4), which requires the State plan to specify the process that the State uses to involve the public in both the design and the initial implementation of the program and the methods it uses to ensure ongoing public involvement once the State plan has been implemented. We have also revised the language in paragraph (a) to clarify that the provisions of this section do not apply to programs that have mandatory managed care enrollment pursuant to a waiver under either section 1115 or section 1915(b) of the Act. We have moved the requirements regarding limitations on enrollment and default enrollment from § 438.56 to this section so that they are only applicable in State plan managed care programs.

Section 438.52

We have revised the definition of ''rural'' area in paragraph (a) to eliminate the State's option to use definitions other than any area outside an ''urban area'' as defined in § 412.62(f)(1)(ii). We have revised the exception for rural area residents in paragraph (c) to clarify that an enrollee must be permitted to obtain services from an out of network provider if the provider is the main source of a service to that individual. We also require that, in rural areas, an enrollee must be permitted to obtain services from an out of network provider if he or she needs related services, not all related services are available within the network, and the enrollee's primary care provider or another provider determines that receiving the services separately would subject the enrollee to unnecessary risk.

Section 438.56

We have moved the requirements regarding limitations on enrollment and default enrollment from this section to § 438.50. We have revised paragraph (a) to provide that the provisions of this section apply to all managed care arrangements whether enrollment is mandatory or voluntary and whether the contract is with an MCO, a PHP, or a PCCM provider.

We have revised paragraph (b) to require that all MCE contracts must specify the reasons for which the MCO, PHP, or PCCM may request disenrollment of an enrollee. The contracts must also provide that the MCO, PHP, or PCCM may not request disenrollment because of a change in the enrollee's health status, or because of the enrollee's utilization of medical services, diminished mental capacity, or uncooperative or disruptive behavior resulting from his or her special needs except where the behavior impairs the ability of the MCO, PHP, or PCCM to furnish services to this enrollee or others.

In paragraph (c), we have clarified that an enrollee may request disenrollment without cause in four instances:

- During the 90 days following the date of the recipient's initial enrollment, or the date the State sends the recipient notice of the enrollment, whichever is later.
- At lease once every 12 months thereafter.
- Upon automatic reenrollment, if the temporary loss of Medicaid eligibility has caused the recipient to miss the annual disenrollment opportunity.
- When the State imposes an intermediate sanction, as specified in § 438.702(a)(3)

We have revised paragraph (d) to permit an enrollee to submit either an oral or a written request for disenrollment. In subparagraph (d)(2), we have significantly revised the provisions relating to ''for cause'' disenrollment. We identify three circumstances that would constitute cause under the final rule:

- The enrollee was homeless (as defined by the State) or a migrant worker at the time of enrollment and was enrolled in the MCO, PHP, or PCCM by default.
- The plan does not, because of moral or religious objects, cover the service the enrollee seeks.
- The enrollee needs related services to be performed at the same time, not all related services are available within the network, and the enrollee's primary care provider or another provider determines that receiving the services separately would subject the enrollee to unnecessary risk.

In subparagraph (d)(iv), we recognize that the enrollee may cite other reasons for requesting disenrollment that could constitute ''cause'' under the rule, including poor quality of care, lack of access to services covered under the contract, or lack of access to providers experienced in dealing with an enrollee's special health care needs.

In paragraph (e), we clarify the time frames for disenrollments to provide that regardless of the procedures followed, the effective date of an approved disenrollment must be no

later than the first day of the second month following the month in which the enrollee or the MCO, PHP, or PCCM files a request.

We have revised paragraph (f) to clarify that if a State restricts disenrollment under this section, it must provide that enrollees are furnished a written notice of their disenrollment rights at least 60 days before the start of each enrollment period. In addition, if a State denies a disenrollment request, it must provide notice to the enrollee of their right to file a request for a State Fair Hearing.

Section 438.60

We have deleted an exception for emergency and post stabilization services from this provision, which had been erroneously included in the NPRM, since duplicate payments are prohibited for these services.

Section 438.62

We have added a new paragraph (b) that requires the State agency to have in effect a mechanism to ensure continued access to services when an enrollee with ongoing health care needs is transitioned from fee-for-service to an MCO, PHP, or PCCM, from one MCO, PHP, or PCCM to another, or from an MCO, PHP, or PCCM to fee-for-service. We require that this mechanism apply at least to the following groups:

- Children and adults receiving SSI benefits.
- Children in Title IV–E foster care.
- Recipients aged 65 or older.
- Any other recipients whose care is paid for under State-established, risk-adjusted, high-cost payment categories.
- Any other category of recipients identified by HCFA.

In addition, we require the State to notify the enrollee that a transition mechanism exists, and provide instructions on how to access the mechanism. We also require the State to ensure that an enrollee's ongoing health care needs are met during the transition period, by establishing procedures to ensure that, at a minimum—

- The enrollee has access to services consistent with the State plan and is referred to appropriate health care providers.
- Consistent with Federal and State law, new providers are able to obtain copies of appropriate medical records.
- Any other necessary procedures are in effect.

Section 438.64

We have deleted this section which required that capitation payments be computed on an actuarially sound basis, and incorporated it into the new § 438.6(c) provisions.

Section 438.68

We have added this new section which requires the State agency to have in effect procedures for educating MCOs, PHPs, or PCCMs and their providers about the clinical and other needs of enrollees with special health care needs.

Subpart C—Enrollee Rights and Protections

Section 438.100

We removed the language relating to benefits and moved the provisions relating to ''Enrollee Rights'' from § 438.320 to this section. We revised the enrollee rights in paragraph (b) to include the following two rights:

- To obtain a second opinion from an appropriately qualified health care professional in accordance with § 438.3206(d)(3).
- To be free from any form of restraint or seclusion used as a means of coercion, discipline, convenience, or retaliation, as specified in other Federal regulations on the use of restraints.

In addition, we have revised three of the enrollee rights to provide that the State must ensure that the enrollee has the right—

- To receive information on available treatment options and alternatives, presented in a manner appropriate to the enrollee's condition and ability to understand. We clarify that if the MCO does not cover a service because of moral or religious objections, then the MCO need not furnish information on where and how to obtain the service, but only on where and how to obtain *information* about the service.
- To participate in decisions regarding his or her health care, including the right to refuse treatment.
- To request and receive a copy of his or her medical records and to request that they be amended or corrected, in accordance with § 438.3224.

We have included a new requirement in paragraph (c) that provides that the State must ensure that an enrollee's free exercise of his or her rights does not adversely affect the way the MCO, PCCM, or PHP, the MCO, PCCM, or PHP's providers, or the State agency treat the enrollee. In paragraph (d), we have revised the list of examples of applicable Federal and State laws for which States must ensure MCO, PCCM, or PHP compliance.

Section 438.102

We have replaced the term ''practitioner'' with ''health care professional'' and revised the definition to mirror the statutory language. We have reorganized the substantive provisions of the section to clarify the requirements. We revised paragraph (c) to include all of the information requirements that apply if an MCO does not provide a counseling or referral service based on moral or religious objections. We have clarified that, if the MCO does not cover a service under this section, then it is not required to inform enrollees and potential enrollees about how and where to obtain the service, but rather how and where to obtain information about a service. In paragraph (d), we require the State to provide information to enrollees on how and where to obtain a service that the MCO does not cover based on moral or religious objections.

Section 438.104

In paragraph (a) we moved the definitions of *choice counseling, enrollment activities,* and *enrollment broker* from this section to § 438.810. We revised the definition of *marketing materials* to mean materials that are produced in any medium, by or on behalf of an MCO, PCCM, or PHP and can reasonably be interpreted as intended to market to enrollees or potential enrollees. We also defined *marketing* to mean any communication from an MCO, PCCM, or PHP, any of its agents or independent contractors, with an enrollee or potential enrollee that can reasonably be interpreted as intended to influence that individual to enroll or reenroll in that particular MCO, PCCM, or PHP's Medicaid product or disenroll from another MCO, PCCM, or PHP's Medicaid product.

In paragraph (b), we have clarified that inaccurate, false, or misleading statements include, but are not limited to, any assertion or statement (whether oral or written) that the beneficiary must enroll in the MCO, PCCM, or PHP in order to obtain benefits or in order to not lose benefits or that the MCO, PCCM, or PHP is endorsed by HCFA, the Federal or the State government, or similar entity. We have also revised two of the provisions in subparagraph (b)(2) in order to clarify that the MCO, PCCM, or PHP contract must provide that the MCO, PCCM, or PHP distributes their marketing materials to its entire service area, as indicated in the contract and that the MCO, PCCM, or PHP does not seek to influence enrollment in conjunction with the sale or offering of any other insurance.

Section 438.108

In § 447.53(e), we now prohibit providers from denying care or services to an individual eligible for the care or services on account of the individual's inability to pay the cost sharing.

Section 438.110

We have moved the provisions related to assurances of adequate capacity and services to § 438.207.

Section 438.114

We have removed the definitions of *emergency medical condition, emergency services,* and *post-stabilization services* and included cross references to the definitions of the same terms in the regulations governing the Medicare+Choice program. We have revised paragraph (c) to provide that the following entities are responsible for coverage and payment of emergency services and post-stabilization services:

- The MCO
- The primary care case manager that has a risk contract
- The State, in the case of a primary care case manager that has a fee-for-service contract.

In paragraph (d), we clarify the specific rules governing coverage and payment for emergency services. We revised paragraph (e) to provide for additional rules that govern emergency services. First, the entity responsible for payment may not limit what constitutes an emergency medical condition based on lists of particular diagnoses or symptoms and it may not refuse to process a claim because it does not contain the primary care provider's authorization number. Second, once a qualified provider determines that an enrollee has an emergency medical condition, the enrollee may not be held liable for subsequent screening and treatment needed to diagnose the specific condition, or stabilize the patient. Third, the attending emergency physician or the provider actually treating the enrollee is responsible for determining when the enrollee is sufficiently stabilized, and that determination is binding on the entities responsible for payment.

We have also revised paragraph (f) to require post-stabilization services to be covered and paid for as provided in the regulations governing the Medicare+Choice program (§ 422.113). We explain that, in applying the Medicare+Choice provisions, reference to ''M+C'' organization'' must be read as reference to the entity responsible for Medicaid payment, as specified in paragraph (c) of this section.

Subpart D—Quality Assessment and Performance Improvement

Note: In the proposed rule, this subpart was subpart E, and the sections were numbered as §§ 438.300 to 438.342. In this final rule, this subpart has been relocated as Subpart D and the sections are numbered as §§ 438.200 to 438.242. Sections referenced herein use the §§ 438.200 to 438.242 numbering of the final rule.

Section 438.202 State responsibilities

In paragraph (b) we require each State contracting with an MCO or PHP to document its quality strategy in writing. In paragraph (c) we require each State to provide for the input of recipients and other stakeholders in the development of the quality strategy, including making the strategy available for public comment before adopting it in final. In paragraph (e) we require the State to update the strategy. In paragraph (f) we require each State to submit to HCFA a copy of the initial strategy and a copy of the revised strategy whenever significant changes are made. In addition, we require the State to submit to HCFA regular reports on the implementation and effectiveness of the strategy.

Section 438.204 Elements of State Strategies

We have revised paragraph (b) to require that the State quality strategy must include procedures for identifying enrollees with special health care needs and assessing the quality and appropriateness of care furnished to those enrollees. We included a new paragraph (c) to require the State quality strategy to incorporate performance measures and levels prescribed by HCFA.

Section 438.206 Availability of Services

We have revised paragraph (d) to clarify that the State must ensure that when each MCO and PHP establishes and maintains its network of providers, each MCO and PHP considers the anticipated enrollment, with particular attention to pregnant women, children, and persons with special health care needs. We have also clarified that each MCO and PHP must consider the training and experience of providers when establishing and maintaining its provider network. In subparagraph (d)(3), we have included a new requirement for MCO and PHP networks (consistent with the scope of the PHP's contracted services) to provide for a second opinion from a qualified health care professional within the network or otherwise arrange for the enrollee to obtain one outside the network at no cost to the enrollee if an additional professional is not currently available within the network. In subparagraph (d)(5) we have added a new requirement that the MCO or PHP must permit an enrollee to access out-of-network providers to receive medical services, if the MCO's or PHP's network is unable to provide the necessary medical services, for as long as the MCO or PHP is unable to provide the services. We have added a new requirement at subparagraph (d)(7) requiring an MCO or PHP to ensure that its providers do not discriminate against Medicaid enrollees. At subparagraph (d)(8) we have added a new requirement that requires the MCO or PHP to require out-of-network providers to coordinate with the MCO or PHP with respect to payment and ensure that the cost to the enrollee is no greater than it would be if the services were furnished within the network. We have moved requirements that MCOs and PHPs must ensure that provider hours of operation are convenient for the enrollees from subparagraph (d)(6) to subparagraph (e)(1)(ii), and have added a requirement that convenience be determined by a State-established methodology, and at least comparable to Medicaid fee-for-service. We have also moved the requirement that services must be available 24 hours a day, 7 days a week, when medically necessary from subparagraph (d)(5) to (e)(1)(iii).

We have moved the requirements relating to initial assessment from this section to § 438.208.

Section 438.207 Assurances of Adequate Capacity and Services

We have created this new section which relocates and adds to the requirements regarding assurances of adequate capacity and services previously located at § 438.110. We have revised paragraph (a) to provide that each MCO and PHP must give assurances to the State (in the NPRM the MCO was to also give assurance to HCFA) that it has the capacity to serve the expected enrollment in its service area in accordance with the State's standards for access to care under this subpart. In paragraph (b), we have required that each MCO and PHP must submit specific documentation that must be in a format specified by the State and acceptable to the HCFA. In subparagraph (b)(4), we have added requirements that each MCO and PHP must document that it has policies and practices in place to address situations in which there is unanticipated need for providers with particular types of experience or unanticipated limitation of the availability of such providers. We revised paragraph (c) to require the submission of the assurance documentation at least once a year as opposed to every two years as stated in the proposed rule. We also added in paragraph (c) circumstances which we believe constitute a significant change in the MCO's or PHP's operation and

which would require the MCO or PHP to resubmit assurances documenting adequate capacity and services. These are: (1) A significant change in the MCO's or PHP's services or benefits; (2) an expansion or reduction of the MCO's or PHP's geographic service area; (3) the enrollment of a new population in the MCO or PHP; and (4) a significant change in the MCO or PHP rates. We also revised paragraph (d) to provide that after the State reviews the documentation submitted by the MCO or PHP, the State must certify to HCFA that the MCO or PHP has complied with the State's requirements for availability of services, as set forth in § 438.206. We have added a new paragraph (e) to provide that the State must make available to HCFA, upon request, all documentation collected by the State from the MCO or PHP.

Section 438.208 Coordination and Continuity of Care

We have made significant changes to the content and organization of this section. As a part of those changes, we have moved section 438.306(e)(2) and (3) pertaining to initial assessment, and pregnancy and complex and serious medical conditions, to this section. We have clarified that the words ''initial assessment'' used in the proposed rule are actually two different functions: screening and assessment. We have also replaced the words ''persons with serious and complex medical conditions'' with the words ''persons with special health care needs.'' In new paragraph (a) we have clarified that the State needs to determine the extent to which requirements pertaining to initial and ongoing screenings and assessments, and primary care are appropriate requirements for PHPs based on the scope of the PHP's services, and the way the State has organized the delivery of managed care services. New paragraph (b) requires the State to implement mechanisms to identify to the MCO and PHP upon enrollment, the following groups:

- Enrollees at risk of having special health care needs, including —
  - ++Children and adults who are receiving SSI benefits;
  - ++Children in Title IV-E foster care;
  - ++Enrollees over the age of 65;
  - ++Enrollees in relevant, State-established, risk-adjusted, higher-cost payment categories; and
  - ++Any other category of recipients identified by HCFA
- Other enrollees known to be pregnant or to have special health care needs
- Children under the age of 2

We have revised paragraph (d) to clarify and expand upon MCO and PHP responsibilities for screening and assessment. In subparagraph (d)(1)(i), we require that for enrollees identified by the State as being at risk of having special health care needs, the MCO (and PHP as determined appropriate by the State) must make a best effort attempt to perform a screening within 30 days of receiving the identification from the State. For any enrollee that the screening identifies as being pregnant or having special health care needs, the MCO (and PHP as determined appropriate by the State) must perform a comprehensive assessment as expeditiously as the enrollee's health requires, but no later than 30 days from the date of identification.

In subparagraph(d)(2), we require that for enrollees under the age of two or other enrollees known by the State to be pregnant or to have special health care needs, each MCO (and PHP as determined appropriate by the State) must perform a comprehensive assessment as expeditiously as the enrollee's health requires, but no later than 30 days from the date of identification.

In subparagraph (d)(3), we require that for all other enrollees, each MCO (and PHP as determined appropriate by the State) must screen them within 90 days from the date of enrollment. For any enrollee that the screening identifies as being pregnant or having special health care needs, each MCO (and PHP as determined appropriate by the State) must perform a comprehensive assessment as expeditiously as the enrollee's health requires, but no later than 30 days from the date of identification.

We have also added a requirement in subparagraph (e) for MCOs (and PHPs as determined appropriate by the State) to implement mechanisms to identify enrollees who develop special health care needs after enrollment in the MCO or PHP and perform comprehensive assessments as expeditiously as the enrollee's health requires, but no later than 30 days from the date of identification.

In subparagraph (f), we have revised the requirements relating to treatment plans. We require that each MCO and PHP must implement a treatment plan for pregnant women and for enrollees determined to have special health care needs. The treatment plan must —

- Be appropriate to the conditions and needs identified and assessed;
- Be for a specific period of time and periodically updated;
- Specify a standing referral or an adequate number of direct access visits to specialists;
- Ensure adequate coordination of care among providers;
- Be developed with enrollee participation; and
- Ensure periodic reassessment of each enrollee as his or her health requires.

In subparagraph (g), we clarify that MCOs and PHPs must use appropriate health care professionals to perform any comprehensive assessments required by this section and develop and implement any treatment plans required by this section. In paragraph (h) and subparagraph (h)(1), we have revised the requirements relating to primary care and over-all coordination to clarify that the MCO (and PHP as determined appropriate by the State) must have a coordination program that meets State requirements and ensures that each enrollee has an ongoing source of primary care appropriate to his or her needs and a person or entity formally designated as primarily responsible for coordinating the health care furnished to the enrollee. In subparagraph (h)(2) we require the MCO or PHP to coordinate the services it furnishes to the enrollee with the services the enrollee receives from any other MCOs or PHPs. In addition, subparagraph (h)(3) requires the MCO's or PHP's coordination program to ensure that the results of its screening and assessment of an enrollee is shared with the other entities serving the enrollee, so that those entities need not duplicate the screening or assessment. Subparagraph (h)(4) requires that in the process of coordinating care, the MCO or PHP ensures that each enrollee's privacy is protected consistent with confidentiality requirements at § 438.224. Subparagraph (h)(5) requires MCOs and PHPs to ensure that each provider maintains health records that meet professional standards and that there is appropriate and confidential sharing of information among providers.

In subparagraph (h)(6), we require each MCO and PHP to have in effect procedures to address factors that hinder enrollee adherence to prescribed treatments or regimens. In subparagraph (h)(7), we require the MCO to ensure that its providers have the information necessary for effective and continuous patient care and quality improvement, consistent with the confidentiality requirements in § 438.224 and the information system requirements of § 438.242.

Section 438.210 Coverage and Authorization of Services

We have revised paragraph (a) to clarify the contract requirements relating to coverage of services. In subparagraph (a)(1), we require that each contract identify, define and specify each service that the MCO or PHP is required to offer. In subparagraph (a)(2), we require that the MCO or PHP make available the services it is required to offer at least in the amount, duration, and scope that are specified in the State plan and can reasonably be expected to achieve the purpose for which the services are furnished. Subparagraph (a)(3) specifies that the MCO or PHP may not arbitrarily deny or reduce the amount, duration, or scope of a required services solely because of the diagnosis, type of illness, or condition and that the MCO or PHP may place appropriate limits on a service on the basis of criteria such as medical necessity or for the purposes of utilization control (provided the services furnished can reasonably be expected to achieve their purpose).

In subparagraph (a)(4), we require the contract to specify what constitutes medically necessary services in a manner that is no more restrictive than the State Medicaid program as indicated in State statutes and regulations, the State plan, and other State policy and procedures. The contract must specify the extent to which ''medically necessary services'' includes services to prevent, diagnose, treat, or cure health impairments, enable the enrollee to achieve age-appropriate growth and development, and enable the enrollee to attain, maintain, or regain functional capacity. Subparagraph (a)(5) requires the MCO or PHP to furnish services in accordance with their contract specifications.

We have revised paragraph (b) to specify that with respect to the processing of requests for initial and continuing authorization of services, each contract must not have information requirements that are unnecessary or unduly burdensome for the provider or the enrollee. We have also included a requirement that any decision to deny a service authorization request or to authorize service in an amount, duration, or scope that is less than requested, be made by an individual who has appropriate expertise in the field of medicine that encompasses the enrollee's condition or disease.

We have revised paragraph (c) to clarify that each contract must provide for the MCO or PHP to notify the requesting provider and give the enrollee written notice of any decision to deny a service authorization request, or to authorize a service in an amount, duration, or scope that is less than requested. We also clarify that the notice must meet the requirements of § 438.404, except that the notice to the provider need not be in writing.

We have revised the time frames for expedited service authorization decisions. In paragraph (e), we require that under specific circumstances, the contract must provide for the MCO or PHP to make a decision as expeditiously as the enrollee's health condition requires but not later than 72 hours after receipt of the request for service.

Section 438.214 Provider Selection

We have changed the name of this section from ''establishment of provider networks'' to ''provider selection.'' We have reorganized this section to clarify the requirements that apply to licensed independent providers (for example, physicians) and other providers. In subparagraph (b)(3), we have created an exception that applies to providers who are permitted to furnish services only under the direct supervision of a physician or other provider and hospital-based providers who provide services only incident to hospital services. The latter exception does not apply if the provider contracts independently with the MCO or PHP or is promoted by the MCO or PHP as part of the provider network. In subparagraph (b)(4) we have added requirements that the initial credentialling application be dated and signed and that applications, updates, and supporting information submitted by the applicant include an attestation of the correctness and completeness of the information. We have added a new requirement in paragraph (d) that specifies that MCOs and PHPs may not employ or contract with providers excluded from participation in Federal health care programs. In addition, we state in paragraph (e) that each MCO and PHP must comply with any additional requirements established by the State.

Section 438.218 Enrollee Information

We have moved the provisions from this section to § 438.10 and clarified that the information requirements that States must meet under § 438.10 constitute part of the State's quality strategy.

Section 438.320 Enrollee Rights

We have moved the requirements regarding enrollee rights to § 438.100.

Section 438.224 Confidentiality and Accuracy of Enrollee Records

We have changed the name of this section from ''confidentiality'' to ''confidentiality and accuracy of enrollee records.'' We have also reorganized this section to clarify the requirements that apply to MCOs and PHPs. We clarify that this section applies to medical records and any other health and enrollment information maintained with respect to enrollees. In paragraph (c) we require MCOs and PHPs to establish and implement procedures that specify for what purposes the MCO or PHP uses the information and to which entities outside the MCO or PHP (and for what purposes) it discloses the information. In paragraph (d), we clarify that MCO and PHP procedures must safeguard the confidentiality of any information (in *any* form) that identifies a particular enrollee. We have revised the requirements of paragraph (e) to provide that MCO and PHP procedures must ensure that originals of medical records are released only in accordance with Federal and State law. We have also revised the requirements for access in paragraph (f) to require that, consistent with applicable Federal and State law, MCO and PHP procedures must ensure that each enrollee may request and receive a copy of his or her records and information and added a requirement that the enrollee may request that they be amended or corrected.

Section 438.228 Grievance Systems

We have added to this section two new paragraphs. Paragraph (b) requires that if the State delegates to the MCO or PHP responsibility for notice of action under subpart E of part 431 of this chapter, the State must conduct random reviews of each MCO and PHP and its providers and subcontractors to ensure that they are notifying enrollees in a timely manner. Paragraph (c) requires the State to establish a process to review, upon request by the enrollee, quality of care grievances not resolved by the MCO or PHP to the satisfaction of the enrollee.

Section 438.230 Subcontractual Relationships and Delegations

We have revised subparagraph (b)(3) to require each MCO and PHP to formally review its subcontractors' performances according to a periodic schedule established by the State, consistent with industry standards or State MCO laws and regulations. In the proposed rule this formal review was to be carried out at least once a year. We have included a new requirement in

subparagraph (b)(5) that, consistent with the requirements in §§ 438.604 and 438.606 pertaining to submission of certain data by the MCO and PHP that must be certified, each MCO and PHP must require subcontractors to provide certifications with respect to the performance of their duties under the contract and submissions that may be related to State payments.

Section 438.236 Practice Guidelines

We have revised the requirements in paragraph (b) to clarify that each MCO and PHP must adopt (as opposed to develop) practice guidelines. We have further revised the regulation to require that the guidelines—

- Are based, in part, on valid and reliable clinical evidence as opposed to ''reasonable medical evidence''; and
- Are reviewed and updated periodically as appropriate.

We include an example of practice guidelines that satisfy the requirements of this section (The Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents and the Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection).

In paragraph (c), we clarify the dissemination requirements by specifying that each MCO and PHP must disseminate the guidelines to affected providers, and upon request to enrollees and potential enrollees.

Section 438.240 Quality Assessment and Performance Improvement Program

We have added additional provisions and made clarifications to this section. We have added in paragraph (a) a provision that HCFA may specify standardized quality measures and topics for performance improvement projects to be required by States in their contracts with MCOs and PHPs. We have added as subparagraph (b)(4) a provision that the State must require each MCO and PHP to have in effect mechanisms to assess the quality and appropriateness of care furnished to enrollees with special health care needs. We have revised subparagraph (c)(1) to clarify that each MCO and PHP must measure its performance annually. We have added in subparagraph (c)(2) a new requirement that the State must, in establishing minimum performance levels for MCOs and PHPs, include any minimum performance levels specified by HCFA.

In subparagraph (d)(2) we clarified that each performance improvement project must represent the entire Medicaid enrolled population to which the measurement specified in paragraph (d)(1)(i) of this section is relevant. In subparagraph (d)(3), we have clarified that the State is to ensure that each MCO and PHP initiates each year one or more performance improvement projects. In subparagraph (d)(4), we have added ''cultural competence'' as a required non-clinical area for MCO and PHP performance improvement projects.

Section 438.242 Health Information Systems

In paragraph (a) we have deleted the requirement that MCO and PHP health information systems should provide information on MCO or PHP solvency. In paragraph (a) we also have clarified that information on Medicaid enrollee disenrollments pertains to disenrollments for other than loss of Medicaid eligibility.

Subpart F—Grievance System

Section 438.400

We have revised the terms used in this section, using ''grievance and appeal'' to replace ''complaint and grievance''. We have added a definition of ''action'' and of ''quality of care grievance''. We have also defined what constitutes an action.

Section 438.402

We have revised this section to include filing requirements as well as general requirements. In the general requirements in paragraph (b), we add that grievances and appeals must be accepted from the representative of the enrollee as well as from the enrollee; that the enrollee or his or her representative is to receive required notices and information; that the MCO or PHP must ensure that punitive action is neither threatened nor taken against a provider who requests an expedited resolution, or supports an enrollee's grievance or appeal; that at the enrollee's request, the MCO or PHP must refer to the State quality of care grievances not resolved to the satisfaction of the enrollee, and the MCO or PHP must require providers to give notice to enrollees of actions. Under the filing requirements in paragraph (c) we add that a provider may file an appeal on behalf of an enrollee with the enrollee's written consent. We clarify that an enrollee has a reasonable time specified by the State, not to exceed 90 days, to file an appeal after the date of an action. We also provide that a appeal may be filed either orally or in writing but that an oral request for standard resolution of the appeal must be followed by a written request. We specify that notice of action for failure to furnish or arrange for a service or provide payment in a timely manner must be provided whenever the entity has delayed access to the service to the point when there is substantial risk that further delay will adversely affect the enrollee's heart condition.

Section 438.404

We have revised paragraph (a) to provide that the notice of action must be in writing and must meet the language and format requirements of § 438.10. In paragraph (b), we specify what must be contained in the notice of action. In this paragraph we have added that the notice must include information on the circumstances under which the enrollee may be required to pay for the costs of services furnished while the appeal is pending and how the enrolees may decline amortization of benefits; that the enrollee has the right to represent himself or herself, to use legal counsel, or to use a relative, or friend or other individual as spokesperson; and that filing an appeal or requesting a State fair hearing will not negatively affect or impact the way the MCO and the PHP and their providers, or the State agency, treat the enrollee. In paragraph (c), we refer to § 438.210 for the time frames that apply to mailing the notice. In paragraph (d), we specify certain notice requirements for subcontractors or providers who are not employees to furnish a notice of action. We also moved to § 438.406 the provision on the right of the enrollee to appear before the MCO or PHP in person and removed the provision that the appearance must be before the person assigned to resolve the grievance.

Section 438.406

We have revised paragraph (a) to clarify that each MCO or PHP must give enrollees any reasonable assistance in completing forms and taking other procedural steps, including providing interpreter services and toll-free numbers that have adequate TTY/TTD and interpreter capability. We also require the MCO or PHP to ensure that the enrollee's communication is correctly classified as a ''grievance'' or an ''appeal'', that each communication is transmitted timely to staff who have the authority to act upon it, and that it is investigated and disposed of or resolved as required. We expanded the provision in the proposed rule concerning the types of appeals that must be decided by a health care professional to include, in addition to denials based on lack of medical necessity, all grievances and appeals that involve clinical issues and grievances regarding a denial to expedite resolution of an appeal. We also clarify that a health care

professional with appropriate clinical expertise, not only a physician, can serve as the decision maker. In paragraph (b), we have included several additional requirements that apply only to appeals, including that the timeframes for resolution of appeals must take account of the enrollee's health condition, that the enrollee and his or her representative have the opportunity to examine the enrollee's case file, and that the enrollee and his or her representative are parties to the appeal.

Section 438.408

In paragraph (a), we added a basic rule that an MCO or PHP must dispose of grievances and resolve appeals as expeditiously as the enrollee's health condition requires within State-established timeframes not exceeding the timeframes specified in this section. We have included in paragraph (b) the provision in paragraph (a)(4) of the proposed rule regarding the basis for decisions. In paragraph (c) we specify the timeframes for disposing of grievances and resolving appeals. We have added timeframes for disposing of grievances, specifying that grievances of a denial of a request to expedite resolution of an appeal must be disposed of within 72 hours of receipt of the grievance. We also added a provision that all other grievances must be disposed of within 90 days. We continue to provide for a 30-day timeframe for resolving appeals that are not expedited. In paragraph (d) we address extensions of timeframes for decisions. In the final rule we eliminated the authority of the MCO or PHP to grant itself an extension when an appeal is expedited. In the final rule we have added a provision that when an MCO or PHP grants itself an extension of the timeframe for decision of an appeal that is not expedited, the enrollee must be given written notice of the reason for the delay and of the enrollee's right to file a grievance with the decision. We added in the final rule the provision in paragraph (e) that the enrollee must be given written notice of the disposition of all grievances filed in writing and of all quality of care grievances. Oral notices can be provided to enrollees who file oral grievances not related to quality of care, unless the enrollee requests a written notice. In paragraph (f) we have added to the final rule that the notice on disposition of a quality of care grievance must include information that the enrollee has the right to seek further review by the State, and how to request it. In paragraph (h) we have revised the requirement of the proposed regulation that the notice of an appeal resolution must include the name of the MCO or PHP contact and now specify that the title of the contact, not the name, must be included. In paragraph (h) we add a requirement that the MCO or PHP must work with the State to dispose of the grievance if the State considers that the MCO or PHP response was insufficient. In paragraph (i) of the final rule we specify that expedited appeals not wholly favorable to the enrollee must be submitted to the State. In paragraph (j) we provide that the timeframe for fair hearing decision is 90 days minus the number of days taken by the MCO or PHP to resolve the internal appeal. The time used by the beneficiary to file for a State fair hearing does not count toward the 90 days. We have added a provision stating that the parties to a State fair hearing are the enrollee and his or er representative, or the representative of the deceased enrollee's estate. Finally, we add that for appeals of service authorization denials that meet the criteria for expedited resolution, the State fair hearing decision must be within 72 hours of receipt of the file.

Section 438.410

In paragraph (a), we retain the requirement from the proposed rule that each MCO and PHP must establish and maintain an expedited review process for grievances and appeals. In paragraph (b), we add to the final rule a requirement for expedited review of certain grievances. In paragraph (c), we describe the requirements that apply to appeals. In the proposed rule we provided for expedited resolution of appeal if non-expedited resolution would jeopardize the enrollee's life or health or the enrollee's ability to regain maximum function. In the final rule we add ''attain and maintain'' maximum function. In paragraph (d), we specify the steps that the MCO or PHP must take if it denies a request for expedited resolution of an appeal. In the final rule we require that the enrollee be notified of the decision within two calendar days. The proposed rule specified the timeframe as two working days. We also specify in the final rule that if the enroll resubmits the request for expedited resolution with a provider's letter of support, the resolution of the appeal will be expedited.

Section 438.414

In this section on information about the grievance system, in the final rule we differentiate between information that must be available with respect to fair hearings from that with respect to grievances and appeals. We added to the required items information about the right of the enrollee to represent himself or herself or to be represented by legal counsel, a friend or relative, or other spokesperson. We also added that information be provided on the fact that benefits will be continued if requested by an enrollee who files an appeal or requests for fair hearing and that the enrollee may be required to pay the cost of services while an appeal is pending if the final decision is adverse to the enrollee. In the proposed rule we provided that benefits would continue only if requested by the enrollee.

Section 438.416

We have added to the reporting requirements that grievances and appeals be tracked according to whether the disposition and resolution was standard or expedited and that a record must be maintained of when grievances and appeals were acknowledged and provide that . We have deleted the requirement to record disenrollments and that the summary submitted to the State include trends by particular providers or services.

Section 438.420

We have revised the provision that for services to be continued they must have been ordered by the MCO or PHP treating physician or another MCO or PHP physician and that the physician is authorized to order services under the MCO or PHP contract. The new requirement is that the services must have been ordered by an authorized provider. The final rule adds in paragraph (d) specifications for the duration of continued or reinstated benefits.

Section 438.421

We have removed this section and moved the provisions relating to effectuation of reversed appeal resolutions from this section to § 438.424.

Section 438.422

We have removed this section and moved the provisions relating to monitoring of the grievance and appeal system from this section to § 438.426.

Section 438.424

We have removed the 30-calendar day and 60-calendar day time periods for providing services originally denied but authorized through an appeal or fair hearing, respectively. We retain as the sole time determinate that the service must be provided as expeditiously as the enrollee's health condition requires. We also add to the final rule a provision that services denied during appeal that were received and are subsequently

authorized must be paid for by the MCO, PHP, or the State, to State policy and regulations.

Section 438.426

We have added this new section and moved the requirements relating to monitoring of the grievance and appeal system from § 438.422 to this section. We also provide in this section that if the summaries of grievances and appeals reveal a need for changing the system, the MCO or PHP must conduct an in-depth review and take corrective action.

Subpart H—Certifications and Program Integrity Protections

Section 438.602

We have revised the name and content of this section to address the basic rule that as a condition for contracting and for receiving payment under the Medicaid managed care program, an MCO and its subcontractors must comply with the certification and program integrity requirements of this subpart.

Section 438.604

We have added this new section to identify the types of data that must be certified. In paragraph (a), we require that when State payments to the MCO is based on data submitted by the MCO, including, but not limited to, enrollment information, encounter data, and other information required by the State, including data in contracts, proposals and other related documents, the State must require certification of the data as provided in § 438.606. In paragraph (b), we require that the certification must ensure that the MCO is in substantial compliance with the terms of the contract, and must be as provided in § 438.606, regardless of whether or not payment is based on data. In paragraph (c), we provide that certification is required for all documents specified by the State.

Section 438.606

We have revised the name and content of this section to address the source, content and timing of certification. In paragraph (a), we provide that subcontractors must certify data that they submit to the MCO and that the MCO certify the data that it submits to the State. One of the following individuals must certify the MCOs data:

- The MCO's Chief Executive Officer (CEO)
- The MCO's Chief Financial Officer (CFO)
- An individual who has delegated authority to sign for, and who reports directly to, the MCO's CEO or CFO.

In paragraph (b), in the case of data and/or other documents specified by the State, we require that the certification must attest to the accuracy, completeness, and truthfulness of the data/documents, based on best knowledge, information, and belief. In paragraph (b), in the case of certification of contract compliance, we require that the MCO attest based on best knowledge, information, and belief that they are in substantial compliance with their contract. In paragraph (c), we require the MCO to submit the certification concurrently with the certified data. In paragraph (c), we require that the MCO submit the certification of substantial compliance when requesting payment.

Section 438.608

We have revised the name and content of this section to include the program integrity requirements. In paragraph (a), we specify that the general rule is that the MCO must have administrative and management arrangements or procedures, including a mandatory compliance plan, that are designed to guard against fraud and abuse. In paragraph (b), we describe the specific requirements that apply to the administrative and management arrangements or procedures, which include:

- Written policies, procedures, and standards of conduct that articulate the organization's commitment to comply with all applicable Federal and State standards.
- The designation of a compliance officer and a compliance committee that are accountable to senior management.
- Effective training and education for the compliance officer and the organization's employees.
- Effective lines of communication between the compliance officer and the organization's employees.
- Enforcement of standards through well-publicized disciplinary guidelines.
- Provision of internal monitoring and auditing.
- Provision for prompt response to detected offenses and development of corrective action initiatives relating to the MCO's contract, including specific reporting requirements.

Subpart I—Sanctions

Section 438.700

We have revised paragraph (a) to clarify that States that contract with either MCOs or PHPs must establish intermediate sanctions. We have added a sentence to paragraph (a) specifying that a State's determination may be based on findings from onsite surveys, enrollee or other complaints, financial audits, or any other means. In paragraph (c) we clarify that the intermediate sanctions may be imposed if the State determines that the MCO or PHP distributes directly, or indirectly through any agent or independent contract, marketing materials that have not been approved by the State or that contain false or materially misleading information.

We have moved the requirements that were previously in § 438.702(b) to this section for clarity. In the new paragraph (d) we provide that the intermediate sanctions described in § 438.702(a)(4) and (a)(5) may be imposed if the State determines that an MCO or PHP violates any of the requirements in section 1903(m) of the Act or an MCO or PHP violates any of the requirements of section 1932 of the Act.

Section 438.702

We have revised subparagraph (a)(4) to provide that the State may impose an intermediate sanction that suspends all new enrollment, including default enrollment, after the effective date of the sanction. We have revised subparagraph (a)(5) to provide that the State may suspend payment for recipients enrolled after the effective date of the sanction. We have revised paragraph (b) to specify that State agencies retain authority to impose additional sanctions under State statutes or State regulations that address areas of noncompliance.

Section 438.704

We have revised subparagraph (b)(3) to clarify that the penalty is subject to the overall limit of $100,000 under subparagraph (b)(2). We have also revised subparagraph (b)(4) to clarify that the limit on the penalty is greater of double the amount of the excess charge or $25,000.

Section 438.706

We have revised paragraph (a) to clarify that the State may impose the sanction of temporary management under certain circumstances. We also removed a reference to § 434.67. We have moved the requirements that were previously in § 438.708 to paragraph (b) of this section. That paragraph provides that the State must impose the sanction of temporary management if it finds that an MCO or PHP has repeatedly failed to meet substantive requirements in section 1903(m) or 1932 of the Act, or this subpart. In addition, the State must also grant enrollees the right to terminate enrollment without cause. In

paragraph (c) we specify that the State may not delay imposition of temporary management to carry out due process procedures and may not provide a hearing before imposing this sanction.

Section 438.708

We have revised the name and content of this section to include the requirements relating to termination of an MCO or PHP contract that were previously in § 438.718. We have moved the requirements relating to mandatory imposition of the sanction of temporary management from this section to § 438.706. We have revised terminology in paragraph (a) from ''substantially'' to ''substantive.''

Section 438.710

We have revised the name and content of this section to include the requirements relating pre-termination hearing that were previously in § 438.720. We have revised paragraph (b) by removing the required time frames. Paragraph (b)(2) provides that prior to a pre-termination hearing, the State must give the MCO or PHP written notice of its intent to terminate, the reason for termination, and the time and place of the hearing. In addition, after the hearing, the State must give the MCO or PHP written notice of the decision affirming or reversing the proposed termination and, for an affirming decision, the effective date of termination. We have added a statement at paragraph (b)(2)(iii) that for an affirming decision, the State must give enrollees of the MCO or PHP notice of the termination along with information on their options for receiving care following the effective date of termination.

Section 438.718

We have removed this section and moved the requirements relating to termination of an MCE contract to § 438.708.

Section 438.720

We have removed this section and moved the requirements relating to pre-termination hearing to § 438.710.

Section 438.724

We have revised the name and content of this section to by removing the requirements for providing notice to HCFA of sanctions and by including new requirements for providing public notice of sanctions. In paragraph (a), we provide that the State must publish a notice that describes the intermediate sanction imposed, explains the reasons for the sanction and specifies the amount of any civil money penalty. In paragraph (b), we require the State to publish the notice no later than 30 days after it imposes the sanction. The notice must be a public announcement in either the newspaper of widest circulation in each city within the MCO's or PHP's service area that has a population of 50,000 or more or the newspaper of widest circulation in the MCO's or PHP's service area, if there is no city with a population of 50,000 or more in that area.

Section 438.726

We have added this new section to include the requirement that was previously in § 438.730(g). We require that the State plan must provide for the State to monitor for violation that involve the actions and failures to act specified in this section and to implement the provisions of this section.

Section 438.730

We have revised paragraph (a) to provide that a State agency may recommend that HCFA impose the denial of payment sanction on an MCO with a comprehensive risk contract if the MCO acts or fails to act as specified in § 438.700(b)(1) through (b)(6). Under paragraph (b), we have clarified that if HCFA accepts a State's recommendation, HCFA must convey the determination to the OIG for consideration of possible imposition of civil money penalties under section 1902(m)(5)(A) of the Act and part 1003 of this title. We also explain that, in accordance with the provisions of part 10003, the OIG may impose civil money penalties in addition to, or in place of, the sanctions that may be imposed under this section.

Subpart J—Conditions for Federal Financial Participation

Section 438.802

We have revised paragraph (b) to provide that FFP is available under an MCO or PHP contract only for periods during which the MCO or PHP and its subcontractors are in substantial compliance with the physician incentive plan requirements and the MCO or PHP and the State are in substantial compliance with the requirements of the MCO or PHP contract and of this part.

Section 438.810

We moved the definitions of *choice counseling, enrollment activities, and enrollment broker* from § 438.104 to paragraph (a) of this section. We have also included a new definition of *enrollment services*, which means choice counseling, enrollment activities, or both. We have revised paragraph (b) to include the conditions that enrollment brokers must meet so that State expenditures for their use qualify for FFP. In subparagraph (b)(1), we require that the broker and its subcontractors are independent of any managed care entity or health care provider in the State in which they provide enrollment services. We clarify that a broker or subcontractor is not considered ''independent'' if it is, is owned by, or owns any MCO, PHP, PCCM or other health care provider in the State in which it provides enrollment services. In subparagraph (b)(2), we require that the broker and its subcontractors be free from conflict of interest.

Section 438.814

We have added this new section to prohibit FFP for payments in accordance with risk corridors or incentive arrangements to the extent that these arrangements result in payments that exceed 105% of the approved capitation rates, for the services or enrollees covered by the risk corridor or incentive arrangement.

Part 447—Payments for Services

Section 447.53

We have revised paragraph (e) to specify that no provider may deny care or services to an individual eligible for the care or services on account of the individual's inability to pay the cost sharing.

Section 447.361

This section, which contained the upper payment limit for risk contracts, has been deleted and replaced by expanded requirements for actuarial soundness of capitation rates in new § 438.6(c).

Part 447—Payments for Services

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Part 447—Payments for Services

Section 447.53

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VIII. Regulatory Impact Analysis

A. Introduction

We have examined the impacts of this final rule as required by Executive Order 12866 and the Regulatory Flexibility Act (RFA). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits, including potential economic, environmental, public health and safety effects, distributive impacts, and equity. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This rule meets the criteria of being economically significant because the impact will be over $100 million.

The RFA requires agencies to analyze options for regulatory relief of small entities. This rule implements Medicaid managed care provisions as directed by BBA. The statute does not permit significant alternatives to regulation; however, we have considered ways to reduce burden on small entities.

This final rule with comment period primarily impacts beneficiaries, State Medicaid agencies, enrollment brokers, MCOs, PHPs, and PCCMs. Small entities include small businesses, nonprofit organizations, and other entities that have annual revenues of $5 million or less. Individuals and State governments are not included in this definition. Thus, most of the entities impacted by this regulation do not qualify as small entities. Individual PCCMs and a limited number of small PHPs would be considered small entities for purposes of this regulation.

In publishing this final rule with comment period, we considered regulatory alternatives that would reduce the burden on small entities. Thus, we have decided against imposing additional requirements on PCCMs beyond those specified in the BBA. We also have not applied all MCO requirements to all PHPs. For example, the advance directives requirements do not apply to PHPs that only cover dental or nonclinical services. In addition, PHPs are only required to comply with quality assessment and performance improvement provisions to the extent that they apply services actually provided by the PHP.

Section 1102(b) of the Act requires us to prepare a regulatory impact analysis for any rule that may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside a Metropolitan Statistical Area and has fewer than 50 beds.

We do not anticipate that the provisions in this final rule with comment period will have a substantial economic impact on most hospitals, including small rural hospitals. The BBA provisions include some new requirements on States, MCOs, and PHPs, but no new direct requirements on individual hospitals. The impact on individual hospitals will vary according to each hospital's current and future contractual relationships with MCOs and PHPs. Furthermore, the impact will also vary according to each hospital's current procedures and level of compliance with existing law and regulation pertaining to Medicaid managed care. For these reasons, this final rule is not expected to have a significant impact on the operations of a substantial number of hospitals.

The Unfunded Mandates Reform Act of 1995 requires that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that may result in an expenditure in any 1 year by State, local and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation). This rule does not impose any mandates on State, local, or tribal governments, or the private sector that will result in an annual expenditure of $100 million or more.

B. Summary of the Final Rule

This rule implements the Medicaid provisions as directed by the BBA. The primary objectives of these provisions are to allow for greater flexibility for State agencies to participate in Medicaid managed care programs and provide greater beneficiary protections and quality assurance standards. The regulation addresses pertinent areas of concern between States and MCOs, PHPs, and PCCMs, including enrollment, access to care, provider network adequacy, and grievance and appeal procedures for beneficiaries.

Specific provisions of the regulation include the following:

- Permitting States to require in their State plan that Medicaid beneficiaries be enrolled in managed care.
- Eliminating the requirement that no more than 75 percent of enrollees in an MCO or PHP be Medicaid or Medicare enrollees.
- Specifying a grievance and appeal procedure for MCO and PHP enrollees.
- Providing for the types of information that must be given to enrollees and potential enrollees, including language and format requirements.
- Requiring that MCOs and PHPs document for the States that they have adequate capacity to serve their enrollees and that States certify this to HCFA.
- Specifying quality standards for States and MCOs and PHPs.
- Increasing program integrity protections and requiring certification of data by MCOs and PHPs.
- Increasing the threshold for prior approval of MCO and PHP contracts from $100,000 to $1 million.
- Permitting cost sharing for managed care enrollees under the same circumstances as permitted in fee-for-service.
- Expanding the managed care population for which States can provide 6 months of guaranteed eligibility.
- Revising the rules for setting capitation rates.

It would be extremely difficult to accurately quantify the overall impact of this regulation on States, MCOs, PHPs, and PCCMs because there is enormous variation among States and these entities regarding their current regulatory and contract requirements, as well as organizational structure and capacity. Any generalization would mask important variations in the impact by State or managed care program type. The Lewin Group, under a contract with the Center for Health Care Strategies, recently completed a study to measure the cost impact of the proposed regulation. The study is the best information we currently have available on the potential incremental impact of the proposed regulation. Further, the study does not include an analysis of the proposed regulation in total, as it only focused on four areas within the proposed regulation: individual treatment plans, initial health assessments, quality improvement porgrams and grievance systems/State fair hearings. While the study's focus is on some of the proposed regulation provisions, of which many have changed, we believe that the overall cost conclusions are relevant to this final rule. In addition to examining the four regulatory requirements, they cited the

need to evaluate the incremental and aggregate effects of the rule; different managed care models (for example, overall enrollment; the Medicare, commercial, and Medicaid mix; geographic location); and State regulatory requirements (for example, State patient rights laws, regulation of noninsurance entities). The Lewin report also points out that many of the BBA provisions were implemented through previous guidance to the States, so the regulatory impact only captures a subset of the actual impact of the totality of BBA requirements.

According to the MCOs included in Lewin's study, many of the proposed provisions are not expected to have large incremental costs. The study mainly focused on the assessment and treatment management components of the regulation, as well as the quality improvement projects. For example, they estimate the incremental cost of an initial assessment (called screening in the final regulation) as ranging from $0.17 to $0.26 per member per month (PMPM), but for an MCO that currently performs an initial assessment, the incremental cost is estimated as $0.03 to $0.06 PMPM. Similarly, the costs of quality improvement projects can vary from $60,000 to $100,000 in the first year (start-up), $80,000 to $100,000 in the second and third years (the intervention and improvement measurement cycle), and $40,000 to $50,000 for the forth and subsequent years (ongoing performance measurement).

In summary, according to the Lewin Study, States and their contracting managed care plans have already implemented many provisions of the BBA. While there are incremental costs associated with the proposed and final regulatory requirements, they will vary widely based on characteristics of individual managed care plans and States. Finally, the BBA requirements are being implemented in an increasingly regulatory environment. Therefore, States, MCOs, and PHPs will likely face additional costs not related to these regulatory requirements. Thus, the incremental impact of these requirements on costs to be incurred would be difficult if not impossible to project.

We believe that the overall impact of this final rule will be beneficial to Medicaid beneficiaries, MCOs, PHPs, States, and HCFA. Many of the BBA Medicaid managed care requirements merely codify in Federal law standards widely in place in State law or in the managed care industry. Some of the BBA provisions represent new requirements for States, MCOs, PHPs, and PCCMs but also provide expanded opportunities for participation in Medicaid managed care.

It is clear that all State agencies will be affected by this Medicaid regulation but in varying degrees. Much of the burden will be on MCOs, PHPs, and PCCMs contracting with States, but this will also vary by existing and continuing relationships between State agencies and MCOs, PHPs, and PCCMs. This regulation is intended to maximize State flexibility and minimize the compliance cost to States, MCOs, and PHPs to the extent possible consistent with the detailed BBA requirements. We believe the final rule will result in improved patient care outcomes and satisfaction over the long term.

Recognizing that a large number of entities, such as hospitals, State agencies, and MCOs will be affected by the implementation of these statutory provisions, and a substantial number of these entities may be required to make changes in their operations, we have prepared the following analysis. This analysis, in combination with the rest of the preamble, is consistent with the standards for analysis set forth by both the RFA and RIA.

C. State Options to Use Managed Care

1. Managed Care Organizations

Under this provision, a State agency may amend its State plan to require all Medicaid beneficiaries in the State to enroll in either an MCO or PCCM without the need to apply for a waiver of ''freedom of choice'' requirements under either section 1915(b) or 1115 of the Act. However, waivers would still be required to include certain exempted populations in mandatory managed care programs, notably SSI populations, American Indians, and other groups of children with special needs. Federal review would be limited to a one-time State Plan Amendment (SPA) approval, while States would no longer need to request waiver renewals every 2 years for section 1915(b) of the Act and 5 years for section 1115 of the Act waivers. State agencies may include ''exempted'' populations as voluntary enrollees in State plan managed care programs to maintain parallel waiver programs. Currently, four States use SPAs to require beneficiary enrollment in capitated managed care organizations. In short, the new State plan option provides State agencies with a new choice of method to require participation in managed care. MCOs, PHPs, and providers would continue to provide care in a manner consistent with current and future standards, regardless of SPAs, and consequently Medicaid beneficiaries would receive the same level of health care in compliance with current and future standards.

Pursuing the SPA option rather than a section 1915(b) or 1115 of the Act waiver may reduce State administrative procedures because it would eliminate the need for States to go through the waiver renewal process. Likewise, we will benefit from a reduced administrative burden if fewer waiver applications and renewals are requested. However, we believe the overall reduction in burden to both States and to us would be small in relation to the overall administrative requirements of the Medicaid program.

2. Primary Care Case Management

Prior to the BBA, many State agencies elected to implement a PCCM system through a freedom of choice waiver under section 1915(b)(1) of the Act. Under the BBA, States may now require beneficiaries to use a PCCM provider under their State plans without the need for a waiver. As of December 2000, five States have chosen this option. Most State agencies, however, have continued to use waiver authority to require enrollment in PCCMs. Therefore, while the BBA provision provides potential for more PCCM programs to come into being, we do not expect expansion of PCCMs to be substantial due to the State plan option. To the extent that the use of PCCMs increases, patients of these providers will benefit from greater continuity of care and patient protections deriving from new and existing standards.

D. Elimination of 75/5 Rule

Prior to the passage of the BBA, nearly all MCOs and PHPs contracting with Medicaid were required to limit combined Medicare and Medicaid participation to 75 percent of their enrollment, and State agencies had to verify enrollment composition as a contract requirement. Elimination of this rule allows MCOs and PHPs to participate without meeting this requirement and eliminates the need for States to monitor enrollment composition in contracting MCOs and PHPs. This will broaden the number of MCOs and PHPs available to States for contracting, leading to more choice for beneficiaries.

With greater flexibility for State and MCO or PHP participation in managed care, providers can serve more Medicaid beneficiaries under managed care programs. Medicaid managed care enrollees will have better access to care and improved satisfaction.

E. Increased Beneficiary Protection—Grievance Procedures

The BBA requires MCOs to establish internal grievance procedures that permit an eligible enrollee, or a provider on behalf of an enrollee, to challenge the denials of coverage of medical assistance or denials of payment. While these requirements were not previously required by statute, we believe, based on recent State surveys, such as the National Academy for State Health Policy survey of 10 States in 1999, and the American Public Human Services Association survey of 13 States in 1997, that they reflect widespread current practice and, therefore, do not impose significant incremental costs on MCOs, PHPs, or State agencies.

F. Provision of Information

In mandatory managed care programs, we have required that beneficiaries be fully informed of the choices available to them in enrolling with MCOs and PHPs. Section 1932(a)(5) of the Act, enacted in section 4701(a)(5) of the BBA, describes the kind of information that must be made available to Medicaid enrollees and potential enrollees. It also requires that this information, and all enrollment notices and instructional materials related to enrollment in MCOs and PHPs, be in a format that can be easily understood by the individuals to which it is directed. We do not believe that these requirements deviate substantially from current practice. Furthermore, there is no way to quantify the degree of burden on State agencies, MCOs, and PHPs for several reasons. We do not have State-specific data on what information States currently provide, or the manner in which they provide it. Variability among States indicates that implementing or continuing enrollee information requirements will represent different degrees of difficulty and expense.

As a requirement under the provision of information section, State agencies opting to implement mandatory managed care programs under the SPA option are required to provide comparative information on MCOs and PCCMs to potential enrollees. Currently only eight States have exercised the option to use an SPA to require beneficiary enrollment in managed care. However, for States that do select this option, we do not believe that providing the comparative data in itself represents a burden, as these are elements of information that most States currently provide. The regulation specifies that the information must be presented in a comparative or chart-like form that facilitates comparison among MCOs, PHPs, and PCCMs. This may be perceived as a burden to States that have previously provided this information in some other manner; however, it is our belief that even in the absence of the regulation, the trend is for States, and many accreditation bodies such as the National Committee for Quality Assurance (NCQA), to use chart-like formats. Consequently, enrollees will benefit from having better information for selecting MCOs, PHPs, and PCCMs. Only a few States have opted for SPAs so far, but it is anticipated that more States will participate over the long term. States that participate in the future will benefit from any comparative tools developed by other States.

G. Demonstration of Adequate Capacity and Services

The BBA requires Medicaid MCOs to provide the State and the Secretary of HHS with assurances of adequate capacity and services, including service coverage within reasonable time frames. States currently require assurances of adequate capacity and services as part of their existing contractual arrangements with MCOs and PHPs. However, certification of adequacy has not been routinely provided to HCFA in the past. Under this rule, each State retains its authority to establish standards for adequate capacity and services within MCO and PHP contracts. This may be perceived as a burden to MCOs and PHPs, and for States which have to date not been required to formally certify that an MCO or PHP meets the State's capacity and service requirements. However, certification to HCFA will ensure an important beneficiary protection while imposing only a minor burden on States to issue a certification to HCFA.

Quantifying the additional burden on States, MCOs, or PHPs as a result of implementing this regulation is not feasible for several reasons. First, HCFA does not have State-specific data on the types of detailed information States currently require of their MCOs and PHPs to assure adequate capacity and services. Second, we do not have State-specific information on the manner in which State agencies collect and evaluate documentation in this area. Rather, each State agency has its own documentation requirements and its own procedures to assure adequate capacity and services. This regulation contemplates that States continue to have that flexibility.

Under this regulation, State agencies will determine and specify both the detail and type of documentation to be submitted by the MCO or PHP to assure adequate capacity and services and the type of certification to be submitted to us. Accordingly, variability among State agencies implementing this regulation represents different degrees of detail and expense. Regardless of the level of additional burden on MCOs, PHPs, State agencies, and us, Medicaid beneficiaries will receive continued protections in access to health care under both State and Federal law.

H. New Quality Standards

The BBA requires that each State agency have an ongoing quality assessment and improvement strategy for its Medicaid managed care contracting program. The strategy, among other things, must include: (1) standards for access to care so that covered services are available within reasonable time frames and in a manner that ensures continuity of care and adequate capacity of primary care and specialized services providers; (2) examination of other aspects of care and service directly related to quality of care, including grievance procedures, marketing, and information standards; (3) procedures for monitoring and evaluating the quality and appropriateness of care and service to enrollees; and (4) regular and periodic examinations of the scope and content of the State's quality strategy.

The provisions of this regulation establish requirements for State quality strategies and requirements for MCOs and PHPs that States are to incorporate as part of their quality strategy. These MCO and PHP requirements address: (1) MCO and PHP structure and operations; (2) Medicaid enrollees' access to care; and (3) MCO and PHP responsibilities for measuring and improving quality. While these new Medicaid requirements are a significant increase in Medicaid regulatory requirements in comparison to the regulatory requirements that existed before the BBA, we believe the increases are appropriate because many of the requirements are either identical to or consistent with quality requirements placed on MCOs and PHPs by private sector purchasers, the Medicare program, State licensing agencies, and private sector accreditation organizations. While these new requirements also will have implications for State Medicaid agencies that will be responsible for monitoring for compliance with the new requirements, we believe that a number of recent statutory, regulatory, and private sector developments will enable State Medicaid agencies to more easily monitor for compliance than in the past at potentially less cost to the State. First, the BBA also included provisions

addressing how States are to fulfill the statutory requirement for an annual, external quality review (EQR) of each Medicaid-contracting MCO and PHP. (These provisions are addressed in a separate rulemaking). Prior to the BBA, 75 percent Federal financial participation in the cost of these activities was available to States only if the State used a narrowly defined list of entities to perform the quality review. The BBA opened up the possibility for use of a much wider array of entities to perform this function. Further, in HCFA's proposed rule to implement these EQR provisions published on December 1, 1999, we specified that the 75 percent Federal match would also be available to EQR organizations that performed activities necessary for monitoring compliance with these BBA quality requirements for MCOs and PHPs. The BBA also provided that States could exercise an option whereby MCOs that were accredited by a private accrediting organization under certain conditions could be determined to meet certain of the quality requirements specified in this rule, thereby avoiding costs to the State of directly monitoring for compliance with these requirements. In response to this, private accrediting organizations such as the National Committee for Quality Assurance have developed Medicaid accreditation product lines.

In addition, prior to issuance of the proposed rule, we worked closely with State Technical Advisory Groups (TAGs) in developing the managed care quality regulations and standards. Requirements under this regulation build on a variety of initiatives of State Medicaid agencies and HCFA to promote the assessment and improvement of quality in plans contracting with Medicaid, including:

- The Quality Improvement System for Managed Care (QISMC), an initiative with State and Federal officials, beneficiary advocates, and the managed care industry to develop a coordinated quality oversight system for Medicare and Medicaid that reduces duplicate or conflicting efforts and emphasizes demonstrable and measurable improvement.
- QARI, serving as a foundation to the development of QISMC, highlights the key elements in the Health Care Quality Improvement System (HCQIS), including internal quality assurance programs, State agency monitoring, and Federal oversight. This guidance emphasizes quality standards developed in conjunction with all system participants, such as managed care contractors, State regulators, Medicaid beneficiaries or their representatives, and external review organizations.

Further, we have built on efforts in other sectors in developing these quality requirements in order to capitalize on current activities and trends in the health care industry. For example, many employers and cooperative purchasing groups and some State agencies already require that organizations be accredited by the National Committee on Quality Assurance (NCQA), the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the American Accreditation Healthcare Commission (AAHC), or other independent bodies. Many also require that organizations report their performance using Health Plan Employer Data & Information Set (HEDIS), Foundation for Accountability (FACCT), or other measures and conduct enrollee surveys using the Consumer Assessment of Health Plans Study (CAHPS) or other instruments. NCQA estimates that more than 90 percent of plans are collecting some or all of HEDIS data for their commercial population. Also, States have heightened their regulatory efforts through insurance or licensing requirements, and the National Association of Insurance Commissioners (NAIC) has developed model acts on network adequacy, quality assessment and improvement, and utilization review.

While we anticipate that many organizations will need to invest in new staff and information systems in order to perform these new quality improvement activities, it is difficult to quantify these financial and operational ''investments,'' as State agencies, MCOs, and PHPs across the country exhibit varying capabilities in meeting these standards. These new quality requirements will present administrative challenges for some State agencies and MCOs; however, PHPs and States have significant latitude in how these requirements will be implemented. Acknowledging that there likely will be some degree of burden on States, MCOs, and PHPs, we also believe that the long-term benefits of greater accountability and improved quality in care delivery will outweigh the costs of implementing and maintaining these processes over time.

I. Administration

1. Certifications and Program Integrity Protections

BBA sections 1902(a)(4) and (19) require that States conduct appropriate processes and methods to ensure the efficient operation of the health plans. This includes mechanisms to not only safeguard against fraud and abuse but also to ensure accurate reporting of data among health plans, States, and HCFA.

Section 438.602 of the regulation addresses the importance of reliable data that are submitted to States and requires MCOs and PHPs to certify the accuracy of these data to the State. These data include enrollment information, encounter data, or other information that is used for payment determination. For the most part, States reimburse MCOs and PHPs on a capitated basis and do not use claims or encounter data as a basis for payment. However, the collection of encounter, provider, and enrollment data will be most useful for States in measuring quality performance and addressing various methodologies of rate-setting and risk adjustment. The Medicaid provision of attesting to the validity of data presents an additional step in the process of data submission. MCOs and PHPs have historically worked closely with States when reporting Medicaid data in order to affirm that the data are accurate and complete. Submitting a certification of validity could take place in a variety of ways and will represent a varying degree of burden for health plans.

Section 438.606 requires MCOs and PHPs to have effective operational capabilities to guard against fraud and abuse. This will result in reporting violations of law by MCOs and PHPs to the State. Providers and health plans have traditionally ensured compliance with Federal and State laws when providing and delivering health care to members. For example, many health plans comply with standards set by the National Association of Insurance Commissioners (NAIC). However, additional resources and procedures will be necessary to have a systematic process for documenting violations and formally notifying the State of these instances.

The requirement for MCOs and PHPs to certify the accuracy and completeness of provider contracts or other documents is consistent with current practices. These demonstrations are evident in NCQA accreditation procedures, Medicaid waiver reviews, and audits that are necessary for compliance with other relevant State and Federal laws. Depending on the MCO or PHP, new processes may be necessary to comply with this standard. This requirement may not necessarily result in new mechanisms or resources for MCOs and PHPs but may create the need for more coordination with additional State Medicaid Agency

representatives in the review of provider contracts.

2. Change in Threshold from $100,000 to $1 Million

Before the passage of the BBA, the Secretary's prior approval was required for all HMO contracts involving expenditures in excess of $100,000. Under the BBA, the threshold amount is increased to $1 million. This change in threshold will have minimal impact on plans currently contracting with State agencies for Medicaid managed care. Currently, only one or two plans in the country have annual Medicaid expenditures of under $1 million. Therefore, this new provision will not affect a significant number of plans or States.

J. Permitting Same Copayments in Managed Care as in FFP

Under section 4708(c) of the BBA, States may now allow copayments for services provided by MCOs and PHPs to the same extent that they allow copayments under fee-for-service. Imposition of copayments in commercial markets typically results in lower utilization of medical services, depending on the magnitude of payments required of the enrollee. Thus, we would normally expect State agencies that implement copayments for MCO or PHP enrollees to realize some savings as a result. However, applying copayments in Medicaid populations may cause States, MCOs, and PHPs to incur overhead costs related to administering these fees that more than offset these savings. This is due to several factors including that copayments are significantly lower for Medicaid beneficiaries than typical commercial copayments, that it is difficult to ensure compliance with these payments, and that collection efforts would be necessary for MCOs or PHPs to obtain all fees due to them. Also, if State agencies take advantage of this option, Medicaid managed care enrollees may defer receipt of health care services and find their health conditions deteriorate such that costs of medical treatment may be greater over the long term. As a result of these variables, it is difficult to predict how many States will take advantage of this new option of permitting copayments for MCO or PHP enrollees.

K. Six-Month Guaranteed Eligibility

The legislation has expanded the States' option to guarantee up to 6 months eligibility in two ways. First, it expands the types of MCOs whose members may have guaranteed eligibility, in that it now includes anyone who is enrolled with a Medicaid managed care organization as defined in section 1903(m)(1)(A) of the Act. Second, it expands the option to include those enrolled with a PCCM as defined in section 1905(t) of the Act. These changes are effective October 1, 1997. To the extent that State agencies choose this option, we expect MCOs, PHPs, and PCCMs in those States to support the use of this provision since it affords health plans with assurance of membership for a specified period of time. Likewise, beneficiaries will gain from this coverage expansion, and continuity of care will be enhanced. The table below displays our estimates of the impact of the expanded option for 6 months of guaranteed eligibility under section 4709 of the BBA.

COST OF 6-MONTH GUARANTEED ELIGIBILITY OPTION

[Dollars in millions rounded to the nearest $5 million]

	FY 2000	FY 2001	FY 2002	FY 2003	FY 2004	FY 2005
Federal	40	55	80	115	165	230
State	30	45	60	905	125	175
Total	70	100	140	205	290	405

The estimates of Federal costs are reflected in the current budget baseline. The estimates assume that half of the current Medicaid population is enrolled in managed care and that this proportion will increase to about two-thirds by 2003. We also assume that 15 percent of managed care enrollees are currently covered by guaranteed eligibility under rules in effect prior to enactment of the BBA and that the effect of the expanded option under section 4709 of the BBA will be to increase this rate to 20 percent initially and to 30 percent by 2003. The guaranteed eligibility provision is assumed to increase average enrollment by 3 percent in populations covered by the option. This assumption is based on computer simulations of enrollment and turnover in the Medicaid program. Per capita costs used for the estimate were taken from the President's FY 1999 budget projections and the costs for children take into account the interaction of this provision with the State option for 12 months of continuous eligibility under section 4731 of the BBA. The distribution between Federal and State costs is based on the average Federal share representing 57 percent of the total costs.

In States electing the 6-month guaranteed eligibility option, Medicaid beneficiaries will have access to increased continuity of care, which should result in better health care management and improved clinical outcomes.

L. Financial Impact of Revised Rules for Setting Capitation Payments

This rule replaces the current upper payment limit (UPL) requirement at § 447.361 with new rate-setting rules incorporating an expanded requirement for actuarial soundness of capitation rates as described in detail in § 438.6(c) below. In general, we do not expect a major budget impact from the use of these new rate setting rules. While the new rate setting rules may provide some States additional flexibility in setting higher capitation rates than what would have been allowed under current rules, we believe that the requirements for actuarial certification of rates, along with budgetary considerations by State policy makers, would serve to limit increases to within reasonable amounts. Moreover, the Secretary would retain the authority to look behind rates that appear questionable and disapprove any that did not comply with the new rate setting requirements.

M. Administrative Costs

This regulation requires States to include certain specifications in their contracts with MCOs, PHPs, and PCCMs and to monitor compliance with those contract provisions. It also requires States to take a proactive role in monitoring the quality of their managed care program. These requirements will add some administrative burden and costs to States. The amount of additional administrative cost will vary by State depending on how inclusive current practice is of the new

requirements. In addition, for those States not using like requirements at present, we believe that most would be adopting similar requirements on their own in the future absent this regulation.

The regulation will also increase Federal responsibilities for monitoring State performance in managing their managed care programs. However, no new Federal costs are expected as HCFA plans to use existing staff to monitor these new requirements.

N. Conclusion

This BBA managed care regulation will affect HCFA, States, MCOs, PHPs, PCCMs, providers, and beneficiaries in different ways. The initial investments that are needed by State agencies and MCOs, PHPs, and PCCMs will result in improved and more consistent standards for the delivery of health care to Medicaid beneficiaries. Greater consumer safeguards will result from new quality improvement and protection provisions. Consequently, long term savings will derive from more consistent standards across States, MCOs, PHPs, and PCCMs and increased opportunities for provider and beneficiary involvement in improved access, outcomes, and satisfaction.

O. Federalism

Under Executive Order 13132, we are required to adhere to certain criteria regarding Federalism in developing regulations. We have determined that this final regulation will not significantly affect States rights, roles, and responsibilities. The BBA requires States that contract with section 1903(m) of the Act organizations to have certain beneficiary protections in place when mandating managed care enrollment. This final rule implements those BBA provisions in accordance with the Administrative Procedure Act. This rule also eliminates certain requirements viewed by States as impediments to the growth of managed care programs, such as disenrollment without cause at any time and the inability to amend the State plan without a waiver for mandatory managed care enrollment. We apply many of these requirements to prepaid health plans as set forth in our September 29, 1998 proposed rule. We believe this is consistent with the intent of the Congress in enacting the quality and beneficiary protection provisions of the BBA.

We worked closely with States in developing this regulation. We met with State officials and other stakeholders to discuss opportunities and concerns before the end of the comment period. Throughout the development of the regulation, we consulted with State Medicaid agency representatives in order to gain more understanding of potential impacts. At the November 1997 meeting of the Executive Board of the National Association of State Medicaid Directors (NASMD), we discussed the process for providing initial guidance to States about the Medicaid provisions of the BBA. We provided this guidance through issuance of a series of letters to State Medicaid Directors. From October 1997 through April 2000, over 50 of these letters were issued. Much of the policy included in this regulation relating to the State plan option provision was included in these letters. In May 1998, the Executive Committee of NASMD was briefed on the general content of the regulation. More specific State input was obtained through discussions throughout the Spring of 1998 with the Medicaid Technical Advisory Groups (TAGs) on Managed Care and Quality. These groups are comprised of Medicaid agency staff with notable expertise in the subject area and our regional office staff and are staffed by the American Public Human Services Association. The Managed Care TAG devoted much of its agenda for several monthly meetings to BBA issues. The Quality TAG participated in two conference calls exclusively devoted to discussion of BBA quality issues. Through these contacts, HCFA explored with State agencies their preferences regarding policy issues and the feasibility and practicality of implementing policy under consideration. We also invited public comments as part of the rulemaking process and received comments from over 300 individuals and organizations. Most of the commenters had substantial comments that addressed many provisions of the regulation.

We also received hundreds of comments on every subpart of the final rule, including comments for many States and membership organizations representing States. Many of the recommendations made by commenters have been incorporated into this final rule. For recommendations not accepted, a response has been included in this preamble. Moreover, we discussed technical issues with State experts through technical advisory groups to make certain that the final rule could be practically applied.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

For the reasons set forth in the preamble, the Health Care Financing Administration is amending 42 CFR Chapter IV as set forth below:

PART 400—INTRODUCTION; DEFINITIONS

1. The authority citation for part 400 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

§ 400.203 [Amended]

2. In § 400.203, the following statements are added, in alphabetical order, and the definition of ''provider'' is revised to read as set forth below.

PCCM stands for primary care case manager.

PCP stands for primary care physician.

Provider means either of the following:

(1) For the fee-for-service program, it means any individual or entity furnishing Medicaid services under an agreement with the Medicaid agency.

(2) For the managed care program, it means any individual or entity that is engaged in the delivery of health care services and is legally authorized to do so by the State in which it delivers the services.

PART 430—GRANTS TO STATES FOR MEDICAL ASSISTANCE PROGRAMS

1. The authority citation for part 430 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

2. In part 430 a new § 430.5 is added, to read as follows:

§ 430.5 Definitions.

As used in this subchapter, unless the context indicates otherwise—

Contractor means any entity that contracts with the State agency, under the State plan and in return for a payment, to process claims, to provide or pay for medical services, or to enhance the State agency's capability for effective administration of the program.

Representative has the meaning given the term by each State consistent with its laws, regulations, and policies.

PART 431—STATE ORGANIZATION AND GENERAL ADMINISTRATION

1. The authority citation for part 431 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

2. In § 431.51, the following changes are made:

a. In paragraph (a) introductory text, ''and 1915(a) and (b) of the Act.'' is

revised to read ''1915(a) and (b) and 1932(a)(3) of the Act.''

b. Paragraphs (a)(4) and (a)(5) are revised and a new paragraph (a)(6) is added, as set forth below.

c. In paragraph (b)(1) introductory text, ''and part 438 of this chapter'' is added immediately before the comma that follows ''this section''.

d. In paragraph (b)(2), ''an HMO'' is revised to read ''a Medicaid MCO''.

The additions and revisions read as follows:

§ 431.51 Free choice of providers.

(a) *Statutory basis.* * * *

(4) Section 1902(a)(23) of the Act provides that a recipient enrolled in a primary care case management system or Medicaid managed care organization (MCO) may not be denied freedom of choice of qualified providers of family planning services.

(5) Section 1902(e)(2) of the Act provides that an enrollee who, while completing a minimum enrollment period, is deemed eligible only for services furnished by or through the MCO or PCCM, may, as an exception to the deemed limitation, seek family planning services from any qualified provider.

(6) Section 1932(a) of the Act permits a State to restrict the freedom of choice required by section 1902(a)(23), under specified circumstances, for all services except family planning services.

* * * * *

3. In § 431.55, a sentence is added at the end of paragraph (c)(1)(i) to read as follows:

§ 431.55 Waiver of other Medicaid requirements.

* * * * *

(c) * * *

(1) * * *

(i) * * * The person or agency must comply with the requirements set forth in part 438 of this chapter for primary care case management contracts and systems.

4. Section 431.200 is revised to read as follows:

§ 431.200 Basis and scope.

This subpart—

(a) Implements section 1902(a)(3) of the Act, which requires that a State plan provide an opportunity for a fair hearing to any person whose claim for assistance is denied or not acted upon promptly;

(b) Prescribes procedures for an opportunity for hearing if the State agency takes action to suspend, terminate, or reduce services, or an MCO or PHP takes action under subpart F of part 438 of this chapter; and

(c) Implements sections 1919(f)(3) and 1919(e)(7)(F) of the Act by providing an appeals process for any person who—

(1) Is subject to a proposed transfer or discharge from a nursing facility; or

(2) Is adversely affected by the pre-admission screening or the annual resident review that are required by section 1919(e)(7) of the Act.

§ 431.201 [Amended]

5. In § 431.201, the following definition is added in alphabetical order:

* * * * *

Service authorization request means a managed care enrollee's request for the provision of a service.

6. In § 431.220, the introductory text of paragraph (a) is revised, the semicolons after paragraphs (a)(1), (a)(2), and (a)(3) and the ''and'' after the third semicolon are removed and periods are inserted in their place, and a new paragraph (a)(5) is added, to read as follows:

§ 431.220 When a hearing is required.

(a) The State agency must grant an opportunity for a hearing to the following:

* * * * *

(5) Any MCO or PHP enrollee who is entitled to a hearing under subpart F of part 438 of this chapter.

* * * * *

§ 431.244 [Amended]

7. In § 431.244, paragraph (f) is revised to read as follows:

* * * * *

(f) The agency must take final administrative action as follows:

(1) Ordinarily, within 90 days from the earlier of the following:

(i) The date the enrollee files an MCO or PHP appeal.

(ii) The date the enrollee files a request for State fair hearing.

(2) As expeditiously as the enrollee's health condition requires, but no later than 72 hours after the agency receives, from the MCO or PHP, the case file and information for any appeal of a denial of a service that, as indicated by the MCO or PHP—

(i) Meets the criteria for expedited resolution as set forth in § 438.410(c)(2) of this chapter, but was not resolved within the timeframe for expedited resolution; or

(ii) Was resolved within the timeframe for expedited resolution, but reached a decision wholly or partially adverse to the enrollee.

(3) As expeditiously as the enrollee's health condition requires, but no later than 72 hours after the agency receives, directly from an MCO or PHP enrollee, a fair hearing request on a decision to deny a service that it determines meets the criteria for expedited resolution, as set forth in § 438.410(c)(2) of this chapter.

PART 434—CONTRACTS

1. The authority citation for part 434 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

2. In § 434.1, paragraph (a) is revised to read as follows:

§ 434.1 Basis and scope.

(a) *Statutory basis.* This part is based on section 1902(a)(4) of the Act, which requires that the State plan provide for methods of administration that the Secretary finds necessary for the proper and efficient operation of the plan.

* * * * *

§ 434.2 [Amended]

3. In § 434.2, the definitions of ''Capitation fee'', ''Clinical laboratory'', ''Contractor'', ''Enrolled recipient'', ''Federally qualified HMO'', ''Health insuring organization (HIO)'', ''Health maintenance organization (HMO)'', ''Nonrisk'', ''Prepaid health plan (PHP)'', ''provisional status HMO'', and ''risk or underwriting risk'' are removed.

§§ 434.6 [Amended]

4. In paragraph (a)(1), ''Appendix G'' is removed.

§ 434.20 through 434.38 [Removed]

5. Subpart C, consisting of §§ 434.20 through 434.38, is removed and reserved.

§§ 434.42 and 434.44 [Removed]

6. In subpart D, §§ 434.42 and 434.44 are removed.

§§ 434.50 and 434.67 [Removed]

7. Subpart E, consisting of §§ 434.50 through 434.67, is removed and reserved.

8. Section 434.70 is revised to read as follows:

§ 434.70 Conditions for Federal financial participation (FFP).

(a) *Basic requirements.* FFP is available only for periods during which the contract—

(1) Meets the requirements of this part;

(2) Meets the applicable requirements of 45 CFR part 74; and

(3) Is in effect.

(b) *Basis for withholding.* HCFA may withhold FFP for any period during which—

(1) The State fails to meet the State plan requirements of this part; or

(2) Either party substantially fails to carry out the terms of the contract.

§§ 434.71 through 434.75 and 434.80 [Removed]

9. Sections 434.71 through 434.75, and 434.80 are removed.

PART 435—ELIGIBILITY IN THE STATES, THE DISTRICT OF COLUMBIA, THE NORTHERN MARIANA ISLANDS, AND AMERICAN SAMOA

1. The authority citation for part 435 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

2. In § 435.212, the following changes are made:

a. Throughout the section, ''HMO'', wherever it appears, is revised to read ''MCO''.

b. The section heading and the introductory text are revised to read as follows:

§ 435.212 Individuals who would be ineligible if they were not enrolled in an MCO or PCCM.

The State agency may provide that a recipient who is enrolled in an MCO or PCCM and who becomes ineligible for Medicaid is considered to continue to be eligible—

* * * * *

3. Section 435.326 is revised to read as follows:

§ 435.326 Individuals who would be ineligible if they were not enrolled in an MCO or PCCM.

If the agency provides Medicaid to the categorically needy under § 435.212, it may provide it under the same rules to medically needy recipients who are enrolled in MCOs or PCCMs.

§ 435.1002 [Amended]

4. In § 435.1002, in paragraph (a), ''§§ 435.1007 and 435.1008'' is revised to read §§ 435.1007, 435.1008, and 438.814 of this chapter,''

5. A new part 438 is added to chapter IV to read as follows:

PART 438—MANAGED CARE PROVISIONS

Subpart A—General Provisions

Sec.
438.1 Basis and scope.
438.2 Definitions.
438.6 Contract requirements.
438.8 Provisions that apply to PHPs.
438.10 Information requirements.
438.12 Provider discrimination prohibited.

Subpart B— State Responsibilities

438.50 State Plan requirements.
438.52 Choice of MCOs, PHPs, and PCCMs.
438.56 Disenrollment: Requirements and limitations.
438.58 Conflict of interest safeguards.
438.60 Limit on payment to other providers.
438.62 Continued services to recipients.
438.66 Monitoring procedures.
438.68 Education of MCOs, PHPs, and PCCMs and subcontracting providers.

Subpart C—Enrollee Rights and Protections

438.100 Enrollee rights.
438.102 Provider-enrollee communications.
438.104 Marketing activities.
438.106 Liability for payment.
438.108 Cost sharing.
438.114 Emergency and post-stabilization services.
438.116 Solvency standards.

Subpart D—Quality Assessment and Performance Improvement

438.200 Scope.
438.202 State responsibilities.
438.204 Elements of State quality strategies.

Access Standards

438.206 Availability of services.
438.207 Assurances of adequate capacity and services.
438.208 Coordination and continuity of care.
438.210 Coverage and authorization of services.

Structure and Operation Standards

438.214 Provider selection.
438.218 Enrollee information.
438.224 Confidentiality and accuracy of enrollee records.
438.226 Enrollment and disenrollment.
438.228 Grievance systems.
438.230 Subcontractual relationships and delegation.

Measurement and Improvement Standards

438.236 Practice guidelines.
438.240 Quality assessment and performance improvement program.
438.242 Health information systems.

Subpart E—[Reserved]

Subpart F—Grievance System

438.400 Statutory basis and definitions.
438.402 General requirements.
438.404 Notice of action.
438.406 Handling of grievances and appeals.
438.408 Resolution and notification: Grievances and appeals.
438.410 Expedited resolution of grievances and appeals.
438.414 Information about the grievance system.
438.416 Recordkeeping and reporting requirements.
438.420 Continuation of benefits while the MCO or PHP appeal and the State Fair Hearing are pending.
438.424 Effectuation of reversed appeal resolutions.
438.426 Monitoring of the grievance system.

Subpart G—[Reserved]

Subpart H—Certifications and Program Integrity Provisions

438.600 Statutory basis.
438.602 Basic rule.
438.604 Data that must be certified.
438.606 Source, content, and timing of certification.
438.608 Program integrity requirements.

Subpart I—Sanctions

438.700 Basis for imposition of sanctions.
438.702 Types of intermediate sanctions.
438.704 Amounts of civil money penalties.
438.706 Special rules for temporary management.
438.708 Termination of an MCO or PCCM contract.
438.710 Due process: Notice of sanction and pre-termination hearing.
438.722 Disenrollment during termination hearing process.
438.724 Public notice of sanction.
438.726 State plan requirement.
438.730 Sanction by HCFA: Special rules for MCOs with risk contracts.

Subpart J—Conditions for Federal Financial Participation

438.802 Basic requirements.
438.806 Prior approval.
438.808 Exclusion of entities.
438.810 Expenditures for enrollment broker services.
438.812 Costs under risk and nonrisk contracts.
438.814 Limit on payments in excess of capitation rates.

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

Subpart A—General Provisions

§ 438.1 Basis and scope.

(a) *Statutory basis.* This part is based on sections 1902(a)(4), 1903(m), 1905(t), and 1932 of the Act.

(1) Section 1902(a)(4) requires that States provide for methods of administration that the Secretary finds necessary for proper and efficient operation of the State Medicaid plan. The application of the requirements of this part to PHPs that do not meet the statutory definition of MCO or to a PCCM is under the authority in section 1902(a)(4).

(2) Section 1903(m) contains requirements that apply to comprehensive risk contracts.

(3) Section 1903(m)(2)(H) provides that an enrollee who loses Medicaid eligibility for not more than 2 months may be enrolled in the succeeding month in the same MCO or PCCM if that MCO or PCCM still has a contract with the State.

(4) Section 1905(t) contains requirements that apply to PCCMs.

(5) Section 1932—

(i) Provides that, with specified exceptions, a State may require

Medicaid recipients to enroll in MCOs or PCCMs;

(ii) Establishes the rules that MCOs, PCCMs, the State, and the contracts between the State and those entities must meet, including compliance with requirements in sections 1903(m) and 1905(t) of the Act that are implemented in this part;

(iii) Establishes protections for enrollees of MCOs and PCCMs;

(iv) Requires States to develop a quality assessment and performance improvement strategy;

(v) Specifies certain prohibitions aimed at the prevention of fraud and abuse;

(vi) Provides that a State may not enter into contracts with MCOs unless it has established intermediate sanctions that it may impose on an MCO that fails to comply with specified requirements; and

(vii) Makes other minor changes in the Medicaid program.

(b) *Scope.* This part sets forth requirements, prohibitions, and procedures for the provision of Medicaid services through MCOs, PHPs, and PCCMs. Requirements vary depending on the type of entity and on the authority under which the State contracts with the entity. Provisions that apply only when the contract is under a mandatory managed care program authorized by section 1932(a)(1)(A) of the Act are identified as such.

§ 438.2 Definitions.

As used in this part—

Capitation payment means a payment the State agency makes periodically to a contractor on behalf of each recipient enrolled under a contract for the provision of medical services under the State plan. The State agency makes the payment regardless of whether the particular recipient receives services during the period covered by the payment.

Comprehensive risk contract means a risk contract that covers comprehensive services, that is, inpatient hospital services and any of the following services, or any three or more of the following services:

(1) Outpatient hospital services.

(2) Rural health clinic services.

(3) FQHC services.

(4) Other laboratory and X-ray services.

(5) Nursing facility (NF) services.

(6) Early and periodic screening diagnostic, and treatment (EPSDT) services.

(7) Family planning services.

(8) Physician services.

(9) Home health services.

Federally qualified HMO means an HMO that HCFA has determined to be a qualified HMO under section 1310(d) of the PHS Act.

Health insuring organization (HIO) means an entity that in exchange for capitation payments, covers services for recipients—

(1) Through payments to, or arrangements with, providers; and

(2) Under a risk contract with the State.

Managed care organization (MCO) means an entity that has, or is seeking to qualify for, a comprehensive risk contract under this part, and that is —

(1) A Federally qualified HMO that meets the advance directives requirements of subpart I of part 489 of this chapter; or

(2) Any public or private entity that meets the advance directives requirements and is determined to also meet the following conditions:

(i) Makes the services it provides to its Medicaid enrollees as accessible (in terms of timeliness, amount, duration, and scope) as those services are to other Medicaid recipients within the area served by the entity.

(ii) Meets the solvency standards of § 438.116.

Nonrisk contract means a contract under which the contractor—

(1) Is not at financial risk for changes in utilization or for costs incurred under the contract that do not exceed the upper payment limits specified in § 447.362 of this chapter; and

(2) May be reimbursed by the State at the end of the contract period on the basis of the incurred costs, subject to the specified limits.

Prepaid health plan (PHP) means an entity that—

(1) Provides medical services to enrollees under contract with the State agency, and on the basis of prepaid capitation payments, or other payment arrangements that do not use State plan payment rates; and

(2) Does not have a comprehensive risk contract.

Primary care means all health care services and laboratory services customarily furnished by or through a general practitioner, family physician, internal medicine physician, obstetrician/gynecologist, or pediatrician, to the extent the furnishing of those services is legally authorized in the State in which the practitioner furnishes them.

Primary care case management means a system under which a PCCM contracts with the State to furnish case management services (which include the location, coordination and monitoring of primary health care services) to Medicaid recipients.

Primary care case manager (PCCM) means a physician, a physician group practice, an entity that employs or arranges with physicians to furnish primary care case management services or, at State option, any of the following:

(1) A physician assistant.

(2) A nurse practitioner.

(3) A certified nurse-midwife.

Risk contract means a contract under which the contractor—

(1) Assumes risk for the cost of the services covered under the contract; and

(2) Incurs loss if the cost of furnishing the services exceeds the payments under the contract.

§ 438.6 Contract requirements.

(a) *Regional office review.* The HCFA Regional Office must review and approve all MCO and PHP contracts, including those risk and nonrisk contracts that, on the basis of their value, are not subject to the prior approval requirement in § 438.806.

(b) *Entities eligible for comprehensive risk contracts.* A State agency may enter into a comprehensive risk contract only with one of the following:

(1) An MCO.

(2) The entities identified in section 1903(m)(2)(B)(i), (ii), and (iii) of the Act.

(3) Community, Migrant, and Appalachian Health Centers identified in section 1903(m)(2)(G) of the Act. Unless they qualify for a total exemption under section 1903(m)(2)(B) of the Act, these entities are subject to the regulations governing MCOs under this part.

(4) An HIO that arranges for services and became operational before January 1986.

(5) An HIO described in section 9517(c)(3) of the Omnibus Budget Reconciliation Act of 1985 (as added by section 4734(2) of the Omnibus Budget Reconciliation Act of 1990).

(c) *Payments under risk contracts.*—

(1) *Terminology.* As used in this paragraph, the following terms have the indicated meanings:

(i) *Actuarially sound capitation rates* means capitation rates that—

(A) Have been developed in accordance with generally accepted actuarial principles and practices;

(B) Are appropriate for the populations to be covered, and the services to be furnished under the contract; and

(C) Have been certified, as meeting the requirements of this paragraph (c), by actuaries who meet the qualification standards established by the American Academy of Actuaries and follow the practice standards established by the Actuarial Standards Board.

(ii) *Adjustments to smooth data* means adjustments made, by cost-neutral methods, across rate cells, to

compensate for distortions in costs, utilization, or the number of eligibles.

(2) *Basic requirements.* (i) All capitation rates paid under risk contracts and all risk-sharing mechanisms in contracts must be actuarially sound.

(ii) The contract must specify the payment rates and any risk-sharing mechanisms, and the actuarial basis for computation of those rates and mechanisms.

(3) *Requirements for actuarially sound rates.* In setting actuarially sound capitation rates, the State must apply the following elements, or explain why they are not applicable:

(i) Base utilization and cost data that are derived from the Medicaid population, or if not, are adjusted to make them comparable to the Medicaid population.

(ii) Adjustments made to smooth data and adjustments to account for factors such as inflation, MCO or PHP administration (subject to the limits in § 438.6(c)(4)(ii) of this section), and utilization;

(iii) Rate cells specific to the enrolled population, by:

(A) Eligibility category;

(B) Age;

(C) Gender;

(D) Locality/region; and

(E) Risk adjustments based on diagnosis or health status (if used).

(iv) Other payment mechanisms and utilization and cost assumptions that are appropriate for individuals with chronic illness, disability, ongoing health care needs, or catastrophic claims, using risk adjustment, risk sharing, or other appropriate cost-neutral methods.

(4) *Documentation.* The State must provide the following documentation:

(i) The actuarial certification of the capitation rates.

(ii) An assurance (in accordance with paragraph (c)(3) of this section) that all payment rates are based only upon services covered under the State plan and to be provided under the contract to Medicaid-eligible individuals.

(iii) Its projection of expenditures under its previous year's contract (or under its FFS program if it did not have a contract in the previous year) compared to those projected under the proposed contract.

(iv) An explanation of any incentive arrangements, or stop-loss, reinsurance, or any other risk-sharing methodologies under the contract.

(5) *Special contract provisions.* (i) Contract provisions for reinsurance, stop-loss limits or other risk-sharing methodologies (other than risk corridors) must be computed on an actuarially sound basis.

(ii) If risk corridors or incentive arrangements result in payments that exceed the approved capitation rates, the FFP limitation of § 438.814 applies.

(iii) For all incentive arrangements, the contract must provide that the arrangement is —

(A) For a fixed period of time;

(B) Not to be renewed automatically;

(C) Designed to include withholds or other payment penalties if the contractor does not perform the specified activities or does not meet the specified targets;

(D) Made available to both public and private contractors;

(E) Not conditioned on intergovernmental transfer agreements; and

(F) Necessary for the specified activities and targets.

(d) *Enrollment discrimination prohibited.* Contracts with MCOs, PHPs, and PCCMs must provide as follows:

(1) The MCO, PHP or PCCM accepts individuals eligible for enrollment in the order in which they apply without restriction (unless authorized by the Regional Administrator), up to the limits set under the contract.

(2) Enrollment is voluntary, except in the case of mandatory enrollment programs that meet the conditions set forth in § 438.50(a).

(3) The MCO, PHP or PCCM will not, on the basis of health status or need for health care services, discriminate against individuals eligible to enroll.

(4) The MCO, PHP or PCCM will not discriminate against individuals eligible to enroll on the basis of race, color, or national origin, and will not use any policy or practice that has the effect of discriminating on the basis of race, color, or national origin.

(e) *Services that may be covered.* An MCO or PHP contract may cover, for enrollees, services that are in addition to those covered under the State plan.

(f) *Compliance with contracting rules.* All contracts under this subpart must:

(1) Comply with all applicable State and Federal laws and regulations including Title VI of the Civil Rights Act of 1964; Title IX of the Education Amendments of 1972 (regarding education programs and activities); the Age Discrimination Act of 1975; the Rehabilitation Act of 1973; and the Americans with Disabilities Act; and

(2) Meet all the requirements of this section.

(g) *Inspection and audit of financial records.* Risk contracts must provide that the State agency and the Department may inspect and audit any financial records of the entity or its subcontractors.

(h) *Physician incentive plans.* (1) MCO and PHP contracts must provide for compliance with the requirements set forth in §§ 422.208 and 422.210 of this chapter.

(2) In applying the provisions of §§ 422.208 and 422.210, references to ''M+C organization'', ''HCFA'', and ''Medicare beneficiaries'' must be read as references to ''MCO or PHP'', ''State agency'' and ''Medicaid recipients'', respectively.

(i) *Advance directives.* (1) All MCO and most PHP contracts must provide for compliance with the requirements of § 422.128 of this chapter for maintaining written policies and procedures with respect to advance directives. This requirement does not apply to PHP contracts where the State has determined such application would be inappropriate, as described in § 438.8(a)(2).

(2) The MCO or PHP must provide adult enrollees with written information on advance directives policies, and include a description of applicable State law.

(3) The information must reflect changes in State law as soon as possible, but no later than 90 days after the effective date of the change.

(j) *Special rules for certain HIOs.* Contracts with HIOs that began operating on or after January 1, 1986, and that the statute does not explicitly exempt from requirements in section 1903(m) of the Act are subject to all the requirements of this part that apply to MCOs and contracts with MCOs. These HIOs may enter into comprehensive risk contracts only if they meet the criteria of paragraph (a) of this section.

(k) *Additional rules for contracts with PCCMs.* A PCCM contract must meet the following requirements:

(1) Provide for reasonable and adequate hours of operation, including 24-hour availability of information, referral, and treatment for emergency medical conditions.

(2) Restrict enrollment to recipients who reside sufficiently near one of the manager's delivery sites to reach that site within a reasonable time using available and affordable modes of transportation.

(3) Provide for arrangements with, or referrals to, sufficient numbers of physicians and other practitioners to ensure that services under the contract can be furnished to enrollees promptly and without compromise to quality of care.

(4) Prohibit discrimination in enrollment, disenrollment, and re-enrollment, based on the recipient's health status or need for health care services.

(5) Provide that enrollees have the right to disenroll from their PCCM in accordance with § 438.56.

(l) *Subcontracts.* All subcontracts must fulfill the requirements of this part that are appropriate to the service or activity delegated under the subcontract.

(m) *Choice of health professional.* The contract must allow each enrollee to choose his or her health professional in the MCO to the extent possible and appropriate.

§ 438.8 Provisions that apply to PHPs.

The following requirements and options apply to PHPs, PHP contracts, and States with respect to PHPs, to the same extent that they apply to MCOs, MCO contracts, and States with respect to MCOs.

(a) The contract requirements of § 438.6, except for the following:

(1) Requirements that pertain to HIOs.

(2) Requirements for advance directives, if the State believes that they are not appropriate, for example, for a PHP contract that covers only dental services or non-clinical services such as transportation services.

(b) The information requirements in § 438.10.

(c) The provision against provider discrimination in § 438.12.

(d) The State responsibility provisions of subpart B except § 438.50.

(e) The enrollee rights and protection provisions in subpart C of this part.

(f) The quality assessment and performance improvement provisions in subpart D of this part to the extent that they are applicable to services furnished by the PHP.

(g) The grievance system provisions in subpart F of this part.

(h) The certification and program integrity protection provisions set forth in subpart H of this part.

§ 438.10 Information requirements.

(a) *Basic rules.* (1) Each State or its contracted representative, and each MCO, PHP, or PCCM must, in furnishing information to enrollees and potential enrollees, meet the requirements that are applicable to it under this section.

(2) The information required for all potential enrollees must be furnished by the State or its contracted representative or, at State option, by the MCO or PHP.

(3) The information required for all enrollees must be furnished by each MCO or PHP, unless the State chooses to furnish it directly or through its contracted representative.

(4) PHPs must comply with the requirements of this section, as appropriate. PHPs that contract as PCCMs must meet all of the requirements applicable to PCCMs. All other PHPs must meet all of the requirements applicable to MCOs.

(5) The language and format requirements of paragraphs (b) and (c) of this section apply to all information furnished to enrollees and potential enrollees, such as enrollment notices and instructions, as well as the information specified in this section.

(6) The State must have in place a mechanism to help enrollees and potential enrollees understand the State's managed care program.

(7) Each MCO and PHP must have in place a mechanism to help enrollees and potential enrollees understand the requirements and benefits of the plan.

(8) If the State plan provides for mandatory enrollment under section 1932(a)(1)(A) of the Act (that is, as a State plan option), the additional requirements of paragraph (h) of this section apply.

(b) *Language.* The State must meet the following requirements:

(1) Establish a methodology for identifying the non-English languages spoken by enrollees and potential enrollees throughout the State.

(2) Provide written information in each non-English language that is necessary for effective communication with a significant number or percentage of enrollees and potential enrollees.

(3) Require each MCO, PHP, and PCCM to make its written information available in the languages that are prevalent in its particular service area.

(4) Make oral interpretation services available and require each MCO, PHP, and PCCM to make those services available free of charge to the recipient to meet the needs of each enrollee and potential enrollee.

(5) Notify enrollees and potential enrollees, and require each MCO, PHP, and PCCM to notify its enrollees and potential enrollees—

(i) That oral interpretation and written information are available in languages other than English; and

(ii) Of how to access those services.

(c) *Format.* (1) The material must—

(i) Use easily understood language and format; and

(ii) Be available in alternative formats and in an appropriate manner that takes into consideration the special needs of those who, for example, are visually limited or have limited reading proficiency.

(2) The State must provide instructions to enrollees and potential enrollees and require each MCO, PHP, and PCCM to provide instructions to its enrollees and potential enrollees on how to obtain information in the appropriate format.

(d) *Information for potential enrollees.*—(1) *To whom and when the information must be furnished.* The State or its contracted representative must provide the information specified in paragraph (d)(2) of this section as follows:

(i) To each potential enrollee residing in the MCO's or PHP's service area;

(ii) At the time the potential enrollee first becomes eligible for Medicaid, is considering choice of MCOs or PHPs under a voluntary program, or is first required to choose an MCO or PHP under a mandatory enrollment program; and

(iii) Within a timeframe that enables the potential enrollee to use the information in choosing among available MCOs or PHPs.

(2) *Required information.* The information for potential enrollees must include the following:

(i) General information about—

(A) The basic features of managed care;

(B) Which populations are excluded from enrollment, subject to mandatory enrollment, or free to enroll voluntarily in an MCO or PHP; and

(C) MCO and PHP responsibilities for coordination of enrollee care;

(ii) Information specific to each MCO and PHP serving an area that encompasses the potential enrollee's service area:

(A) Benefits covered;

(B) Cost sharing, if any;

(C) Service area;

(D) Names, locations, telephone numbers of, and non-English language spoken by current network providers, including at a minimum information on primary care physicians, specialists, and hospitals, and identification of providers that are not accepting new patients.

(E) Benefits that are available under the State plan but are not covered under the contract, including how and where the enrollee may obtain those benefits, any cost sharing, and how transportation is provided. For a counseling or referral service that the MCO or PHP does not cover because of moral or religious objections, the MCO or PHP need not furnish information about how and where to obtain the service, but only about how and where to obtain information about the service. The State must furnish information about where and how to obtain the service.

(e) *Information for enrollees.*—(1) *To whom and when the information must be furnished.* The MCO or PHP must—

(i) Furnish to each of its enrollees the information specified in paragraph (e)(2) of this section within a reasonable time

after the MCO or PHP receives, from the State or its contracted representative, notice of the recipient's enrollment, and once a year thereafter.

(ii) Give each enrollee written notice of any change (that the State defines as ''significant'') in the information specified in paragraph (e)(2) of this section, at least 30 days before the intended effective date of the change.

(iii) Make a good faith effort to give written notice of termination of a contracted provider, within 15 days after receipt or issuance of the termination notice, to each enrollee who received his or her primary care from, or was seen on a regular basis by, the terminated provider.

(2) *Required information.* The information for enrollees must include the following:

(i) Kinds of benefits, and amount, duration, and scope of benefits available under the contract. There must be sufficient detail to ensure that enrollees understand the benefits to which they are entitled, including pharmaceuticals, and mental health and substance abuse benefits.

(ii) Enrollee rights as specified in § 438.100.

(iii) Procedures for obtaining benefits, including authorization requirements.

(iv) Names, locations, telephone numbers of, and non-English languages spoken by current network providers, including information at least on primary care physicians, specialists, and hospitals, and identification of providers that are not accepting new patients.

(v) Any restrictions on the enrollee's freedom of choice among network providers.

(vi) The extent to which, and how, enrollees may obtain benefits, including family planning services, from out-of-network providers.

(vii) The extent to which, and how, after-hours and emergency coverage are provided.

(viii) Policy on referrals for specialty care and for other benefits not furnished by the enrollee's primary care provider.

(ix) Cost sharing, if any.

(x) Grievance, appeal, and fair hearing procedures for enrollees, including timeframes, required under § 438.414(b).

(xi) Any appeal rights that the State chooses to make available to providers to challenge the failure of the organization to cover a service.

(xii) Any benefits that are available under the State plan but are not covered under the contract, including how and where the enrollee may obtain those benefits, any cost sharing, and how transportation is provided. For a counseling or referral service that the MCO or PHP does not cover because of moral or religious objections, the MCO or PHP need not furnish information on how and where to obtain the service, but only on how and where to obtain information about the service. The State must furnish information about how and where to obtain the service.

(xiii) Information on how to obtain continued services during a transition, as provided in § 438.62.

(xiv) The rules for emergency and post-stabilization services, as set forth in § 438.114.

(xv) Additional information that is available upon request, and how to request that information.

(3) *Annual notice.* At least once a year, the MCO or PHP, or the State or its contracted representative, must notify enrollees of their right to request and obtain the information listed in paragraphs (e)(2) and (f) of this section.

(f) *MCO or PHP information available upon request.* The following information must be furnished to enrollees and potential enrollees upon request, by the MCO or PHP, or by the State or its contracted representative if the State prohibits the MCO or PHP from providing it:

(1) With respect to MCOs and health care facilities, their licensure, certification, and accreditation status.

(2) With respect to health care professionals, information that includes, but is not limited to, education, licensure, and Board certification and recertification.

(3) Other information on requirements for accessing services to which they are entitled under the contract, including factors such as physical accessibility and non-English languages spoken.

(4) A description of the procedures the MCO or PHP uses to control utilization of services and expenditures.

(5) A summary description of the methods of compensation for physicians.

(6) Information on the financial condition of the MCO or PHP, including the most recently audited information.

(7) Any element of information specified in paragraphs (d) and (e) of this section.

(g) *Information on PCCMs and PHPs.*—(1) *To whom and when the information must be furnished.* The State or its contracted representative must furnish information on PCCMs and PHPs to potential enrollees—

(i) When potential enrollees first become eligible for Medicaid or are first required to choose a PCCM or PHP under a mandatory enrollment program; and

(ii) Within a timeframe that enables them to use the information in choosing among available PCCMs or PHPs .

(2) *Required information.*—(i) *General rule.* The information must include the following:

(A) The names of and non-English languages spoken by PCCMs and PHPs and the locations at which they furnish services.

(B) Any restrictions on the enrollee's choice of the listed PCCMs and PHPs.

(C) Except as provided in paragraph (g)(2)(ii) of this section, any benefits that are available under the State plan but not under the PCCM or PHP contract, including how and where the enrollee may obtain those benefits, any cost-sharing, and how transportation is provided.

(ii) *Exception.* For counseling and referral services that are not covered under the PCCM or PHP contract because of moral or religious objections, the PCCM or PHP need not furnish information about how and where to obtain the service but only about how and where to obtain information about the service. The State must furnish the information on how and where to obtain the service.

(3) *Additional information available upon request.* Each PCCM and PHP must, upon request, furnish information on the grievance procedures available to enrollees, including how to obtain benefits during the appeals process.

(h) *Special rules: States with mandatory enrollment.*—(1) *Basic rule.* If the State plan provides for mandatory enrollment under section 1932(a)(1)(A) of the Act, the State or its contracted representative must furnish information on MCOs, PHPs, and PCCMs (as specified in paragraph (h)(3) of this section), either directly or through the MCO, PHP, or PCCM.

(2) *When and how the information must be furnished.* The information must be furnished to all potential enrollees—

(i) At least once a year; and

(ii) In a comparative, chart-like format.

(3) *Required information.* Some of the information is the same as the information required for potential enrollees under paragraph (d) of this section. However, all of the information in this paragraph is subject to the timeframe and format requirements of paragraph (h)(2) of this section, and includes the following for each contracting MCO, PHP, or PCCM:

(i) The MCO's, PHP's, or PCCM's service area.

(ii) The benefits covered under the contract.

(iii) Any cost sharing imposed by the MCO, PHP, or PCCM.

(iv) To the extent available, quality and performance indicators, including, but not limited to, disenrollment rates as defined by the State, and enrollee satisfaction.

§ 438.12 Provider discrimination prohibited.

(a) *General rules.* (1) An MCO or PHP may not discriminate with respect to the participation, reimbursement, or indemnification of any provider who is acting within the scope of his or her license or certification under applicable State law, solely on the basis of that license or certification. If an MCO or PHP declines to include individual or groups of providers in its network, it must give the affected providers written notice of the reason for its decision.

(2) In all contracts with health care professionals an MCO or PHP must comply with the requirements specified in § 438.214.

(b) *Construction.* Paragraph (a) of this section may not be construed to—

(1) Require the MCO or PHP to contract with providers beyond the number necessary to meet the needs of its enrollees;

(2) Preclude the MCO or PHP from using different reimbursement amounts for different specialties or for different practitioners in the same specialty; or

(3) Preclude the MCO or PHP from establishing measures that are designed to maintain quality of services and control costs and are consistent with its responsibilities to enrollees.

Subpart B—State Responsibilities

§ 438.50 State plan requirements.

(a) *General rule.* A State plan that provides for requiring Medicaid recipients to enroll in managed care entities must comply with the provisions of this section, except when the State imposes the requirement—

(1) As part of a demonstration project under section 1115 of the Act; or

(2) Under a waiver granted under section 1915(b) of the Act.

(b) *State plan information.* The plan must specify—(1) The types of entities with which the State contracts;

(2) The payment method it uses (for example, whether fee-for-service or capitation);

(3) Whether it contracts on a comprehensive risk basis; and

(4) The process the State uses to involve the public in both design and initial implementation of the program and the methods it uses to ensure ongoing public involvement once the State plan has been implemented.

(c) *State plan assurances.* The plan must provide assurances that the State meets applicable requirements of the following laws and regulations:

(1) Section 1903(m) of the Act, with respect to MCOs and MCO contracts.

(2) Section 1905(t) of the Act, with respect to PCCMs and PCCM contracts.

(3) Section 1932(a)(1)(A) of the Act, with respect to the State's option to limit freedom of choice by requiring recipients to receive their benefits through managed care entities.

(4) This part, with respect to MCOs and PCCMs.

(5) Part 434 of this chapter, with respect to all contracts.

(6) Section 438.6(c), with respect to payments under any risk contracts, and § 447.362 with respect to payments under any nonrisk contracts.

(d) *Limitations on enrollment.* The State must provide assurances that, in implementing the State plan managed care option, it will not require the following groups to enroll in an MCO or PCCM:

(1) Recipients who are also eligible for Medicare.

(2) Indians who are members of Federally recognized tribes, except when the MCO or PCCM is—

(i) The Indian Health Service; or

(ii) An Indian health program or Urban Indian program operated by a tribe or tribal organization under a contract, grant, cooperative agreement or compact with the Indian Health Service.

(3) Children under 19 years of age who are—

(i) Eligible for SSI under title XVI;

(ii) Eligible under section 1902(e)(3) of the Act;

(iii) In foster care or other out-of-home placement;

(iv) Receiving foster care or adoption assistance; or

(v) Receiving services through a family-centered, community-based, coordinated care system that receives grant funds under section 501(a)(1)(D) of title V, and is defined by the State in terms of either program participation or special health care needs.

(e) *Priority for enrollment.* The State must have an enrollment system under which recipients already enrolled in an MCO or PCCM are given priority to continue that enrollment if the MCO or PCCM does not have the capacity to accept all those seeking enrollment under the program.

(f) *Enrollment by default.* (1) For recipients who do not choose an MCO or PCCM during their enrollment period, the State must have a default enrollment process for assigning those recipients to contracting MCOs and PCCMs.

(2) The process must seek to preserve existing provider-recipient relationships and relationships with providers that have traditionally served Medicaid recipients. If that is not possible, the State must distribute the recipients equitably among qualified MCOs and PCCMs available to enroll them, excluding those that are subject to the intermediate sanction described in § 438.702(a)(4).

(3) An ''existing provider-recipient relationship'' is one in which the provider was the main source of Medicaid services for the recipient during the previous year. This may be established through State records of previous managed care enrollment or fee-for-service experience, or through contact with the recipient.

(4) A provider is considered to have ''traditionally served'' Medicaid recipients if it has experience in serving the Medicaid population.

§ 438.52 Choice of MCOs, PHPs, and PCCMs.

(a) *General rule.* Except as specified in paragraphs (b) and (c) of this section, a State that requires Medicaid recipients to enroll in an MCO, PHP, or PCCM must give those recipients a choice of at least two entities.

(b) *Exception for rural area residents.* (1) Under any of the following programs, and subject to the requirements of paragraph (b)(2) of this section, a State may limit a rural area resident to a single MCO, PHP, or PCCM system:

(i) A program authorized by a plan amendment under section 1932(a) of the Act.

(ii) A waiver under section 1115 of the Act.

(iii) A waiver under section 1915(b) of the Act.

(2) A State that elects the option provided under paragraph(b)(1) of this section, must permit the recipient—

(i) To choose from at least two physicians or case managers; and

(ii) To obtain services from any other provider under any of the following circumstances:

(A) The service or type of provider is not available within the MCO, PHP, or PCCM network.

(B) The provider is not part of the network, but is the main source of a service to the recipient. (This provision applies as long as the provider continues to be the main source of the service).

(C) The only plan or provider available to the recipient does not, because of moral or religious objections, provide the service the enrollee seeks.

(D) The recipient's primary care provider or other provider determines

that the recipient needs related services that would subject the recipient to unnecessary risk if received separately (for example, a cesarean section and a tubal ligation) and not all of the related services are available within the network.

(E) The State determines that other circumstances warrant out-of-network treatment.

(3) As used in this paragraph, ''rural area''is any area other than an ''urban area'' as defined in § 412.62(f)(1)(ii) of this chapter.

(c) *Exception for certain health insuring organizations (HIOs).* The State may limit recipients to a single HIO if—

(1) The HIO is one of those described in section 1932(a)(3)(C) of the Act;

(2) The recipient who enrolls in the HIO has a choice of at least two primary care providers within the entity.

(d) *Limitations on changes between primary care providers.* For an enrollee of a single MCO, PHP, or HIO under paragraph (b)(2) or (b)(3) of this section, any limitation the State imposes on his or her freedom to change between primary care providers may be no more restrictive than the limitations on disenrollment under § 438.56(c).

§ 438.56 Disenrollment: Requirements and limitations.

(a) *Applicability.* The provisions of this section apply to all managed care arrangements whether enrollment is mandatory or voluntary and whether the contract is with an MCO, a PHP, or a PCCM.

(b) *Disenrollment requested by the MCO, PHP or PCCM.* All MCO, PHP, and PCCM contracts must—(1) Specify the reasons for which the MCO, PHP or PCCM may request disenrollment of an enrollee;

(2) Provide that the MCO, PHP or PCCM may not request disenrollment because of a change in the enrollee's health status, or because of the enrollee's utilization of medical services, diminished mental capacity, or uncooperative or disruptive behavior resulting from his or her special needs (except where his or her continued enrollment in the MCO, PHP or PCCM seriously impairs the entity's ability to furnish services to either this particular enrollee or other enrollees); and

(3) Specify the methods by which the MCO, PHP or PCCM assures the agency that it does not request disenrollment for reasons other than those permitted under the contract.

(c) *Disenrollment requested by the enrollee.* If the State chooses to limit disenrollment, its MCO, PHP, and PCCM contracts must provide that a recipient may request disenrollment as follows:

(1) For cause, at any time.

(2) Without cause, at the following times:

(i) During the 90 days following the date of the recipient's initial enrollment with the MCO, PHP or PCCM, or the date the State sends the recipient notice of the enrollment, whichever is later.

(ii) At least once every 12 months thereafter.

(iii) Upon automatic reenrollment under paragraph (g) of this section, if the temporary loss of Medicaid eligibility has caused the recipient to miss the annual disenrollment opportunity.

(iv) When the State imposes the intermediate sanction specified in § 438.702(a)(3).

(d) *Procedures for disenrollment.* (1) *Request for disenrollment.* The recipient (or his or her representative) must submit an oral or written request—

(i) To the State agency (or its agent); or

(ii) To the MCO, PHP or PCCM, if the State permits MCOs, PHPs, and PCCMs to process disenrollment requests.

(2) *Cause for disenrollment.* The following are cause for disenrollment:

(i) The enrollee was homeless (as defined by the State) or a migrant worker at the time of enrollment and was enrolled in the MCO, PHP or PCCM by default.

(ii) The plan does not, because of moral or religious objections, cover the service the enrollee seeks.

(iii) The enrollee needs related services (for example a cesarean section and a tubal ligation) to be performed at the same time; not all related services are available within the network; and the enrollee's primary care provider or another provider determines that receiving the services separately would subject the enrollee to unnecessary risk.

(iv) Other reasons, including but not limited to, poor quality of care, lack of access to services covered under the contract, or lack of access to providers experienced in dealing with the enrollee's health care needs.

(3) *MCO, PHP or PCCM action on request.* (i) An MCO, PHP or PCCM may either approve a request for disenrollment or refer the request to the State.

(ii) If the MCO, PHP, PCCM, or State agency (whichever is responsible) fails to make a disenrollment determination so that the recipient can be disenrolled within the timeframes specified in paragraphs (e)(1) of this section, the disenrollment is considered approved.

(4) *State agency action on request.* For a request received directly from the recipient, or one referred by the MCO, PHP or PCCM, the State agency must take action to approve or disapprove the request based on the following:

(i) Reasons cited in the request.

(ii) Information provided by the MCO, PHP or the PCCM at the agency's request.

(iii) Any of the reasons specified in paragraph (d)(2) of this section.

(5) *Use of the MCO, PHP, or PCCM grievance procedures.* (i) The State agency may require that the enrollee seek redress through the MCO, PHP, or PCCM's grievance system before making a determination on the enrollee's request.

(ii) The grievance process, if used, must be completed in time to permit the disenrollment (if approved) to be effective in accordance with the timeframe specified in § 438.56(e)(1).

(iii) If, as a result of the grievance process, the MCO, PHP, or PCCM approves the disenrollment, the State agency is not required to make a determination.

(e) *Timeframe for disenrollment determinations.* (1) Regardless of the procedures followed, the effective date of an approved disenrollment must be no later than the first day of the second month following the month in which the enrollee or the MCO, PHP or PCCM files the request.

(2) If the MCO, PHP or PCCM or the State agency (whichever is responsible) fails to make the determination within the timeframes specified in paragraphs (e)(1) and (e)(2) of this section, the disenrollment is considered approved.

(f) *Notice and appeals.* A State that restricts disenrollment under this section must take the following actions:

(1) Provide that enrollees and their representatives are given written notice of disenrollment rights at least 60 days before the start of each enrollment period.

(2) Ensure access to State fair hearing for any enrollee dissatisfied with a State agency determination that there is not good cause for disenrollment.

(g) *Automatic reenrollment: Contract requirement.* If the State plan so specifies, the contract must provide for automatic reenrollment of a recipient who is disenrolled solely because he or she loses Medicaid eligibility for a period of 2 months or less.

§ 438.58 Conflict of interest safeguards.

(a) As a condition for contracting with MCOs or PHPs, a State must have in effect safeguards against conflict of interest on the part of State and local officers and employees and agents of the State who have responsibilities relating to MCO or PHP contracts or the default

enrollment process specified in § 438.50(f).

(b) These safeguards must be at least as effective as the safeguards specified in section 27 of the Office of Federal Procurement Policy Act (41 U.S.C. 423).

§ 438.60 Limit on payment to other providers.

The State agency must ensure that no payment is made to a provider other than the MCO or PHP for services available under the contract between the State and the MCO or PHP, except where such payments are provided for in title XIX of the Act or 42 CFR.

§ 438.62 Continued services to recipients.

(a) The State agency must arrange for Medicaid services to be provided without delay to any Medicaid enrollee of an MCO, PHP or PCCM whose contract is terminated and for any Medicaid enrollee who is disenrolled from an MCO, PHP or PCCM for any reason other than ineligibility for Medicaid.

(b) The State agency must have in effect a mechanism to ensure continued access to services when an enrollee with ongoing health care needs is transitioned from fee-for-service to an MCO, PHP or PCCM, from one MCO, PHP or PCCM to another, or from an MCO, PHP or PCCM to fee-for-service.

(1) The mechanism must apply at least to the following:

(i) Children and adults receiving SSI benefits.

(ii) Children in title IV–E foster care.

(iii) Recipients aged 65 or older.

(iv) Pregnant women.

(v) Any other recipients whose care is paid for under State-established, risk-adjusted, high-cost payment categories.

(vi) Any other category of recipients identified by HCFA.

(2) The State must notify the enrollee that a transition mechanism exists, and provide instructions on how to access the mechanism.

(3) The State must ensure that an enrollee's ongoing health care needs are met during the transition period, by establishing procedures to ensure that, at a minimum—

(i) The enrollee has access to services consistent with the State plan, and is referred to appropriate health care providers;

(ii) Consistent with Federal and State law, new providers are able to obtain copies of appropriate medical records; and

(iii) Any other necessary procedures are in effect.

§ 438.66 Monitoring procedures.

The State agency must have in effect procedures for monitoring the MCO's or PHP's operations, including, at a minimum, operations related to:

(a) Recipient enrollment and disenrollment.

(b) Processing of grievances and appeals.

(c) Violations subject to intermediate sanctions, as set forth in subpart I of this part.

(d) Violations of the conditions for FFP, as set forth in subpart J of this part.

(e) All other provisions of the contract, as appropriate.

§ 438.68 Education of MCOs, PHPs, and PCCMs and subcontracting providers.

The State agency must have in effect procedures for educating MCOs, PHPs, PCCMs and any subcontracting providers about the clinical and other needs of enrollees with special health care needs.

Subpart C—Enrollee Rights and Protections

§ 438.100 Enrollee rights.

(a) *General rule.* The State must ensure that—

(1) Each MCO and each PHP has written policies regarding the enrollee rights specified in this section; and

(2) Each MCO, PHP, and PCCM complies with any applicable Federal and State laws that pertain to enrollee rights, and ensures that its staff and affiliated providers take those rights into account when furnishing services to enrollees.

(b) *Specific rights*—(1) *Basic requirement.* The State must ensure that each managed care enrollee is guaranteed the rights as specified in paragraphs (b)(2) and (b)(3) of this section.

(2) An enrollee of an MCO, PHP, or PCCM has the following rights: The right

(i) To receive information in accordance with § 438.10.

(ii) To be treated with respect and with due consideration for his or her dignity and privacy.

(iii) To receive information on available treatment options and alternatives, presented in a manner appropriate to the enrollee's condition and ability to understand. (The information requirements for services that are not covered under the contract because of moral or religious objections are set forth in § 438.10(e).)

(iv) To participate in decisions regarding his or her health care, including the right to refuse treatment.

(v) To be free from any form of restraint or seclusion used as a means of coercion, discipline, convenience or retaliation, as specified in other Federal regulations on the use of restraints and seclusion.

(3) An enrollee of an MCO or a PHP also has the following rights—The right

(i) To be furnished health care services in accordance with §§ 438.206 through 438.210.

(ii) To obtain a second opinion from an appropriately qualified health care professional in accordance with § 438.206(d)(3).

(iii) To request and receive a copy of his or her medical records, and to request that they be amended or corrected, as specified in § 438.224.

(c) *Free exercise of rights.* The State must ensure that each enrollee is free to exercise his or her rights, and that the exercise of those rights does not adversely affect the way the MCO, PHP or PCCM and its providers or the State agency treat the enrollee.

(d) *Compliance with other Federal and State laws.* The State must ensure that each MCO, PHP, and PCCM complies with any other applicable Federal and State laws (such as: Title VI of the Civil Rights Act of 1964 as implemented by regulations at 45 CFR part 484; the Age Discrimination Act of 1975 as implemented by regulations at 45 CFR part 91; the Rehabilitation Act of 1973; and Titles II and III of the Americans with Disabilities Act and other laws regarding privacy and confidentiality).

§ 438.102 Provider-enrollee communications.

(a) *Health care professional defined.* As used in this subpart, ''health care professional'' means a physician or any of the following: a podiatrist, optometrist, chiropractor, psychologist, dentist, physician assistant, physical or occupational therapist, therapist assistant, speech-language pathologist, audiologist, registered or practical nurse (including nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, and certified nurse midwife), licensed certified social worker, registered respiratory therapist, and certified respiratory therapy technician.

(b) *General rules.* (1) An MCO or PHP may not prohibit, or otherwise restrict a health care professional acting within the lawful scope of practice, from advising or advocating on behalf of an enrollee who is his or her patient, with respect to the following:

(i) The enrollee's health status, medical care, or treatment options, including any alternative treatment that may be self-administered.

(ii) Any information the enrollee needs in order to decide among all relevant treatment options.

(iii) The risks, benefits, and consequences of treatment or non-treatment.

(iv) The enrollee's right to participate in decisions regarding his or her health care, including the right to refuse treatment, and to express preferences about future treatment decisions.

(2) MCOs and PHPs must take steps to ensure that health care professionals—

(i) Furnish information about treatment options (including the option of no treatment) in a culturally competent manner; and

(ii) Ensure that enrollees with disabilities have effective communication with all health system participants in making decisions with respect to treatment options.

(3) Subject to the information requirements of paragraph (c) of this section, an MCO or PHP that would otherwise be required to provide, reimburse for, or provide coverage of, a counseling or referral service because of the requirement in paragraph (b)(1) of this section is not required to do so if the MCO or PHP objects to the service on moral or religious grounds.

(c) *Information requirements: MCO and PHP responsibility.* (1) An MCO or PHP that elects the option provided in paragraph (b) (3) of this section must furnish information about the services it does not cover as follows:

(i) To the State—

(A) With its application for a Medicaid contract; and

(B) Whenever it adopts the policy during the term of the contract.

(ii) Consistent with the provisions of § 438.10—

(A) To potential enrollees, before and during enrollment; and

(B) To enrollees, within 90 days after adopting the policy with respect to any particular service. (Although this timeframe would be sufficient to entitle the MCO or PHP to the option provided in paragraph (b)(3) of this section, the overriding rule in § 438.10(e)(1)(ii) requires the MCO or the PHP to furnish the information at least 30 days before the effective date of the policy.)

(2) As specified in § 438.10(d) and (e), the information that MCOs and PHPs must furnish to enrollees and potential enrollees does not include how and where to obtain the service excluded under paragraph (b)(3) of this section, but only how and where to obtain information about the service.

(d) *Information requirements: State responsibility.* For each service excluded by an MCO or PHP under paragraph (b)(2) of this section, the State must furnish information on how and where to obtain the service, as specified in §§ 438.10(e)(2)(xii) and 438.206(c).

(e) *Sanction.* An MCO or PHP that violates the prohibition of paragraph (b)(1) of this section is subject to intermediate sanctions under subpart I of this part.

§ 438.104 Marketing activities.

(a) *Terminology.* As used in this section, the following terms have the indicated meanings:

Cold-call marketing means any unsolicited personal contact by the MCO, PHP, or PCCM with a potential enrollee for the purpose of marketing as defined in this paragraph.

Marketing means any communication, from an MCO, PHP, or PCCM to an enrollee or potential enrollee, that can reasonably be interpreted as intended to influence the recipient to enroll or reenroll in that particular MCO's, PHP's, or PCCM's Medicaid product, or either to not enroll in, or to disenroll from, another MCO's, PHP's, or PCCM's Medicaid product.

Marketing materials means materials that—

(1) Are produced in any medium, by or on behalf of an MCO, PHP, or PCCM; and

(2) Can reasonably be interpreted as intended to market to enrollees or potential enrollees.

MCO, PHP, PCCM, and *entity* include any of the entity's employees, affiliated providers, agents, or contractors.

(b) *Contract requirements.* Each contract with an MCO, PHP, or PCCM must comply with the following requirements:

(1) Provide that the entity—

(i) Does not distribute any marketing materials without first obtaining State approval;

(ii) Distributes the materials to its entire service area as indicated in the contract;

(iii) Complies with the information requirements of § 438.10 to ensure that, before enrolling, the recipient receives, from the entity or the State, the accurate oral and written information he or she needs to make an informed decision on whether to enroll;

(iv) Does not seek to influence enrollment in conjunction with the sale or offering of any other insurance; and

(v) Does not, directly or indirectly, engage in door-to-door, telephone, or other cold-call marketing activities.

(2) Specify the methods by which the entity assures the State agency that marketing, including plans and materials, is accurate and does not mislead, confuse, or defraud the recipients or the State agency. Statements that would be considered inaccurate, false, or misleading include, but are not limited to, any assertion or statement (whether written or oral) that—

(i) The recipient must enroll in the MCO, PHP, or PCCM in order to obtain benefits or in order to not lose benefits; or

(ii) The MCO, PHP, or PCCM is endorsed by HCFA, the Federal or State government, or similar entity.

(c) *State agency review.* In reviewing the marketing materials submitted by the entity, the State must consult with the Medical Care Advisory Committee established under § 431.12 of this chapter or an advisory committee with similar membership.

§ 438.106 Liability for payment.

Each MCO and PHP must provide that its Medicaid enrollees are not held liable for any of the following:

(a) The MCO's or PHP's debts, in the event of the entity's insolvency.

(b) Covered services provided to the enrollee, for which—

(1) The State does not pay the MCO or the PHP; or

(2) The State, or the MCO or PHP does not pay the individual or health care provider that furnishes the services under a contractual, referral, or other arrangement.

(c) Payments for covered services furnished under a contract, referral, or other arrangement, to the extent that those payments are in excess of the amount that the enrollee would owe if the MCO or PHP provided the services directly.

§ 438.108 Cost sharing.

The contract must provide that any cost sharing imposed on Medicaid enrollees is in accordance with §§ 447.50 through 447.60 of this chapter.

§ 438.114 Emergency and post-stabilization services.

(a) *Definitions.* As used in this section—

Emergency medical condition has the meaning given the term in § 422.113(b) of this chapter.

Emergency services has the meaning given the term in § 422.113(b) of this chapter.

Post-stabilization care services has the meaning given the term in § 422.113(c) of this chapter.

(b) *Information requirements.* To enrollees and potential enrollees upon request, and to enrollees during enrollment and at least annually thereafter, each State (or at State option, each MCO, PHP, and PCCM) must provide, in clear, accurate, and

standardized form, information that describes or explains at least the following:

(1) What constitutes emergency medical condition, emergency services, and post-stabilization services, with reference to the definitions in paragraph (a) of this section.

(2) The fact that prior authorization is not required for emergency services.

(3) The process and procedures for obtaining emergency services, including use of the 911 telephone system or its local equivalent.

(4) The locations of any emergency settings and other locations at which MCO, PHP, and PCCM providers and hospitals furnish emergency services and post-stabilization services covered under the contract.

(5) The fact that, subject to the provisions of this section, the enrollee has a right to use any hospital or other setting for emergency care.

(6) The post-stabilization care services rules set forth at § 422.113(c) of this chapter.

(c) *Coverage and payment: General rule.* The following entities are responsible for coverage and payment of emergency services and post-stabilization care services.

(1) The MCO or PHP.

(2) The PCCM that has a risk contract that covers such services.

(3) The State, in the case of a PCCM that has a fee-for-service contract.

(d) *Coverage and payment: Emergency services.* (1) The entities identified in paragraph (c) of this section—

(i) Must cover and pay for emergency services regardless of whether the entity that furnishes the services has a contract with the MCO, PHP, or PCCM; and

(ii) May not deny payment for treatment obtained under either of the following circumstances:

(A) An enrollee had an emergency medical condition, including cases in which the absence of immediate medical attention would not have had the outcomes specified in paragraphs (b)(1)(A), (B), and (C) of the definition of emergency medical condition in § 422.113 of this chapter.

(B) A representative of the MCO, PHP, or PCCM instructs the enrollee to seek emergency services.

(2) A PCCM must—

(i) Allow enrollees to obtain emergency services outside the primary care case management system regardless of whether the case manager referred the enrollee to the provider that furnishes the services; and

(ii) Pay for the services if the manager's contract is a risk contract that covers those services.

(e) *Additional rules for emergency services.* (1) The entities specified in paragraph (c) of this section—

(i) May not limit what constitutes an emergency medical condition with reference to paragraph (a) of this section, on the basis of lists of diagnoses or symptoms; and

(ii) May not refuse to process any claim because it does not contain the primary care provider's authorization number.

(2) An enrollee who has an emergency medical condition may not be held liable for payment of subsequent screening and treatment needed to diagnose the specific condition or stabilize the patient.

(3) The attending emergency physician, or the provider actually treating the enrollee, is responsible for determining when the enrollee is sufficiently stabilized for transfer or discharge, and that determination is binding on the entities identified in paragraph (c) of this section as responsible for coverage and payment.

(f) *Coverage and payment: Post-stabilization services.* Post-stabilization care services are covered and paid for in accordance with provisions set forth at § 422.113(c) of this chapter. In applying those provisions, reference to ''M+C organization'' must be read as reference to the entities responsible for Medicaid payment, as specified in paragraph (c) of this section.

§ 438.116 Solvency standards.

(a) *Requirement for assurances.* (1) Each MCO and PHP that is not a Federally qualified HMO (as defined in section 1310 of the Public Health Service Act) must provide assurances satisfactory to the State showing that its provision against the risk of insolvency is adequate to ensure that its Medicaid enrollees will not be liable for the MCO's or PHP's debts if the entity becomes insolvent.

(2) Federally qualified HMOs, as defined in section 1310 of the Public Health Service Act, are exempt from this requirement.

(b) *Other requirements.*—(1) *General rule.* Except as provided in paragraph (b)(2) of this section, a MCO and a PHP must meet the solvency standards established by the State for private health maintenance organizations, or be licensed or certified by the State as a risk-bearing entity.

(2) *Exception.* Paragraph (b)(1) of this section does not apply to an MCO or PHP that meets any of the following conditions:

(i) Does not provide both inpatient hospital services and physician services.

(ii) Is a public entity.

(iii) Is (or is controlled by) one or more Federally qualified health centers and meets the solvency standards established by the State for those centers.

(iv) Has its solvency guaranteed by the State.

Subpart D—Quality Assessment and Performance Improvement

§ 438.200 Scope.

This subpart implements section 1932(c)(1) of the Act and sets forth specifications for quality assessment and performance improvement strategies that States must implement to ensure the delivery of quality health care by all MCOs and PHPs. It also establishes standards that States, MCOs and PHPs must meet.

§ 438.202 State responsibilities.

Each State contracting with an MCO or PHP must—

(a) Have a strategy for assessing and improving the quality of managed care services offered by all MCOs and PHPs:

(b) Document the strategy in writing.

(c) Provide for the input of recipients and other stake-holders in the development of the strategy, including making the strategy available for public comment before adopting it in final;

(d) Ensure compliance with standards established by the State, consistent with this subpart; and

(e) Conduct periodic reviews to evaluate the effectiveness of the strategy, and update the strategy as often as the State considers appropriate, but at least every 3 years.

(f) Submit to HCFA the following:

(1) A copy of the initial strategy, and a copy of the revised strategy, whenever significant changes are made.

(2) Regular reports on the implementation and effectiveness of the strategy, consistent with paragraph (e), at least every 3 years.

§ 438.204 Elements of State quality strategies.

At a minimum, State strategies must include the following—

(a) MCO and PHP contract provisions that incorporate the standards specified in this subpart.

(b) Procedures for assessing the quality and appropriateness of care and services furnished to all Medicaid enrollees under the MCO and PHP contracts. These include, but are not limited to—

(1) Procedures that—

(i) Identify enrollees with special health-care needs; and

(ii) Assess the quality and appropriateness of care furnished to

enrollees with special health-care needs; and

(iii) Identify the race, ethnicity, and primary language spoken of each Medicaid enrollee. States must provide this information to the MCO and PHP for each Medicaid enrollee at the time of enrollment.

(2) Continuous monitoring and evaluation of MCO and PHP compliance with the standards.

(c) Performance measures and levels prescribed by HCFA consistent with section 1932(c)(1) of the Act.

(d) Arranging for annual, external independent reviews of the quality outcomes and timeliness of, and access to the services covered under each MCO and PHP contract.

(e) Appropriate use of intermediate sanctions that, at a minimum, meet the requirements of Subpart I of this part.

(f) An information system that supports initial and ongoing operation and review of the State's quality strategy.

(g) Standards, at least as stringent as those in the following sections of this subpart, for access to care, structure and operations, and quality measurement and improvement.

Access Standards

§ 438.206 Availability of services.

(a) *Basic rule.* Each State must ensure that all covered services are available and accessible to enrollees.

(b) *Choice of entities.* If a State limits freedom of choice, it must comply with the requirements of § 438.52, which specifies the choices that the State must make available.

(c) *Services not covered by an MCO, PHP, or PCCM contract.* If an MCO, PHP, or PCCM contract does not cover all of the services under the State plan, the State must make those services available from other sources and provide to enrollees information on where and how to obtain them, including how transportation is provided.

(d) *Delivery network.* The State must ensure that each MCO, and each PHP consistent with the scope of PHP's contracted services, meets the following requirements:

(1) Maintains and monitors a network of appropriate providers that is supported by written agreements and is sufficient to provide adequate access to all services covered under the contract. In establishing and maintaining the network, each MCO and PHP must consider the following:

(i) The anticipated Medicaid enrollment, with particular attention to pregnant women, children, and persons with special health-care needs.

(ii) The expected utilization of services, considering Medicaid enrollee characteristics and health care needs.

(iii) The numbers and types (in terms of training, experience, and specialization) of providers required to furnish the contracted Medicaid services.

(iv) The numbers of network providers who are not accepting new Medicaid patients.

(v) The geographic location of providers and Medicaid enrollees, considering distance, travel time, the means of transportation ordinarily used by Medicaid enrollees, and whether the location provides physical access for Medicaid enrollees with disabilities.

(2) Provides female enrollees with direct access to a women's health specialist within the network for covered care necessary to provide women's routine and preventive health care services. This is in addition to the enrollee's designated source of primary care if that source is not a women's health specialist.

(3) Provides for a second opinion from a qualified health care professional within the network, or arranges for the enrollee to obtain one outside the network, at no cost to the enrollee, if an additional qualified professional is not currently available within the network.

(4) When seeking an expansion of its service area, demonstrates that it has sufficient numbers and types (in terms of training, experience, and specialization) of providers to meet the anticipated additional volume and types of services the added Medicaid enrollee population may require.

(5) If the network is unable to provide necessary medical services, covered under the contract, to a particular enrollee, the MCO or PHP must adequately and timely cover these services out of network for the enrollee, for as long as the MCO or PHP is unable to provide them.

(6) Demonstrates that its providers are credentialed as required by § 438.214.

(7) Ensures that its providers do not discriminate against Medicaid enrollees.

(8) Requires out-of-network providers to coordinate with the MCO or PHP with respect to payment and ensures that cost to the enrollee is no greater than it would be if the services were furnished within the network.

(e) *Furnishing of services.* The State must ensure that each MCO and PHP complies with the requirements of this paragraph.

(1) *Timely access.* Each MCO and each PHP must —

(i) Meet and require its providers to meet State standards for timely access to care and services, taking into account the urgency of need for services;

(ii) Ensure that its network's provider hours of operation are convenient for the enrollees, as determined by a State-established methodology, and at least comparable to Medicaid fee-for-service.

(iii) Make services available 24 hours a day, 7 days a week, when medically necessary.

(iv) Establish mechanisms to ensure compliance;

(v) Monitor continuously to determine compliance; and

(vi) Take corrective action if there is a failure to comply.

(2) *Cultural considerations.* Each MCO and each PHP ensures that services are provided in a culturally competent manner to all enrollees, including those with limited English proficiency and diverse cultural and ethnic backgrounds.

§ 438.207 Assurances of adequate capacity and services.

(a) *Basic rule.* Each MCO and each PHP must give assurances to the State that it has the capacity to serve the expected enrollment in its service area in accordance with the State's standards for access to care under this subpart.

(b) *Nature of assurances.* Each MCO and each PHP must submit documentation to the State, in a format specified by the State and acceptable to HCFA, to demonstrate that it complies with the following requirements:

(1) Offers an appropriate range of services, including preventive services, primary care services and specialty services that is adequate for the anticipated number of enrollees for the service area.

(2) Maintains a network of providers that is sufficient in number, mix, and geographic distribution to meet the needs of the anticipated number of enrollees in the service area.

(3) Meets the availability of services requirements in § 438.206.

(4) Has in place policies and practices to deal with situations in which there is—

(i) Unanticipated need for providers with particular types of experience; or

(ii) Unanticipated limitation of the availability of such providers.

(c) *Timing of documentation.* Each MCO and each PHP must submit the documentation described in paragraph (b) of this section at least once a year, and specifically—

(1) At the time it enters into a contract with the State; and

(2) At any time there has been a significant change (as defined by the State) in the MCO's or PHP's operations that would affect adequate capacity and services, including—

(i) A significant change in the MCO's or PHP's services or benefits;

(ii) An expansion or reduction of the MCO's or PHP's geographic service area;

(iii) The enrollment of a new population in the MCO or PHP; and

(iv) A significant change in the MCO or PHP rates.

(d) *State review and submission to HCFA.* After the State reviews the documentation submitted by the MCO or PHP, the State must certify to HCFA that the MCO or PHP has complied with the State's requirements for availability of services, as set forth in § 438.206.

(e) *HCFA's right to inspect documentation.* The State must make available to HCFA, upon request, all documentation collected by the State from the MCO or PHP.

§ 438.208 Coordination and continuity of care.

(a) *Basic requirement.*—(1) *General rule.* Except as specified in paragraphs (a)(2) and (a)(3) of this section, the State must ensure that MCOs and PHPs comply with the requirements of this section.

(2) *PHP exception.* For PHPs, the State determines, based on the scope of the entity's services, and on the way the State has organized the delivery of managed care services, whether a particular PHP is required—

(i) To perform the initial and ongoing screenings and assessments specified in paragraphs (d) and (e) of this section; and

(ii) To meet the primary care requirement of paragraph (h)(1) of this section.

(3) *Exception for MCOs that serve dually eligible enrollees.* (i) For an MCO that serves enrollees who are also enrolled in a Medicare+Choice plan and also receive Medicare benefits, the State determines to what extent that MCO must meet the initial screening, assessment, and treatment planning provisions of paragraphs (d), (e), and (f) of this section.

(ii) The State bases its determination on the services it requires the MCO to furnish to dually eligible enrollees.

(b) *State responsibility to identify enrollees with special health care needs.* The State must implement mechanisms to identify to the MCO and PHP, upon enrollment, the following groups:

(1) Enrollees at risk of having special health care needs, including—

(i) Children and adults who are receiving SSI benefits;

(ii) Children in Title IV–E foster care;

(iii) Enrollees over the age of 65; and

(iv) Enrollees in relevant, State-established, risk-adjusted, higher-cost payment categories.

(v) Any other category of recipients identified by HCFA.

(2) Children under the age of 2.

(3) Other enrollees known by the State to be pregnant or to have special health care needs.

(c) *Requirements for MCOs and PHPs.* The State must ensure—

(1) That each MCO, and each PHP for which the State determines it is appropriate in accordance with paragraphs (a)(2) and (a)(3) of this section, meets the requirements of paragraphs (d), (e), and (h)(1) of this section; and

(2) That each MCO and each PHP meets the requirements of paragraphs (f), (g), and (h)(2) through (h)(6) of this section.

(d) *Initial screening and assessment.* Each MCO and each PHP must make a best effort attempt to meet the following standards:

(1) For enrollees identified under paragraph (b)(1) of this section,

(i) Performs enrollee screening within 30 days of receiving the identification; and

(ii) For any enrollee the screening identifies as being pregnant or having special health care needs, performs a comprehensive health assessment as expeditiously as the enrollee's health requires, but no later than 30 days from the date of identification.

(2) For enrollees identified under paragraphs (b)(2) and (b)(3) of this section, or who identify themselves as being pregnant or having special health care needs, performs a comprehensive health assessment as expeditiously as the enrollee's health requires, but no later than 30 days from the date of identification.

(3) For all other enrollees—

(i) Performs screening within 90 days from the date of enrollment; and

(ii) For any enrollee the screening identifies as being pregnant or having special health care needs, performs the comprehensive health assessment as expeditiously as the enrollee's health requires but no later than 30 days from the date of identification.

(e) *On-going screening and assessment.* Each MCO and each PHP must implement mechanisms to—

(1) Identify enrollees who develop special health care needs after they enroll in the MCO or PHP; and

(2) Perform comprehensive health assessments as expeditiously as the enrollee's health requires, but no later than 30 days from the date of identification.

(f) *Treatment plans.* For pregnant women and for enrollees determined to have special health care needs, each MCO and each PHP implements a treatment plan that—

(1) Is appropriate to the conditions and needs identified and assessed under paragraphs (d) and (e) of this section;

(2) Is for a specific period of time and is updated periodically;

(3) Specifies a standing referral or an adequate number of direct access visits to specialists;

(4) Ensures adequate coordination of care among providers;

(5) Is developed with enrollee participation; and

(6) Ensures periodic reassessment of each enrollee as his or her health condition requires.

(g) *Use of health care professionals.* Each MCO and each PHP uses appropriate health care professionals to—

(1) Perform any comprehensive health assessments required by this section; and

(2) Develop, implement, and update any treatment plans required by this section.

(h) *Primary care and coordination program.* Each MCO and each PHP must implement a coordination program that meets State requirements and achieves the following:

(1) Ensures that each enrollee has an ongoing source of primary care appropriate to his or her needs and a person or entity formally designated as primarily responsible for coordinating the health care services furnished to the enrollee.

(2) Coordinates the services the MCO or PHP furnishes to the enrollee with the services the enrollee receives from any other MCOs and PHPs;

(3) Shares with other MCOs and PHPs serving the enrollee the results of its screenings and assessments of the enrollee so that those activities need not be duplicated.

(4) Ensures that in the process of coordinating care, each enrollee's privacy is protected consistent with the confidentiality requirements in § 438.224.

(5) Ensures that each provider maintains health records that meet professional standards and that there is appropriate and confidential sharing of information among providers.

(6) Has in effect procedures to address factors (such as a lack of transportation) that may hinder enrollee adherence to prescribed treatments or regimens.

(7) Ensures that its providers have the information necessary for effective and continuous patient care and quality improvement, consistent with the confidentiality and accuracy requirements of § 438.224 and the information system requirements of § 438.242.

§ 438.210 Coverage and authorization of services.

(a) *Coverage.* Each contract with an MCO, PHP, or PCCM must identify, define, and specify each service that the MCO, PHP, or PCCM is required to offer, and each contract with an MCO or PHP must meet the following requirements:

(1) Require that the MCO or PHP make available the services it is required to offer at least in the amount, duration, and scope that—

(i) Are specified in the State plan; and

(ii) Are sufficient to reasonably be expected to achieve the purpose for which the services are furnished.

(2) Provide that the MCO or PHP—

(i) May not arbitrarily deny or reduce the amount, duration, or scope of a required service solely because of the diagnosis, type of illness, or condition; and

(ii) May place appropriate limits on a service—

(A) On the basis of criteria such as medical necessity; or

(B) For the purpose of utilization control, provided the services furnished can reasonably be expected to achieve their purpose, as required in paragraph (a)(1)(ii) of this section.

(3) Specify what constitutes ''medically necessary services'' in a manner that—

(i) Is no more restrictive than the State Medicaid program as indicated in State statutes and regulations, the State Plan, and other State policy and procedures; and

(ii) Addresses the extent to which the MCO or PHP is responsible for covering services related to the following:

(A) The prevention, diagnosis, and treatment of health impairments.

(B) The ability to achieve age-appropriate growth and development.

(C) The ability to attain, maintain, or regain functional capacity.

(4) Provide that the MCO or PHP furnishes the services in accordance with the specifications of paragraph (a)(3) of this section.

(b) *Processing of requests.* With respect to the processing of requests for initial and continuing authorizations of services, each contract must require—

(1) That the MCO or PHP and its subcontractors have in place, and follow, written policies and procedures that reflect current standards of medical practice;

(2) That the MCO or PHP—

(i) Not have information requirements that are unnecessary, or unduly burdensome for the provider or the enrollee;

(ii) Have in effect mechanisms to ensure consistent application of review criteria for authorization decisions; and

(iii) Consult with the requesting provider when appropriate.

(3) That any decision to deny a service authorization request or to authorize a service in an amount, duration, or scope that is less than requested, be made by a health care professional who has appropriate clinical expertise in treating the enrollees's condition or disease.

(c) *Notice of adverse action.* Each contract must provide for the MCO or PHP to notify the requesting provider, and give the enrollee written notice of any decision by the MCO or PHP to deny a service authorization request, or to authorize a service in an amount, duration, or scope that is less than requested. The notice must meet the requirements of § 438.404, except that the notice to the provider need not be in writing.

(d) *Timeframe for standard authorization decisions.* Each contract must provide for the MCO or PHP to make a standard authorization decision and provide notice—

(1) As expeditiously as the enrollee's health condition requires and within State-established timeframes that may not exceed 14 calendar days following receipt of the request for service, with a possible extension of up to 14 additional calendar days, if—

(i) The enrollee, or the provider, requests extension; or

(ii) The MCO or the PHP justifies (to the State agency upon request) a need for additional information and how the extension is in the enrollee's interest.

(e) *Timeframe for expedited authorization decisions.* (1) For cases in which a provider indicates, or the MCO or PHP determines, that following the standard timeframe could seriously jeopardize the enrollee's life or health or ability to attain, maintain, or regain maximum function, each contract must provide for the MCO or PHP to make an expedited authorization decision and provide notice as expeditiously as the enrollee's health condition requires and no later than 72 hours after receipt of the request for service.

(2) The MCO or PHP may extend the 72-hour time period by up to 14 calendar days if the enrollee requests extension.

(f) *Compensation for utilization management activities.* Each contract must provide that, consistent with § 438.6(g), and § 422.208 of this chapter, compensation to individuals or entities that conduct utilization management activities is not structured so as to provide incentives for the individual or entity to deny, limit, or discontinue medically necessary services to any enrollee.

Structure and Operation Standards

§ 438.214 Provider selection.

(a) *General rules.* The State must ensure that each contracted MCO and PHP implements written policies and procedures for selection and retention of providers and that those policies and procedures include, at a minimum, the requirements of this section.

(b) *Credentialing and recredentialing requirements.* Each MCO and each PHP must follow a documented credentialing process for providers who have signed contracts or participation agreements with the MCO or the PHP.

(1) *Physicians and other licensed independent providers.* The process for physicians, including members of physician groups, and other licensed independent providers, includes—

(i) Initial credentialing when a physician or other provider enters the MCO or PHP network or a physician enters a physician group; and

(ii) Recredentialing within timeframes set by the State, which may be no less than the State requires for private MCOs.

(2) *Other providers.* The process for other providers must include an initial determination, and redetermination at specified intervals. The redetermination cycles must be the same as Federal or State credentialing cycles. The purpose is to ensure that, at a minimum, the provider—

(i) Is licensed (if required by the State); and

(ii) Has met any other applicable Federal or State requirements.

(3) *Exception.* The requirements of paragraphs (b)(1) and (b)(2) of this section do not apply to either of the following:

(i) Providers who are permitted to furnish services only under the direct supervision of a physician or other provider.

(ii) Hospital-based providers (such as emergency room physicians, anesthesiologists, or certified nurse anesthetists) who provide services only incident to hospital services. This exception does not apply if the provider contracts independently with the MCO or PHP or is promoted by the MCO or PHP as part of the provider network.

(4) *Initial credentialing.* Initial credentialing—

(i) Requires a written, dated and signed application that is updated in writing at recredentialing;

(ii) Requires that applications, updates, and supporting information submitted by the applicant include an attestation of the correctness and completeness of the information; and

(iii) Is based on primary source verification of licensure, disciplinary status, and a site visit as appropriate.

(5) *Recredentialing.* Recredentialing includes updating of information obtained during initial credentialing and an assessment of provider performance indicators obtained through the following:

(i) Quality Assessment and Performance Improvement Programs.

(ii) The utilization management system.

(iii) The grievance system.

(iv) Enrollee satisfaction surveys.

(v) Other MCO or PHP activities specified by the State.

(c) *Nondiscrimination.* MCO and PHP provider selection policies and procedures, consistent with § 438.12, do not discriminate against particular providers that serve high risk populations or specialize in conditions that require costly treatment.

(d) *Excluded providers.* MCOs or PHPs may not employ or contract with providers excluded from participation in Federal health care programs under either section 1128 or section 1128A of the Act.

(e) *State requirements.* Each MCO and PHP must comply with any additional requirements established by the State.

§ 438.218 Enrollee information.

The requirements that States must meet under § 438.10 constitute part of the State's quality strategy at § 438.204.

§ 438.224 Confidentiality and accuracy of enrollee records.

The State must ensure that (consistent with subpart F of part 431 of this chapter), for medical records and any other health and enrollment information that identifies a particular enrollee, each MCO and PHP establishes and implements procedures to do the following:

(a) Maintain the records and information in a timely and accurate manner.

(b) Abide by all Federal and State laws regarding confidentiality and disclosure.

(c) Specify—

(1) For what purposes the MCO or PHP uses the information; and

(2) To which entities outside the MCO or PHP, and for what purposes, it discloses the information.

(d) Except as provided in applicable Federal and State law, ensure that each enrollee may request and receive a copy of records and information pertaining to him or her and request that they be amended or corrected.

(e) Ensure that each enrollee may request and receive information on how the MCO or PHP uses and discloses information that identifies the enrollee.

§ 438.226 Enrollment and disenrollment.

The State must ensure that each MCO and PHP complies with the enrollment and disenrollment requirements and limitations set forth in § 438.56.

§ 438.228 Grievance systems.

(a) The State must ensure that each MCO and PHP has in effect a grievance system that meets the requirements of subpart F of this part.

(b) If the State delegates to the MCO or PHP responsibility for notice of action under subpart E of part 431 of this chapter, the State must conduct random reviews of each delegated MCO or PHP and its providers and subcontractors to ensure that they are notifying enrollees in a timely manner.

(c) The State must establish a process to review, upon request by the enrollee, any quality of care grievance that the MCO or the PHP does not resolve to the enrollee's satisfaction.

§ 438.230 Subcontractual relationships and delegation.

(a) *General rule.* The State must ensure that each MCO and PHP—

(1) Oversees and is accountable for any functions and responsibilities that it delegates to any subcontractor; and

(2) Meets the conditions of paragraph (b) of this section.

(b) *Specific conditions.* (1) Before any delegation, each MCO and PHP evaluates the prospective subcontractor's ability to perform the activities to be delegated.

(2) There is a written agreement that—

(i) Specifies the activities and report responsibilities delegated to the subcontractor; and

(ii) Provides for revoking delegation or imposing other sanctions if the subcontractor's performance is inadequate.

(3) The MCO or PHP monitors the subcontractor's performance on an ongoing basis and subjects it to formal review according to a periodic schedule established by the State, consistent with industry standards or State MCO laws and regulations.

(4) If any MCO or PHP identifies deficiencies or areas for improvement, the MCO and the subcontractor take corrective action.

(5) Consistent with §§ 438.604 and 438.606, each MCO and PHP requires from subcontractors certifications with respect to—

(i) Submissions that may be related to State payments; and

(ii) The performance of their duties under the contract.

Measurement and Improvement Standards

§ 438.236 Practice guidelines.

(a) *Basic rule.* The State must ensure that each MCO and PHP meets the requirements of this section.

(b) *Adoption of practice guidelines.* Each MCO and PHP adopts practice guidelines (for example, The Guidelines for the Use of Antiretroviral Agents in HIV–Infected Adults and Adolescents and the Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection) that meet the following requirements:

(1) Are based on valid and reliable clinical evidence or a consensus of health care professionals in the particular field;

(2) Consider the needs of the MCO's or PHP's enrollees;

(3) Are adopted in consultation with contracting health care professionals; and

(4) Are reviewed and updated periodically as appropriate.

(c) *Dissemination of guidelines.* Each MCO and PHP disseminates the guidelines to all affected providers and, upon request, to enrollees and potential enrollees.

(d) *Application of guidelines.* Decisions with respect to utilization management, enrollee education, coverage of services, and other areas to which the guidelines apply are consistent with the guidelines.

§ 438.240 Quality assessment and performance improvement program.

(a) *General rules.* (1) The State must require, through its contracts, that each MCO and PHP have an ongoing quality assessment and performance improvement program for the services it furnishes to its enrollees.

(2) Paragraphs (b) through (d) of this section set forth the basic elements, minimum performance levels, and performance improvement projects required for MCOs and PHPs.

(3) HCFA may specify standardized quality measures, and topics for performance improvement projects to be required by States in their contracts with MCOs and PHPs.

(b) *Basic elements of MCO and PHP quality assessment and performance improvement programs.* At a minimum, the State must require that each MCO and PHP comply with the following requirements:

(1) Achieve required minimum performance levels on standardized quality measures, in accordance with paragraph (c) of this section;

(2) Conduct performance improvement projects as described in

paragraph (d) of this section. These projects must achieve, through ongoing measurements and intervention, demonstrable and sustained improvement in significant aspects of clinical care and non-clinical care areas that can be expected to have a favorable effect on health outcomes and enrollee satisfaction; and

(3) Have in effect mechanisms to detect both underutilization and overutilization of services.

(4) Have in effect mechanisms to assess the quality and appropriateness of care furnished to enrollees with special health care needs.

(c) *Minimum performance levels.* (1) Each MCO and PHP must meet the following requirements:

(i) Annually measure its performance, using standard measures required by the State, consistent with the requirements of § 438.204(c), and report its performance to the State.

(ii) Achieve all minimum performance levels that the State establishes with respect to the standard measures.

(2) The State—

(i) May specify the standard measures in uniform data collection and reporting instruments; and

(ii) Must, in establishing minimum performance levels for the MCOs and PHPs—

(A) Include any minimum performance measures and levels specified by HCFA;

(B) Consider data and trends for both the MCOs and PHPs and fee-for-service Medicaid in that State; and

(C) Establish the minimum performance levels prospectively, each time a contract is initiated or renewed.

(d) *Performance improvement projects.* (1) Performance improvement projects are MCO and PHP initiatives that focus on clinical and non-clinical areas, and that involve the following:

(i) Measurement of performance using objective quality indicators.

(ii) Implementation of system interventions to achieve improvement in quality.

(iii) Evaluation of the effectiveness of the interventions.

(iv) Planning and initiation of activities for increasing or sustaining improvement.

(2) Each project must represent the entire Medicaid enrollee population to which the measurement specified in paragraph (d)(1)(i) of this section is relevant.

(3) The State must ensure that each MCO and PHP initiates each year one or more projects among the required clinical and non-clinical areas specified in paragraphs (d)(4) and (d)(5) of this section. To ensure that the projects are representative of the entire spectrum of clinical and non-clinical areas associated with MCOs and PHPs, the State must specify the appropriate distribution of projects.

(4) Clinical areas include—

(i) Prevention and care of acute and chronic conditions;

(ii) High-volume services;

(iii) High-risk services; and

(iv) Continuity and coordination of care.

(5) Non-clinical areas include—

(i) Grievances and appeals;

(ii) Access to, and availability of, services; and

(iii) Cultural competence.

(6) In addition to requiring each MCO and PHP to initiate its own performance improvement projects, the State may require that an MCO or PHP—

(i) Conduct particular performance improvement projects on a topic specified by the State; and

(ii) Participate annually in at least one Statewide performance improvement project.

(7) For each project, each MCO and PHP must assess its performance using quality indicators that are—

(i) Objective, clearly and unambiguously defined, and based on current clinical knowledge or health services research; and

(ii) Capable of measuring outcomes such as changes in health status, functional status, and enrollee satisfaction, or valid proxies of these outcomes.

(8) Performance assessment on the selected indicators must be based on systematic ongoing collection and analysis of valid and reliable data.

(9) Each MCO's and PHP's interventions must achieve improvement that is significant and sustained over time.

(10) Each MCO and PHP must report the status and results of each project to the State as requested.

(e) *Program review by the State.* (1) The State must review, at least annually, the impact and effectiveness of each MCO's and PHP's quality assessment and performance improvement program. The review must include—

(i) The Each MCO's and PHP's performance on the standard measures on which it is required to report; and

(ii) The results of the each MCO's and PHP's performance improvement projects.

(2) The State may require that an MCO or PHP have in effect a process for its own evaluation of the impact and effectiveness of its quality assessment and performance improvement program.

§ 438.242 Health information systems.

(a) *General rule.* The State must ensure that each MCO and PHP maintains a health information system that collects, analyzes, integrates, and reports data and can achieve the objectives of this subpart. The system should provide information on areas including, but not limited to, utilization, grievances, and disenrollments for other than loss of Medicaid eligibility.

(b) *Basic elements of a health information system.* The State must require, at a minimum, that each MCO and PHP comply with the following:

(1) Collect data on enrollee and provider characteristics as specified by the State, and on services furnished to enrollees through an encounter data system or such other methods as may be specified by the State.

(2) Ensure that data received from providers is accurate and complete by—

(i) Verifying the accuracy and timeliness of reported data;

(ii) Screening the data for completeness, logic, and consistency; and

(iii) Collecting service information in standardized formats to the extent feasible and appropriate.

(3) Make all collected data available to the State and upon request to HCFA, as required in this subpart.

Subpart E [Reserved]

Subpart F—Grievance System

§ 438.400 Statutory basis and definitions.

(a) *Statutory basis.* This subpart is based on sections 1902(a)(3), 1902(a)(4), and 1932(b)(4)of the Act.

(1) Section 1902(a)(3) requires that a State plan provide an opportunity for a fair hearing to any person whose claim for assistance is denied or not acted upon promptly.

(2) Section 1902(a)(4) requires that the State plan provide for methods of administration that the Secretary finds necessary for the proper and efficient operation of the plan.

(3) Section 1932(b)(4) requires Medicaid managed care organizations to establish internal grievance procedures under which Medicaid enrollees, or providers acting on their behalf, may challenge the denial of coverage of, or payment for, medical assistance.

(b) *Definitions.* As used in this subpart, the following terms have the indicated meanings:

Action means—

(1) In the case of an MCO or PHP or any of its providers—

(i) The denial or limited authorization of a requested service, including the type or level of service;

(ii) The reduction, suspension, or termination of a previously authorized service;

(iii) The denial, in whole or in part, of payment for a service;

(iv) For a resident of a rural area with only one MCO or PHP, the denial of a Medicaid enrollee's request to exercise his or her right to obtain services outside the network; or

(v) The failure to furnish or arrange for a service or provide payment for a service in a timely manner.

(vi) The failure, of an MCO or PHP, to resolve an appeal within the timeframes provided in § 408(i)(2).

(2) In the case of a State agency, the denial of a Medicaid enrollee's request for disenrollment. An appeal of this type is to the State Fair Hearing Office.

Appeal means a request for review of an action, as ''action'' is defined in this section.

Governing body means the MCO's or PHP's Board of Directors, or a designated committee of its senior management.

Grievance means an expression of dissatisfaction about any matter other than an action, as ''action'' is defined in this section. The term is also used to refer to the overall system that includes grievances and appeals handled at the MCO or PHP level and access to the State Fair Hearing process. (Possible subjects for grievances include, but are not limited to, the quality of care or services provided, and aspects of interpersonal relationships such as rudeness of a provider or employee, or failure to respect the enrollee's rights.)

Quality of care grievance means a grievance filed because the enrollee believes that any aspect of the care or treatment that he or she received failed to meet accepted standards of health care and caused or could have caused harm to the enrollee.

§ 438.402 General requirements.

(a) *The grievance system.* Each MCO and PHP must have a system that includes a grievance process, an appeal process, and access to the State's fair hearing system.

(b) *General requirements for the grievance system.* The MCO or PHP must—

(1) Base its grievance and appeal processes on written policies and procedures that, at a minimum, meet the conditions set forth in this subpart;

(2) Obtain the State's written approval of the policies and procedures before implementing them;

(3) Provide for its governing body to approve and be responsible for the effective operation of the system;

(4) Provide for its governing body to review and dispose of grievances and resolve appeals, or make written delegation of this responsibility to a grievance committee;

(5) Ensure that punitive action is neither threatened nor taken against a provider who requests an expedited resolution, or supports an enrollee's grievance or appeal;

(6) Accept grievances and appeals, and requests for expedited disposition or resolution or extension of timeframes from the enrollee, from his or her representative, or from the provider acting on the enrollee's behalf and with the enrollee's written consent.

(7) Provide to the enrollee and to his or her representative the notices and information required under this subpart; and

(8) At the enrollee's request, refer for State review any quality of care grievance resolution with which the enrollee is dissatisfied.

(9) Require providers to give notice in accordance with § 438.404(d).

(c) *Filing requirements.*—(1) *Authority to file.* (i) An enrollee may file a grievance and an MCO or PHP level appeal, and may request a State fair hearing.

(ii) A provider, acting on behalf of the enrollee and with the enrollee's written consent, may file an appeal. A provider may not file a grievance or request a State fair hearing.

(2) *Timing.* (i) For an action as defined in § 438.400 (b)(1)(v), the enrollee or the provider may file an appeal whenever the entity has delayed access to the service to the point where there is a substantial risk that further delay will adversely affect the enrollee's health condition.

(ii) For all other actions, the State specifies a reasonable timeframe that may be no less than 20 days and not to exceed 90 days from the date on the MCO's or PHP's notice of action.

Within that timeframe—

(A) The enrollee or the provider may file an appeal; and

(B) In a State that does not require exhaustion of MCO and PHP level appeals, the enrollee may request a State fair hearing.

(3) *Procedures.* (i) The enrollee may file a grievance either orally or in writing and, as determined by the State, either with the State or with the MCO or the PHP.

(ii) The enrollee or the provider may file an appeal either orally or in writing, and unless he or she requests expedited resolution, must follow an oral filing with a written, signed, appeal.

§ 438.404 Notice of action.

(a) *Language and format requirements.* The notice must be in writing and must meet the language and format requirements of § 438.10(b) and (c) of this chapter to ensure ease of understanding.

(b) *Content of notice.* The notice must explain the following:

(1) The action the MCO or PHP or its contractor has taken or intends to take.

(2) The reasons for the action.

(3) Any laws and rules that require or permit the action.

(4) The enrollee's or the provider's right to file an MCO or PHP appeal.

(5) The enrollee's right to request a State fair hearing.

(6) The enrollee's right to present evidence in person if he or she chooses.

(7) The procedures for exercising the rights specified in this paragraph.

(8) The circumstances under which expedited resolution is available and how to request it.

(9) The enrollees right to have benefits continue pending resolution of the appeal or issuance of a fair hearing decision, if the enrollee or the provider timely files the appeal or the enrollee timely requests a State fair hearing.

(10) The circumstances under which the enrollee may be required to pay the costs of any services furnished while the appeal is pending if the final outcome is an adverse decision.

(11) How the enrollee may request continuation of benefits.

(12) How to contact the MCO or PHP to receive assistance in filing an appeal or requesting a State fair hearing.

(13) How to obtain copies of enrollee records, including records other than medical records.

(14) That the enrollee has the right to represent himself or herself, to use legal counsel, or to use a relative, or friend or other individual as spokesperson.

(15) That filing an appeal or requesting a State fair hearing will not negatively affect or impact the way the MCO and the PHP and their providers, or the State agency, treat the enrollee.

(c) *Timing of notice.* Except as provided in paragraph (d) of this section, the MCO or PHP must mail the notice within the following timeframes:

(1) For termination, suspension, or reduction of previously authorized Medicaid-covered services, within the timeframes specified in §§ 431.211, 431.213, and 431.214 of this chapter.

(2) For denial of payment, at the time of any action affecting the claim.

(3) For standard service authorization decisions that deny or limit services, within the timeframe specified in § 438.210(d)

(4) If the MCO or PHP extends the timeframe in accordance with § 438.210(d), it must—

(i) Give the enrollee written notice of the reason for the decision to extend the

timeframe and inform the enrollee of the right to file a grievance if he or she disagrees with that decision; and

(ii) Issue and carry out its determination as expeditiously as the enrollee's health condition requires and no later than the date the extension expires.

(5) For service authorization decisions not reached within the timeframes specified in § 438.210(d) (which constitutes a denial and is thus an adverse action), on the date that the timeframes expire.

(6) For expedited service authorization decisions, within the timeframes specified in § 438.210(e).

(d) *Special rule for subcontractors and providers who are not employees.* (1) An MCO or PHP may permit its subcontractors and providers who are not employees to give enrollees notice that includes only the information specified in paragraphs (b)(4) through (b)(15) of this section.

(2) If the MCO or PHP elects the option provided in paragraph (d)(1) of this section, and receives an appeal on any action by the subcontractor or provider who is not an employee, the MCO or PHP must, in acknowledging the appeal, include the information required under paragraphs (b)(1) through (b)(3) of this section.

§ 438.406 Handling of grievances and appeals.

(a) *General requirements.* In handling grievances and appeals, each MCO and each PHP must meet the following requirements:

(1) Have an adequately staffed office that is designated as the central point for enrollee issues, including grievances and appeals.

(2) Establish an appeals process that meets the requirements of paragraph (b) of this section.

(3) Give enrollees any reasonable assistance in completing forms and taking other procedural steps. This includes providing interpreter services and toll-free numbers that have adequate TTY/TTD and interpreter capability.

(4) Ensure that the enrollee's communication is correctly classified as a ''grievance'' or an ''appeal'.

(5) Acknowledge receipt of each grievance and appeal.

(6) Ensure that each grievance and appeal—

(i) Is transmitted timely to staff who have authority to act upon it; and

(ii) Is investigated and disposed of or resolved in accordance with § 438.408.

(7) Ensure that the individuals who make decisions on grievances and appeals are individuals—

(i) Who were not involved in any previous level of review or decision-making; and

(ii) Who, if deciding any of the following, are health care professionals who have the appropriate clinical expertise in treating the enrollee's condition or disease.

(A) An appeal of a denial that is based on lack of medical necessity.

(B) A grievance regarding denial of expedited resolution of an appeal.

(C) A grievance or appeal that involves clinical issues.

(b) *Special requirements for appeals.* The process for appeals must consist of clearly explained steps that meet the following requirements:

(1) Include, for each step, timeframes that take account of the enrollee's health condition and provide for expedited resolution in accordance with § 438.410.

(2) Provide that oral inquiries about the opportunity to appeal are treated as appeals (to establish the earliest possible filing date for the appeal) and must be confirmed in writing, unless the enrollee or the provider requests expedited resolution.

(3) Ensure that the acknowledgment of an oral appeal specifies that, although the time allowed for the MCO or PHP to resolve the appeal has begun, unless the request is for expedited resolution, the MCO or PHP cannot complete the resolution until the enrollee or the provider submits the appeal in writing.

(4) Provide the enrollee a reasonable opportunity to present evidence, and allegations of fact or law, in person as well as in writing. (The MCO or PHP must inform the enrollee of the limited time available for this in the case of expedited resolution.)

(5) Provide the enrollee and his or her representative opportunity, before and during the appeals process, to examine the enrollee's case file, including medical records, and any other documents and records considered during the appeals process.

(6) Include, as parties to the appeal—

(i) The enrollee and his or her representative; or

(ii) The legal representative of a deceased enrollee's estate.

§ 438.408 Resolution and notification: Grievances and appeals.

(a) *Basic rule.* The MCO or PHP must dispose of each grievance and resolve each appeal, and provide notice, as expeditiously as the enrollee's health condition requires, within State-established timeframes that may not exceed the timeframes specified in this section.

(b) *Basis for decision.* The MCO or PHP must base the decision on the record of the case, including all relevant Federal and State statutes, program regulations and policies, and any evidence presented under § 438.406(b)(4), in connection with the filing of the appeal.

(c) *Specific timeframes.*—(1) *Standard disposition of grievances.* For standard disposition of a grievance and notice to the affected parties, the timeframe is established by the State but may not exceed 90 days from the day the MCO or PHP receives the grievance.

(2) *Expedited disposition of grievances.* For a grievance on a denial of a request to expedite resolution of an appeal, the timeframe is 72 hours after receipt of the grievance.

(3) *Standard resolution of appeals.* For standard resolution of an appeal and notice to the affected parties, the timeframe is 30 days after the MCO or the PHP receives the appeal. This timeframe may be extended under paragraph (d) of this section.

(4) *Expedited resolution of appeals.* For expedited resolution of an appeal, the timeframe for resolution and notice to the enrollee is 72 hours after the MCO or PHP receives the appeal. This timeframe may be extended under paragraph (d) of this section.

(d) *Extension of timeframes.*—(1) *Limits on extension.* (i) For a grievance on denial of a request to expedite resolution of an appeal, the timeframe may not be extended.

(ii) For expedited resolution of an appeal, the MCO or PHP may extend the 72-hour timeframe by up to 14 calendar days only if the enrollee requests extension.

(iii) For standard resolution of an appeal or for a quality of care grievance, the MCO or PHP may extend the 30-day timeframe for up to 14 calendar days if—

(A) The enrollee requests extension; or

(B) The MCO or PHP shows (to the satisfaction of the State agency, upon its request) that there is need for additional information and how the delay is in the enrollee's interest.

(2) *Requirements following extension.* If the MCO or PHP extends the timeframes, it must—

(i) For any extension not requested by the enrollee, give the enrollee written notice of the reason for the delay and of the enrollee's right to file a grievance if he or she disagrees with the decision to extend the timeframe; and

(ii) For any extension, dispose of the grievance or resolve the appeal no later than the date on which the extension expires.

(e) *Format of notice*—(1) *Grievances.* (i) For all written grievances and all

grievances that relate to quality of care, the MCO or PHP must provide a written notice of disposition.

(ii) For an oral grievance that does not relate to quality of care, the MCO may provide oral notice unless the enrollee requests that it be written.

(2) *Appeals.* (i) For all appeals, the MCO or PHP must provide written notice of disposition.

(ii) For notice of expedited resolution, the MCO or PHP must also provide oral notice.

(f) *Content of notice of MCO or PHP grievance disposition.* The written notice must explain the following:

(i) The disposition of the grievance.

(ii) The fact that, if dissatisfied with the disposition of a quality of care grievance, the enrollee has the right to seek further State review, and how to request it.

(g) *Content of notice of appeal resolution.* The written notice of the resolution must include the following:

(1) The title of the MCO or PHP contact for the appeal.

(2) The results of the resolution process and the date it was completed.

(3) A summary of the steps the MCO or the PHP has taken on the enrollee's behalf in resolving the issue.

(4) For appeals not resolved wholly in favor of the enrollees—

(i) The right to request a State Fair Hearing, and how to do so;

(ii) The right to request to receive benefits while the hearing is pending, and how to make the request; and

(iii) That the enrollee may be held liable for the cost of those benefits if the hearing decision upholds the MCO's or PHP's action.

(h) *Collaboration on State review of grievances.* The MCO or PHP must work with the State to dispose of the grievance if the State considers that the MCO or PHP response was insufficient.

(i) *Referral of adverse or delayed appeal decisions to the State Fair Hearing Office*—(1) *Basis for submission.* The MCO or PHP must submit to the State Fair Hearing Office the file and all supporting documentation—

(i) For any appeal that was subject to expedited resolution and for which the MCO or PHP—

(A) Reaches a decision that is wholly or partially adverse to the enrollee; or

(B) Fails to reach a decision within the timeframes specified in paragraph (i)(2) of this section.

(ii) For any appeal that was not expedited, at the request of the State.

(2) *Timeframes for decision*—(i) *Standard resolution.* For a standard resolution, the basic timeframe is 30 days from receipt of the appeal, and may be extended for an additional 14 calendar days if the enrollee requests extension or the MCO or PHP justifies (to the State agency upon request) a need for additional information and how the extension is in the enrollee's interest.

(ii) *Expedited resolution.* For an expedited resolution, the basic timeframe is 72 hours from receipt of the appeal and may be extended for up to 14 calendar days, but only if the enrollee requests extension.

(3) *Timeframes for submission.* The timeframes for submission to the State Fair Hearing Office are as follows:

(i) For a standard resolution: 72 hours after the MCO or PHP receives the State's request.

(ii) For an expedited resolution: 24 hours after the MCO or PHP reaches an adverse decision, or the basic or extended timeframe for decision expires.

(j) *Requirements for State fair hearings*—(1) *Availability.* The State must permit the enrollee to request a State fair hearing within a reasonable time period specified by the State, but not less than 20 or in excess of 90 days if—

(i) The State requires exhaustion of the MCO or PHP level appeal procedures, from the date of the MCO's or PHP's notice of resolution; and

(ii) The State does not require exhaustion of the MCO or PHP level appeal procedures and the enrollee appeals directly to the State for a fair hearing, from the date on the MCO's or PHP's notice of action.

(2) *Parties.* The parties to the State fair hearing include the MCO or PHP as well as the enrollee and his or her representative or the representative of a deceased enrollee's estate.

(3) *Timeframes for decision.* The State agency must take final administrative action as follows:

(i) Other than as specified in paragraph (j)(3)(ii) of this section, within a period of time not to exceed 90 days minus the number of days taken by the MCO or PHP to resolve the internal appeal. This timeframe begins on the date the State receives the beneficiaries' request for a State Fair Hearing.

(ii) For service authorization appeals that meet the criteria for expedited resolution as set forth in § 438.410, as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of a fair hearing request from the enrollee, or the file from the MCO or PHP.

§ 438.410 Expedited resolution of grievances and appeals.

(a) *General rule.* Each MCO and PHP must establish and maintain an expedited review process for grievances and appeals.

(b) *Requirements for grievances.* (1) The MCO or PHP must expedite disposition of grievances that pertain to denial of a request for expedited resolution of an appeal.

(2) The MCO or PHP may expedite disposition of other grievances, consistent with State guidelines.

(c) *Requirements for appeals.* Each MCO and PHP must meet the following requirements with respect to appeals:

(1) Establish a convenient and efficient means for an enrollee or a provider to request expedited resolution of an appeal;

(2) Provide expedited resolution of an appeal in response to an oral or written request if the MCO or PHP determines (with respect to a request from the enrollee) or the provider indicates (in making the request on the enrollee's behalf or supporting the enrollee's request) that taking the time for a standard resolution could seriously jeopardize the enrollee's life or health or ability to attain, maintain, or regain maximum function.

(3) Document all oral requests in writing; and

(4) Maintain the documentation in the case file.

(d) *Action following denial of a request for expedited resolution.* If the MCO or PHP denies a request for expedited resolution of an appeal, it must—

(1) Transfer the appeal to the timeframe for standard resolution, beginning the 30-day period as of the day it received the request for expedited resolution;

(2) Give the enrollee prompt oral notice of the denial, and follow up within two calendar days with a written notice that includes the following:

(i) Informs the enrollee of the right to—

(A) File a grievance if he or she is dissatisfied with the MCO's or PHP's decision not to expedite resolution of the appeal; or

(B) Resubmit the request with a provider's letter of support.

(ii) Explains that—

(A) If the enrollee files a grievance, the MCO or PHP will process the appeal using the 30-day timeframe for standard resolution; and

(B) If the enrollee resubmits the request with a provider's letter of support, the MCO or PHP will expedite resolution of the appeal.

(iii) Provides instructions about grievance procedures, including timeframes.

§ 438.414 Information about the grievance system.

(a) *To whom information must be furnished.* (1) Each MCO and PHP must provide the information specified in paragraph (b) of this section to enrollees and to all providers and subcontractors at the time they enter into a contract.

(2) Each MCO or PHP or, at State option, the State or its contracted representative must provide the information specified in paragraph (b) to all potential enrollees.

(b) *Required information.* The information that is provided under paragraph (a) of this section must explain the grievance system through a State-developed or State-approved description, in the format required under § 438.10(c), and must include the following:

(1) With respect to State fair hearing—

(i) The right to hearing;

(ii) The method for obtaining a hearing; and

(iii) The rules that govern representation at the hearing.

(2) The right to file grievances and appeals.

(3) The requirements and timeframes for filing a grievance or appeal.

(4) The availability of assistance in the filing process.

(5) The right to represent himself or herself or to be represented by legal counsel or a relative or friend or other spokesperson.

(6) The toll-free numbers that the enrollee can use to file a grievance or an appeal by phone.

(7) The fact that filing a grievance or appeal or requesting a State fair hearing will not adversely affect or impact the way the MCO or the PHP and their providers or the State agency treat the enrollee.

(8) The fact that, when requested by the enrollee

(i) Benefits will continue if the enrollee files an appeal or a request for State fair hearing within the timeframes specified for filing; and

(ii) The enrollee may be required to pay the cost of services furnished while the appeal is pending, if the final decision is adverse to the enrollee.

(c) *Language, format, and timing requirements.* The information furnished under this section must meet the language and format requirements of § 438.10(b) and (c), and must be furnished to enrollees and potential enrollees at the times specified in § 438.10(e) through (h).

(d) *Aggregate information.* Upon request, the MCO or PHP must provide to enrollees, potential enrollees, and the general public, aggregate information based on the information required under § 438.416(d).

§ 438.416 Record keeping and reporting requirements.

Each MCO and PHP must comply with the following requirements, and in so doing must also comply with the confidentiality requirements of § 438.224.

(a) *Log.* Maintain a log of all grievances and appeals, showing the date of acknowledgment, the MCO's or PHP's decision, and the date of disposition or resolution.

(b) *Tracking.* Track each grievance and appeal until its final disposition or resolution, and classify them in terms of whether the disposition or resolution was standard or expedited.

(c) *Retention of records.* (1) Retain the record of each grievance and appeal, and its disposition or resolution in a central location, and accessible to the State, for at least 3 years.

(2) If any litigation, claim negotiation, audit, or other activity involving these records is initiated before the end of the 3-year period, retain the record until the later of the following:

(i) The date the activity is completed and any issues arising from it are resolved.

(ii) The end of the 3-year period.

(d) *Reporting.* As often as the State requests, but at least once a year, each MCO and PHP must analyze the records maintained under this paragraph and submit to the State a summary that includes the following information:

(1) The number and nature of all grievances and appeals.

(2) The timeframes within which they were acknowledged and disposed of or resolved.

(3) The nature of the decisions.

§ 438.420 Continuation of benefits while the MCO or PHP appeal and the State Fair Hearing are pending.

(a) *Terminology.* As used in this section, ''timely'' filing means filing on or before the later of the following:

(1) The expiration of the timeframe specified by the State (in accordance with § 438.404(c)(3)) and communicated in the notice of action.

(2) The intended effective date of the MCO's or PHP's proposed action.

(b) *Continuation of benefits.* The MCO or PHP must continue the enrollee's benefits if—

(1) The enrollee or the provider files the appeal timely;

(2) The appeal involves the termination, suspension, or reduction of a previously authorized course of treatment;

(3) The services were ordered by an authorized provider;

(4) The period covered by the authorization has not expired; and

(5) The enrollee requests extension of benefits.

(c) *Reinstatement of benefits.* The MCO or PHP must reinstate the enrollee's benefits under any of the circumstances specified in § 431.231 of this chapter.

(d) *Duration of continued or reinstated benefits.* If the MCO or PHP continues or reinstates the enrollee's benefits while the appeal is pending, the following rules apply:

(1) The MCO or PHP must continue the benefits until one of the following occurs:

(i) The enrollee withdraws the appeal.

(ii) The MCO or PHP resolves the appeal in the enrollee's favor.

(iii) The State Fair Hearing Office issues a hearing decision on a request received directly from the enrollee or referred by the MCO or PHP.

(2) If the MCO or PHP appeals the decision or the State fair hearing decision is favorable to the enrollee, the MCO or PHP must restore regular benefits.

(e) *Enrollee responsibility for services furnished while the appeal is pending.* If the final resolution of the appeal is adverse to the enrollee, that is, upholds the MCO's or PHP's action, the MCO or PHP may recover the cost of the services furnished to the enrollee while the appeal is pending, to the extent that they were furnished solely because of the requirements of this section, and in accordance with the policy set forth in § 431.230(b) of this chapter.

§ 438.424 Effectuation of reversed appeal resolutions.

(a) *Services not furnished while the appeal is pending.* If the MCO or PHP, or the State fair hearing officer reverses a decision to deny, limit, or delay services that were not furnished while the appeal was pending, the MCO or PHP must authorize or provide the disputed services promptly, and as expeditiously as the enrollee's health condition requires.

(b) *Services furnished while the appeal is pending.* If the MCO or PHP, or the State fair hearing officer reverses a decision to deny authorization of services, and the enrollee received the disputed services while the appeal was pending, the MCO or the PHP or the State must pay for those services, in accordance with State policy and regulations.

§ 438.426 Monitoring of the grievance system.

(a) *Basis for monitoring.* The records that the MCOs and PHPs are required to maintain and summarize under § 438.416 provide the basis for

monitoring by the MCO or PHP, and by the State.

(b) *Responsibility for corrective action.* If the summaries required under paragraph (d) of § 438.416 reveal a need for changing the system, the MCO or the PHP must conduct an in-depth review, and take corrective action.

Subpart G—[Reserved]

Subpart H—Certifications and Program Integrity Provisions

§ 438.600 Statutory basis.

This subpart is based on sections 1902(a)(4) and 1902(a)(19) of the Act.

(a) Section 1902(a)(4) requires that the State plan provide for methods of administration that the Secretary finds necessary for the proper and efficient operation of the plan.

(b) Section 1902(a)(19) requires that the State plan provide the safeguards necessary to ensure that eligibility is determined and services are provided in a manner consistent with simplicity of administration and the best interests of the recipients.

§ 438.602 Basic rule.

As a condition for contracting and for receiving payment under the Medicaid managed care program, an MCO or PHP and its subcontractors must comply with the certification and program integrity requirements of this section.

§ 438.604 Data that must be certified.

(a) *Data certifications.* When State payments to the MCO or PHP are based on data submitted by the MCO or PHP, the State must require certification of the data as provided in § 438.606. The data that must be certified includes, but is not limited to, enrollment information, encounter data, and other information required by the State and contained in contracts, proposals, and related documents.

(b) *Certification of substantial compliance with contract.* Regardless of whether payment is based on data, each MCO and PHP must certify that it is in substantial compliance with its contract.

(c) *Additional certifications.* Certification is required, as provided in § 438.606, for all documents specified by the State.

§ 438.606 Source, content, and timing of certification.

(a) *Source of certification.* With respect to the data specified in § 438.604, the MCO or PHP must require—

(1) That subcontractors certify the data they submit to the MCO or PHP; and

(2) That one of the following certify the data the MCO or PHP submits to the State:

(i) The MCO's or PHP's Chief Executive Officer.

(ii) The MCO's or PHP's Chief Financial Officer.

(iii) An individual who has delegated authority to sign for, and who reports directly to, the MCO's or PHP's Chief Executive Officer or Chief Financial Officer.

(b) *Content of certification.* The certification must attest, based on best knowledge, information, and belief, as follows:

(1) To the accuracy, completeness and truthfulness of data.

(2) That the MCO or PHP is in substantial compliance with its contract.

(3) To the accuracy, completeness and truthfulness of documents specified by the State.

(c) *Timing of certification.* The MCO or PHP must submit the certification concurrently with the certified data or, in the case of compliance with the terms of the contract, when requesting payment.

§ 438.608 Program integrity requirements.

(a) *General requirement.* The MCO or PHP must have administrative and management arrangements or procedures, including a mandatory compliance plan, that are designed to guard against fraud and abuse.

(b) *Specific requirements.* The arrangements or procedures must include the following:

(1) Written policies, procedures, and standards of conduct that articulate the organization's commitment to comply with all applicable Federal and State standards.

(2) The designation of a compliance officer and a compliance committee that are accountable to senior management.

(3) Effective training and education for the compliance officer and the organization's employees.

(4) Effective lines of communication between the compliance officer and the organization's employees.

(5) Enforcement of standards through well-publicized disciplinary guidelines.

(6) Provision of internal monitoring and auditing.

(7) Provision for prompt response to detected offenses, and for development of corrective action initiatives relating to the MCO's or PHP's contract.

Subpart I—Sanctions

§ 438.700 Basis for imposition of sanctions.

(a) Each State that contracts with an MCO must, and each State that contracts with a PCCM may, establish intermediate sanctions, as specified in § 438.702, that it may impose if it makes any of the determinations specified in paragraphs (b) through (d) of this section. The State's determination may be based on findings from onsite survey, enrollee or other complaints, financial status, or any other source.

(b) An MCO acts or fails to act as follows:

(1) Fails substantially to provide medically necessary services that the MCO is required to provide, under law or under its contract with the State, to an enrollee covered under the contract.

(2) Imposes on enrollees premiums or charges that are in excess of the premiums or charges permitted under the Medicaid program.

(3) Acts to discriminate among enrollees on the basis of their health status or need for health care services. This includes termination of enrollment or refusal to reenroll a recipient, except as permitted under the Medicaid program, or any practice that would reasonably be expected to discourage enrollment by recipients whose medical condition or history indicates probable need for substantial future medical services.

(4) Misrepresents or falsifies information that it furnishes to HCFA or to the State.

(5) Misrepresents or falsifies information that it furnishes to an enrollee, potential enrollee, or health care provider.

(6) Fails to comply with the requirements for physician incentive plans, as set forth (for Medicare) in §§ 422.208 and 422.210 of this chapter.

(c) An MCO or a PCCM distributes directly, or indirectly through any agent or independent contractor, marketing materials that have not been approved by the State or that contain false or materially misleading information.

(d) An MCO violates any of the requirements in section 1903(m) of the Act and implementing regulations, or an MCO or a PCCM violates any of the requirements of section 1932 of the Act and implementing regulations. (For these violations, only the sanctions specified in § 438.702(a)(4) and (a)(5) may be imposed.)

§ 438.702 Types of intermediate sanctions.

(a) The types of intermediate sanctions that a State may impose under this subpart include the following:

(1) Civil money penalties in the amounts specified in § 438.704.

(2) Appointment of temporary management as provided in § 438.706. (The State may not impose this sanction on a PCCM.)

(3) Granting enrollees the right to terminate enrollment without cause. (The State must notify the affected enrollees of their right to disenroll.)

(4) Suspension of all new enrollment, including default enrollment, after the effective date of the sanction.

(5) Suspension of payment for recipients enrolled after the effective date of the sanction and until HCFA or the State is satisfied that the reason for imposition of the sanction no longer exists and is not likely to recur.

(b) State agencies retain authority to impose additional sanctions under State statutes or State regulations that address areas of noncompliance specified in § 438.700, as well as additional areas of noncompliance. Nothing in this subpart prevents State agencies from exercising that authority.

§ 438.704 Amounts of civil money penalties

(a) *General rule.* The limit on, or specific amount of, a civil money penalty the State may impose varies depending on the nature of the MCO's or PCCM's action or failure to act, as provided in this section.

(b) *Specific limits.* (1) The limit is $25,000 for each determination under the following paragraphs of § 438.700:

(i) Paragraph (b)(1) (Failure to provide services).

(ii) Paragraph (b)(5) (Misrepresentation or false statements to enrollees, potential enrollees, or health care providers).

(iii) Paragraph (b)(6) (failure to comply with physician incentive plan requirements).

(iv) Paragraph (c) (Marketing violations).

(2) The limit is $100,000 for each determination under paragraph (b)(3) (discrimination) or (b)(4) (Misrepresentation or false statements to HCFA or the State) of § 438.700.

(3) The limit is $15,000 for each recipient the State determines was not enrolled because of a discriminatory practice under paragraph (b)(3) of § 438.700. (This is subject to the overall limit of $100,000 under paragraph (b)(2) of this section).

(c) *Specific amount.* For premiums or charges in excess of the amounts permitted under the Medicaid program, the amount of the penalty is $25,000 or double the amount of the excess charges, whichever is greater. The State must deduct from the penalty the amount of overcharge and return it to the affected enrollees.

§ 438.706 Special rules for temporary management.

(a) *Optional imposition of sanction.* The State may impose temporary management if it finds (through onsite survey, enrollee complaints, financial audits, or any other means) that —

(1) There is continued egregious behavior by the MCO, including but not limited to behavior that is described in § 438.700, or that is contrary to any requirements of sections 1903(m) and 1932 of the Act;

(2) There is substantial risk to enrollees' health; or

(3) The sanction is necessary to ensure the health of the MCO's enrollees—

(i) While improvements are made to remedy violations under § 438.700; or

(ii) Until there is an orderly termination or reorganization of the MCO.

(b) *Required imposition of sanction.* (1) The State must impose temporary management (regardless of any other sanction that may be imposed) if it finds that an MCO has repeatedly failed to meet substantive requirements in section 1903(m) or 1932 of the Act, or this subpart. The State must also grant enrollees the right to terminate enrollment without cause, as described in § 438.702(a)(3).

(c) *Hearing.* The State may not delay imposition of temporary management to provide a hearing before imposing this sanction.

(d) *Duration of sanction.* The State may not terminate temporary management until it determines that the MCO can ensure that the sanctioned behavior will not recur.

§ 438.708 Termination of an MCO or PCCM contract.

A State has the authority to terminate an MCO or PCCM contract and enroll that entity's enrollees in other MCOs or PCCMs, or provide their Medicaid benefits through other options included in the State plan, if the State determines that the MCO or PCCM—

(a) Has failed to carry out the substantive terms of its contract; or

(b) Has failed to meet applicable requirements in sections 1932, 1903(m), and 1905(t) of the Act.

§ 438.710 Due process: Notice of sanction and pre-termination hearing.

(a) *Notice of sanction.* Before imposing any of the alternative sanctions specified in this subpart, the State must give the affected entity timely written notice that explains—

(1) The basis and nature of the sanction; and

(2) Any other due process protections that the State elects to provide.

(b) *Pre-termination hearing.*—(1) *General rule.* Before terminating an MCO or PCCM contract under § 438.708, the State must provide the entity a pretermination hearing.

(2) *Procedures.* The State must—

(i) Give the MCO or PCCM written notice of its intent to terminate, the reason for termination, and the time and place of the hearing;

(ii) After the hearing, give the entity written notice of the decision affirming or reversing the proposed termination of the contract and, for an affirming decision, the effective date of termination; and

(iii) For an affirming decision, give enrollees of the MCO or PCCM notice of the termination and information, consistent with § 438.10, on their options for receiving Medicaid services following the effective date of termination.

§ 438.722 Disenrollment during termination hearing process.

After a State notifies an MCO or PCCM that it intends to terminate the contract, the State may—

(a) Give the entity's enrollees written notice of the State's intent to terminate the contract; and

(b) Allow enrollees to disenroll immediately without cause.

§ 438.724 Public notice of sanction.

(a) *Content of notice.* The State must publish a notice that describes the intermediate sanction imposed, explains the reasons for the sanction and specifies the amount of any civil money penalty.

(b) *Publication of notice.* The State must publish the notice—

(1) No later than 30 days after it imposes the sanction; and

(2) As a public announcement in—

(i) The newspaper of widest circulation in each city within the MCO's service area that has a population of 50,000 or more; or

(ii) The newspaper of widest circulation in the MCO's service area, if there is no city with a population of 50,000 or more in that area.

§ 438.726 State plan requirement.

The State plan must provide for the State to monitor for violations that involve the actions and failures to act specified in this section and to implement the provisions of this section.

§ 438.730 Sanction by HCFA: Special rules for MCOs with risk contracts.

(a) *Basis for sanction.* (1) A State agency may recommend that HCFA impose the denial of payment sanction on an MCO with a comprehensive risk contract if the MCO acts or fails to act as specified in § 438.700(b)(1) through (b)(6).

(2) The State agency's recommendation becomes HCFA's recommendation unless HCFA rejects it within 15 days of receipt.

(b) *Notice of sanction.* If HCFA accepts the recommendation, the State agency and HCFA take the following actions:

(1) The State agency—

(i) Gives the MCO written notice of the proposed sanction;

(ii) Allows the MCO 15 days from date of receipt of the notice to provide evidence that it has not acted or failed to act in the manner that is the basis for the recommended sanction;

(iii) May extend the initial 15-day period for an additional 15 days if, before the end of the initial period, the MCO submits a written request that includes a credible explanation of why it needs additional time; and

(iv) May not grant an extension if HCFA determines that the MCO's conduct poses a threat to an enrollee's health or safety.

(2) HCFA conveys the determination to the OIG for consideration of possible imposition of civil money penalties under section 1903(m)(5)(A) of the Act and part 1003 of this title. In accordance with the provisions of part 1003, the OIG may impose civil money penalties in addition to, or in place of, the sanctions that may be imposed under this section.

(c) *Informal reconsideration.* (1) If the MCO submits a timely response to the notice of sanction, the State agency—

(i) Conducts an informal reconsideration that includes review of the evidence by a State agency official who did not participate in the original recommendation; and

(ii) Gives the MCO a concise written decision setting forth the factual and legal basis for the decision.

(2) The State agency decision under paragraph (c)(1) of this section, forwarded to HCFA, becomes HCFA's decision unless HCFA reverses or modifies the decision within 15 days from date of receipt.

(3) If HCFA reverses or modifies the State agency decision, the agency sends the MCO a copy of HCFA's decision.

(d) *Effective date of sanction.* (1) If the MCO does not seek reconsideration, a sanction is effective 15 days after the date of the notice of sanction under paragraph (b) of this section.

(2) If the MCO seeks reconsideration, the following rules apply:

(i) Except as specified in paragraph (d)(2)(ii) of this section, the sanction is effective on the date specified in HCFA's reconsideration notice.

(ii) If HCFA, in consultation with the State agency, determines that the MCO's conduct poses a serious threat to an enrollee's health or safety, HCFA may make the sanction effective earlier than the date of HCFA's reconsideration decision under paragraph (c) of this section.

(e) *HCFA's role.* HCFA retains the right to independently perform the functions assigned to the State agency under this section.

Subpart J—Conditions for Federal Financial Participation

§ 438.802 Basic requirements.

FFP is available in expenditures for payments under an MCO contract only for the periods during which the following conditions are met:

(a) The contract—

(1) Meets the requirements of this part; and

(2) Is in effect.

(b) The MCO and its subcontractors are in substantial compliance with the physician incentive plan requirements set forth in §§ 422.208 and 422.210 of this chapter.

(c) The MCO and the State are in substantial compliance with the requirements of the MCO contract and of this part.

§ 438.806 Prior approval.

(a) *Comprehensive risk contracts.* FFP is available under a comprehensive risk contract only if—

(1) The Regional Office has confirmed that the contractor meets the definition of MCO or is one of the entities described in paragraphs (a)(2) through (a)(5) of § 438.6; and

(2) The contract meets all the requirements of section 1903(m)(2)(A) of the Act, the applicable requirements of section 1932 of the Act, and the implementing regulations in this part.

(b) *MCO contracts.* Prior approval by HCFA is a condition for FFP under any MCO contract that extends for less than one full year or that has a value equal to, or greater than, the following threshold amounts:

(1) For 1998, the threshold is $1,000,000.

(2) For subsequent years, the amount is increased by the percentage increase in the consumer price index for all urban consumers.

(c) FFP is not available in an MCO contract that does not have prior approval from HCFA under paragraph (b) of this section.

§ 438.808 Exclusion of entities.

(a) *General rule.* FFP is available in payments under MCO contracts only if the State excludes from such contracts any entities described in paragraph (b) of this section.

(b) *Entities that must be excluded.* (1) An entity that could be excluded under section 1128(b)(8) of the Act as being controlled by a sanctioned individual.

(2) An entity that has a substantial contractual relationship as defined in § 431.55(h)(3), either directly or indirectly, with an individual convicted of certain crimes as described in section 1128(b)(8)(B) of the Act.

(3) An entity that employs or contracts, directly or indirectly, for the furnishing of health care, utilization review, medical social work, or administrative services, with one of the following:

(i) Any individual or entity excluded from participation in Federal health care programs under either section 1128 or section 1128A of the Act.

(ii) Any entity that would provide those services through an excluded individual or entity.

§ 438.810 Expenditures for enrollment broker services.

(a) *Terminology.* As used in this section—

Choice counseling means activities such as answering questions and providing information (in an unbiased manner) on available MCO, PHP, or PCCM delivery system options, and advising on what factors to consider when choosing among them and in selecting a primary care provider;

Enrollment activities means activities such as distributing, collecting, and processing enrollment materials and taking enrollments by phone or in person; and

Enrollment broker means an individual or entity that performs choice counseling or enrollment activities, or both.

Enrollment services means choice counseling, or enrollment activities, or both.

(b) *Conditions that enrollment brokers must meet.* State expenditures for the use of enrollment brokers are considered necessary for the proper and efficient operation of the State plan and thus eligible for FFP only if the broker and its subcontractors meet the following conditions:

(1) *Independence.* The broker and its subcontractors are independent of any MCO, PHP, PCCM, or other health care provider in the State in which they provide enrollment services. A broker or subcontractor is not considered ''independent'' if it—

(i) Is an MCO, PHP, PCCM or other health care provider in the State

(ii) Is owned or controlled by an MCO, PHP, PCCM, or other health care provider in the State; or

(iii) Owns or controls an MCO, PHP, PCCM or other health care provider in the State.

(2) *Freedom from conflict of interest.* The broker and its subcontractor are free from conflict of interest. A broker or subcontractor is not considered free from conflict of interest if any person who is the owner, employee, or consultant of the broker or subcontractor or has any contract with them—

(i) Has any direct or indirect financial interest in any entity or health care provider that furnishes services in the State in which the broker or subcontractor provides enrollment services;

(ii) Has been excluded from participation under title XVIII or XIX of the Act;

(iii) Has been debarred by any Federal agency; or

(iv) Has been, or is now, subject to civil money penalties under the Act.

(c) *Prior approval.* The initial contract or memorandum of agreement (MOA) for services performed by the broker has been reviewed and approved by HCFA before the effective date of the contract or MOA.

§ 438.812 Costs under risk and nonrisk contracts.

(a) Under a risk contract, the total amount the State agency pays for carrying out the contract provisions is a medical assistance cost.

(b) Under a nonrisk contract—

(1) The amount the State agency pays for the furnishing of medical services to eligible recipients is a medical assistance cost; and

(2) The amount the State agency pays for the contractor's performance of other functions is an administrative cost.

§ 438.814 Limit on payments in excess of capitation rates.

FFP is not available for payments pursuant to risk corridors or incentive arrangements that exceed 105 percent of that portion of the aggregate amount approved capitation payments attributable to the enrollees or services covered by the risk corridor or incentive management.

PART 440—SERVICES: GENERAL PROVISIONS

1. The statutory citation for part 440 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

2. In subpart A, a new § 440.168 is added, to read as follows:

§ 440.168 Primary care case management services.

(a) Primary care case management services means case management related services that—

(1) Include location, coordination, and monitoring of primary health care services; and

(2) Are provided under a contract between the State and either of the following:

(i) A PCCM who is a physician or may, at State option, be a physician assistant, nurse practitioner, or certified nurse-midwife.

(ii) A physician group practice, or an entity that employs or arranges with physicians to furnish the services.

(b) Primary care case management services may be offered by the State—

(1) As a voluntary option under the regular State plan program; or

(2) On a mandatory basis under section 1932 (a)(1) of the Act or under section 1915(b) or section 1115 waiver authority.

PART 447—PAYMENTS FOR SERVICES

1. The authority citation for part 447 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

2. A new § 447.46 is added, to read as follows:

§ 447.46 Timely claims payment by MCOs.

(a) *Basis and scope.* This section implements section 1932(f) of the Act by specifying the rules and exceptions for prompt payment of claims by MCOs.

(b) *Definitions.* ''Claim'' and ''clean claim'' have the meaning given those terms in § 447.45.

(c) *Contract requirements.*—(1) *Basic rule.* A contract with an MCO must provide that the organization will meet the requirements of paragraphs (d)(2), (d)(3) of § 447.45, and abide by the specifications of paragraphs (d)(5) and (d)(6) of that section..

(2) *Exception.* The MCO and its providers may, by mutual agreement, establish an alternative payment schedule.

(3) Any alternative schedule must be stipulated in the contract.

§ 447.53 [Amended]

3. In § 447.53(b), the following changes are made:

A. In paragraph (b) introductory text, the parenthetical phrase is removed.

B. Paragraph (b)(6) is removed.

4. A new paragraph (e) is added to read as follows:

(e) No provider may deny services, to an individual who is eligible for the services, on account of the individual's inability to pay the cost sharing.

§ 447.58 [Amended]

5. In § 447.58, ''Except for HMO services subject to the copayment exclusion in § 447.53(b)(6), if '' is removed and ''If'' is inserted in its place.

6. A new § 447.60 is added to subpart A to read as follows:

§ 447.60 Cost-sharing requirements for services furnished by MCOs.

Contracts with MCOs must provide that any cost-sharing charges the MCO imposes on Medicaid enrollees are in accordance with the requirements set forth in §§ 447.50 and 447.53 through 447.58 for cost-sharing charges imposed by the State agency.

§ 447.361 [Removed]

Section 447.361 is removed.

(Catalog of Federal Domestic Assistance Program No. 93778, Medical Assistance)

Dated: December 21, 2000.

Robert A. Berenson,

Acting Deputy Administrator, Health Care Financing Administration.

Dated: December 20, 2000.

Donna E. Shalala,

Secretary.

[FR Doc. 01–1447 Filed 1–18–01; 8:45 am]

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Note: The List of Public Laws for the 106th Congress, Second Session has been completed and will resume when bills are enacted into public law during the next session of Congress.

A cumulative List of Public Laws was published in Part II of the **Federal Register** on January 16, 2001.

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